Trust, Trustworthiness, and the Conflict Between Community Consent and Individual Autonomy

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Abstract

In both the bioethical literature and guidelines, community consent in biomedical research involving human subjects increasingly promoted. Community consent can take different forms, but commonly involves asking permission to community leaders before approaching potential research subjects individually. Although there is an intuitive appeal to community consent, it can conflict with standard informed consent and autonomy by restricting the choice of (some) community members. In this thesis I will address both sides of this conflict and offer a way in which it can be decreased. I will argue that community consent can be of significant value for community members by protecting their self-understanding. When this is based on trust and trustworthiness, community consent is likely to be in line with the theory of autonomous action that justifies informed consent. Since it is not always clear that this is the case, I end by arguing that communities must demonstrate that their community consent involves trust and trustworthiness and suggest ways in which this can be shown.

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Introduction

Kassena-Nankana is an administrative district in northern Ghana (Tindana, Kass, & Akweongo, 2006; Tindana et al., 2011). The area is a rural area mainly inhabited by two ethnic groups – the Kassenas and the Nankanis – who have different languages, but share similarities in traditions, political organization, and other (cultural) practices. The Navorongo Health Research Centre (NHRC) is based in this area. This is a biomedical research center which conducts research (mainly) around the topic of infectious diseases.[1] The studies conducted by the NHRC widely vary in their nature and target population: the research includes both public health research (e.g. Nonterah et al., 2019; Welaga et al., 2018) as well as human subject research (e.g. Agono et al., 2018; Oduro et al., 2004), which including research involving children (e.g. Sirima et al., 2016).

What is interesting about this research center is the relationship it has with the communities in the Kassena-Nankana district and the informed consent procedures followed in their research. These procedures, as well as the conception of consent of community members, has been well described by Tindana et al. (Tindana et al., 2006). In 2006, Tindana et al. conducted a survey of people living in the Kassena-Nankana district. The researchers spoke with both chiefs, as well as community members who were previously enrolled in research conducted by the NHRC or had children that were enrolled. The purpose of this study was to assess the conception of informed consent of research subjects in this area, as well as to describe the (already established) informed consent procedures taken in this area. In this paper, Tindana et al. summarize part of this process as follows:

> [T]he protocol for approaching chiefs involves paying respects to the chief and the presentation of small gifts of cola nuts and a bottle of spirit. The research is explained to the chiefs, and then permission from chiefs to conduct activities in a community is given verbally. Similarly, household heads give verbal consent to approach individuals. Only after these steps have been completed may researchers approach individuals to invite them to participate in research. (Tindana et al., 2006, p. 2)

Thus, before individual informed consent is obtained, permission is asked from leaders on different levels, e.g. communities and households. This process of engagement with the community prior to research is accepted and endorsed by most community members. By following this procedure, the NHRC follows the existing decision-making practices, as well as the community members' conception of what is appropriate around decision-making. By aligning the research practice with the cultural

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[1] http://www.navrongo-hrc.org/

practices around decision-making, the NHRC can respect cultural practices and the value community members attach to these practices.

This example is not unique. These consent procedures (henceforth: *community consent*) have been recommended for (non-Western) communities in both the bioethical literature and guidelines, and have been applied to a variety of medical activities (e.g. Diallo et al., 2005; Emanuel, Wendler, Killen, & Grady, 2004; Lavery et al., 2010; Marsh, Kamuya, Mlamba, Williams, & Molyneux, 2010; National Health and Medical Research Council, 2018; Pratt & Vries, 2018; Resnik, 2018). At the same time, these procedures stand in contrast to standard informed consent procedures, in which gaining the consent of potential research subjects should not require asking permission from others (World Medical Association, 2013). Asking permission from people other than the potential research subjects themselves would be unethical according to this standard conception of informed consent. Especially when that (third) person declines to give permission, this could significantly restrict the decision of potential research subjects. In the protocol used by the NHRC, the choice to enroll in a study is not solely up to the individual, but also depends on others. In other words, the consent procedure employed by the NHRC potentially conflicts with a value central to bioethics: *autonomy*.

This problem is most present in cases which concern the consent of women. In the Kassena-Nankana district, all the community leaders (chiefs) are men (Tindana et al., 2006). Furthermore, the communities generally have a gate-keeping system, which requires woman to ask permission to the head of their household for various activities (Ngom, Debpuur, Akweongo, Adongo, & Binka, 2003). This is, as Tindana et al. describe, also the case for research enrollment (Tindana et al., 2006). The ten women interviewed all stated that they had to consult their husband before enrolling in a study. Similar restrictions of women's autonomy have been noted in other communities in Africa and India (DeCosta et al., 2004; Molyneux, Wassenaar, Peshu, & Marsh, 2005; Nyika, Wassenaar, & Mamotte, 2009). Since community practices can significantly restrict the individual autonomy of community members, especially women, the question can be raised whether community consent should be endorsed (Davis, 2000).

In this thesis, I will aim to further explore this conflict. To do so, it is necessary to look at what justifies community consent. Although there exists a significant body of literature on community consent, which is commonly part of a more general discussion on community engagement, the underlying justification of community consent remains implicit most of the time. A number of studies have pointed out the goals and potential benefits of community engagement, such as reducing harms and showing respect to communities (Dickert & Sugarman, 2005; Emanuel et al., 2004; King, Kolopack, Merritt, & Lavery, 2014; Lavery et al., 2010; MacQueen, Bhan, Frohlich, Holzer, & Sugarman, 2015;

Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, 2013; Resnik, 2018; Tindana et al., 2007; Weijer & Emanuel, 2000). These potential benefits do provide important reasons for community engagement and consent, but community consent is only valuable insofar it is the best ways to reach those goals.

The best accounts that try to justify community consent have been provided by Lomelino, and Pratt and De Vries (Lomelino, 2015; Pratt & Vries, 2018). Lomelino has argued for different mechanisms for community engagement and consent on the basis of relational autonomy (Lomelino, 2015). Although I am sympathetic to relational autonomy, it is not uncontroversial within bioethics. Furthermore, the more individualistic conception of autonomy still underlies influential ethical guidelines for human research (e.g. World Medical Association, 2013). Thus, this line of argumentation requires a defense of relational autonomy, before being able to make a case for community consent. I do not claim that that is infeasible, but it would be preferable to work from a consensus in bioethics, or at least a less controversial standpoint. As I will argue in this thesis, community consent can also be defended from the individualistic conception of autonomy. Another problem with Lomelino’s argumentation is that she, like multiple authors, emphasizes that it is important to respect cultural differences, but it remains implicit why this is the case. This thesis aims to clarify the underlying concern.

Pratt and De Vries defend community engagement and consent as a form of collective decision-making and argue that collective decision-making in healthcare is important in general (Pratt & Vries, 2018). However, this only justifies community consent insofar it is the best level of decision-making. In other words, it only defends community consent indirectly, by arguing for collective decision-making in general. This is of course not problematic for community consent, but this kind of justification does not do justice to the intuition that there is something special about communities in comparison to other groups that can make decisions as a collective. Community consent seems to deserve a more tailored justification.

Thus, community consent seems in need of a justification that can incorporate and involve the special feature of communities that demands our respect. This thesis aims to make a beginning with this justification by arguing that the value that communities pose for members’ self-understanding provides a strong reason to avoid disruption of community practices. This means that if communities (i.e. community leaders) are able to show that certain decision-making practices are central to the community and, consequently, to the self-understanding of its members, there is a strong reason to apply these forms of decision-making in the research. Note that this does not involve a relativistic conception of autonomy. A different conception of autonomy held in a community can be valuable for its members and, at the same time, incorrect. However, as I will argue below, even if a different conception of “an autonomous person” is false, this conception can still be of great importance for a community and their members.

It is important to note that this only provides a prima facie reason for community consent. As will be pointed out throughout the thesis, a lot of questions are in need of more examination and some issues can only be addressed in practice. Rather than addressing all these issues, this thesis will only explore one reason for community consent, namely the value of communities for people’s self-understanding. Although I think this provides a very strong reason, it is important to keep in mind that this will not support every form of community consent in every community.

The argumentation here does also not justify all possible cases of community consent – as said, community consent is used in a variety of different contexts. Therefore, it is good to specify the type of biomedical intervention I have in mind. I will focus on research instead of medical care. Care is meant to help a patient and the decision-making process is therefore aimed at finding out what is best for the patient. Medical research, on the other hand, has a more general goal of finding answers to medical questions (sometimes a distinction is made between therapeutic and nontherapeutic research, but this is very controversial) (Miller & Brody, 2003). The benefit to research subjects is not a priority of research and is therefore not the aim of a decision-making process prior to consenting to a study. Rather, potential subjects consent to carrying the risks related to a study and the decision-making process aims to balance these risks against other considerations (e.g. duties to society). This consent generally requires more caution because the research does not promise any benefit to the subject. Because I think it is more interesting to see whether community consent can be justified in a context where the protections for people are generally higher I choose to focus on medical research.

Furthermore, I will assume a specific type of research, namely human research for which informed consent is required according to current ethical guidelines. This excludes (most) community consent applied to public health cases (e.g. Resnik, 2018). Since public health research, especially health surveillance, is generally less invasive in people’s life and lacks great risks, it is debated whether individual consent is necessarily needed (Drue H Barrett et al., 2016). In those cases, community consent could be a way to involve people in the decision-making about public health research and ensure acceptance of the research. It is not meant to be part of an individual informed consent process, since this is most of the time not required. Because I want to focus on the conflict between personal autonomy protected by individual informed consent and the value of communities protected by community consent, I will leave aside public health research and focus on biomedical research on human subjects for which individual informed consent is normally required. It is this latter form of research that I will mean when referring to “biomedical interventions”.

Note that different studies on the consent process in non-Western communities concerned research (mainly vaccine trails) on children (Angwenyi et al., 2014; Molyneux, Wassenaar, et al., 2005). This complicates the informed consent process, because (young) children are most of the time not able to give informed consent (Buchanan & Brock, 1990). However, even though the informed consent process will be complicated by requiring parents to consent for their children, we should not reject their perceptions on the informed consent process as inapplicable to informed consent in research on adults. In both contexts, similar questions arise. Most notably: should community leaders be asked permission prior to the research? And is the permission of the head of the household necessary for consent? Although some caution is needed, the questions addressed in these papers are relevant for the consent process for more than pediatric research. Therefore, I will use these studies in my discussion of community consent.

Finally, I will focus on community consent, instead of the more general category of community engagement. As mentioned, community consent can be a part of community engagement, however this is not necessarily the case. Although, as Dickert and Sugarman point out, it might be hard to draw a distinction between community consultation (only exchanging information) and community consent (also involving a community in decision-making), my argument will defend a form of community engagement where the decision-making practices of communities are part of the research procedure (Dickert & Sugarman, 2005).[2] Thus, although there might be borderline cases between community consultation and community consent, this thesis will focus on clear examples of community consent. It is in those cases where the conflict between community and autonomy most strongly arises.

After having argued in the first chapter that there is a strong reason in favor of community consent, the second and the third chapter will discuss the conflict between individual autonomy and community consent. Different papers have pointed out that trust is a central value in community consent. The last two chapters will therefore zoom into the relation between trust, trustworthiness and consent. The second chapter will argue that, when community consent is indeed based on trust and the people involved in the decision-making are trustworthy, community consent community consent is able to satisfy all three conditions for autonomous action as described by Faden et al. – *understanding*, *intentionality*, and *non-control* (Faden, Beauchamp, & King, 1986). In this way, community consent is compatible with the conception of individual autonomy that underlies the traditional account of informed consent.

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[2] Dickert and Sugarman argue that if communities are to be consulted about biomedical interventions, it seems necessary to involve them in the decision-making process in some way. As they put it: "[i]t would be disingenuous to enter into a consulting arrangement where the consulting party does not intend, ex ante, to take the consultants' advice (Dickert & Sugarman, 2005, p. 1124)."

In many cases however, community consent is not clearly based on trust and trustworthiness. Rather, like in the example of the Kassena-Nankana district, (some) community members are forced to comply with community consent. In those cases, the individual autonomy of those people is not protected. The third chapter will therefore focus on ways in which we can distinguish trust and trustworthiness in community consent which can be used to evaluate whether community consent is justified in a community. It will first argue that exit and voice can help to indicate trust in community consent. Secondly, it will argue that there are mechanisms that promote trustworthiness. The presence of those mechanisms in communities demonstrates that people involved in community consent are likely to be trustworthy. Together, the second and the third chapter are meant to address the tension between individual autonomy and community consent. Although community consent can still be suppressive, the two chapters hopefully help to decrease the chance of justifying suppressive decision-making practices.

Chapter 1

The Value of Communities, Practices, and Community Decision-Making

In the introduction I have described the consent procedure of the NHRC in the Kassena-Nankana district in Ghana. The NHRC follows traditional decision-making practices that exist in communities in this district. One of the important aspects of this process is asking permission from community leaders and heads of households before approaching individual participants. However, this procedure can significantly limit the individual freedom of community members, especially women. Thus, we appear to be caught in a dilemma. On the one hand, it seems valuable to respect other communities and their practices when conducting research in that community. On the other, we would want to avoid any restrictions on personal autonomy, especially in biomedical research, for which autonomy (in the form of informed consent) is a central value. To get a grip on this dilemma, we have to examine the appeal of both sides. In this chapter, I want to discuss the first part of this conflict, that of respecting other communities and their cultural practices. Although different theorists argue that one of the reasons for community consent is respect for other communities, the justification of this reason is lacking in this debate (Emanuel et al., 2004; King et al., 2014; Lomelino, 2015). In other words, we have to ask why it is important to respect cultural practices of communities. What is the value of communities?

I will argue that communities have a value as constituting part of the identity to their members and helping them to develop their values. I will do so by discussing two theorists who have defended protections for cultural communities, namely Taylor and Kymlicka (Kymlicka, 1989, 1995; Taylor, 1994). Although these two writers do not end up with the same protections or rights for communities, they share similarities in their conception of the value of communities. Community practices shape the identity and the conception of values of community members (i.e. their self-understanding). Since community practices have this value for member’s self-understanding, there is a strong reason to avoid disruption of community practices. From this follows that if certain decision-making practices are of central value for a community (i.e. its members), there is a strong reason to make consent procedures sensitive to those practices. In other words, there is a strong reason for community consent when it helps to avoid potential disruption of important decision-making practices.

In this chapter, I will first elaborate on what I mean by “communities”. I will argue that community practices are of central importance in distinguishing communities as well as their members. This idea of social practices will also help to explicate the value of communities, based on the accounts of Taylor and Kymlicka, in the second section. It will be argued that communities provide members with a background of meaning which is important for both their identity and autonomy, which are both needed for people's self-understanding. In the last section, I will defend community consent in the context of biomedical interventions. It will be argued that biomedical interventions could disrupt community practices that are important for members' self-understanding. From this will follow that community consent, by helping to avoid disruption of community practices, protects the self-understanding of community members. I will end by responding to a common objection to Taylor and Kymlicka, namely that their argument presupposes an incorrect conception of communities as static social entities.

1.1 What are communities?

Before discussing their value, it is of course necessary to give a conceptualization of what I mean by "community". The term community is used to refer to a variety of different groups that all seem to intuitively qualify as communities (Weijer & Emanuel, 2000). For example, "internet-community" is commonly applied to people who connect over the internet through e.g. chat forums. At the same time, ethnic groups with a shared history and culture, who have a political system and traditions are also called communities. This puts some restrictions on the definition of "community". On the one hand, it would be bad to define a community in a way that excludes one of these groups, as the label "community" seems appropriate in both cases. On the other, we do not want to equate these different communities, since there are obvious and important differences between these (and other) communities. Thus, a conceptualization of "community" should be able to include the different types of communities and also leave room for the specification of different communities.[3]

Although there should be room for this kind of specification, I will not give a typology of different types of communities. Such a typology would go beyond the purpose of this section. Rather, I will try to give a conceptualization of communities that enables us to distinguish between communities and non-communal groups of people. This conceptualization will leave room for a further specification of different communities. Later in this chapter, I will further restrict my focus to a certain type of communities, namely "cultural communities". As will be argued, those are the kind of communities that have practices that are important for members' self-understanding. Although there will be a more

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[3] Weijer and Emanuel argue for a list of characteristics that communities can possess to differentiate between different communities (Weijer & Emanuel, 2000). Although I like this approach, they do not explain how they came to these characteristics. They do note of the characteristics that "these are not meant to be exhaustive lists, but to be the ones relevant to medical research (Weijer & Emanuel, 2000, p. 1142)", but for a systematic approach to community characteristics it seems desirable to avoid arbitrariness. I will therefore not directly use their characterization of communities.

specific conception of communities employed later on, I think it is still useful to start by conceptualizing "communities" in general before thinking about a specific form.

Kymlicka's conceptualization seems to be a good starting point (Kymlicka, 1989). Although he does not want to use a strict definition, instead relying on examples, he argues that a definition of minority cultural communities must contain at least: "(1) an objective component dealing with such things as a common heritage and language; (2) a subjective component dealing with self-identification with the group (Kymlicka, 1989, p. 179, footnote 2)." We can broaden this (already) abstract definition to include a greater variety of communities: (1) communities should be based on common or shared characteristic (e.g. ethnicity, a certain conception of a good life, or a lifestyle); (2) members should identify themselves with this community and therefore as a community.

Although I do think this conception gives us some conditions which groups must meet in order to be communities, I agree with Kymlicka that it is too vague. It can include a wide variety of groups of which we do not think of as communities. For example, if we use this as a definition, smokers could qualify as a community. Smokers have a clear membership criterion – i.e. smoking – which satisfies the objective component, and there are certainly smokers that identify themselves as smokers and relate to other smokers as a group. However, a smokers-community does not match our intuitions about what "communities" are. Both the membership criterion and the self-identification seem too weak to match the general conception of "community". But requiring a stronger identification and membership criteria would not solve the problem of including groups that do not seem to be communities. It still seems possible to label noncommunal groups as communities. Consider a village in which the inhabitants strongly identify themselves as part of the village and the village is seen by its inhabitants as a community. However, though there is a strong identification as villagers, there is no engagement between these villagers. Would it be appropriate to call this a community? I think the answer is no. One might complain that this example is far-fetched, because a situation in which there is no engagement between inhabitants and, at the same time, the inhabitants have a strong self-identification with a group seems almost impossible. I would not disagree. On the contrary, I think this objection reveals an important point about communities. Namely, communities are more than people with common characteristics who identify as a community. To be a community, there has to be some engagement between members: some social practices in which community members participate, which (directly or indirectly) foster the self-identification of community members with the community.

It seems that a common characteristic and self-identification are not enough to distinguish non-communal groups (or sets) from communities. There is more needed to distinguish between these two. Without interactions between members and, consequently, social practices, we can only talk about a groups (or a set) of people. Based on this argument, an extra condition must be added to our conception of communities: (3) communities should have social practices through which community members interact with each other.

1.1.1 Social practices

To explain the importance of social practices for a conception of communities, it is necessary to briefly discuss what social practices are. There are different accounts of what social practices are and how they structure our social life (Giddens, 1984; Schatzki, 1996; Sewell, 1992). I will mainly rely on Schatzki's account of practices (Schatzki, 1996). However, since I will only give a general account of practices (which suffices for our purpose) and leave out much of the details, this discussion is compatible with other practice theories. Social practices are made up of actions of people which relate in a specific way to other actions within that practice. As Schatzki points out, we have to distinguish between *dispersed practices* – which can be found in different areas of social life, like greeting or answering a question – and *integrative practices* – which relate to specific parts of social life, like cooking (Schatzki, 1996). Dispersed practices can be part of integrative practices, but also exist apart from any other practice. At the same time, integrative practices are not a collection of dispersed practices but also involve practice-specific activities. Cooking, for example, involves the dispersed practice of following rules (e.g. cooking instructions), but also the practice-specific activity of cutting vegetables.

The actions that constitute practices also create implicit or explicit norms which reinforce the practice.[4] The practice of teaching can illustrate this. In a classroom people are expected to behave a certain way – according to certain roles. The behavior of participants is regulated in different ways. This can be through explicit rules (e.g. you are required to be on time and to not disturb class), or implicit norms (e.g. if you want to ask a question, you raise your hand). By acting in accordance with these norms, people reinforce these norms and therefore maintain the practice. If a number of students raise their hand before asking a question, other students are likely to act in accordance with this norm. At the same time, the nature of the practice and the practice itself depends on people acting according to these norms. If all students stop accepting the authority of the teacher and act in line with that refusal of authority, the whole practice of teaching changes or even stops.

To take part in a practice you must have an understanding of the norms that organize the practice. The kind of understanding which is important is not an intellectual or cognitive understanding, in which

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[4] Since the distinction between explicit and implicit, as well as the related distinction between formal and informal rules do not carry normative significance in this thesis, I will not specify these distinctions or draw a strict line between the two. Rather, I will rely on intuitions and the common-sense use of the two.

the participants are able grasp the different actions and make sense of them (Schatzki, 2003). What is needed is a *practical understanding*, which means a that a participant is "able to carry on a practice and being able to participate in a form of life" (Schatzki, 2003, p. 15). In other words, participants must be able to act in line with the norms of the practice, i.e. to act in a way that seems right or acceptable to other participants (Schatzki, 1996). Although cognitive understanding might be important in order to come to a practical understanding, the latter requires more than learning about the practice from an external point of view. Only by interacting within a practice one can learn what actions are right and acceptable within this practice. Since practices as well as the norms of similar practices can of course differ from community to community – e.g. though teaching practices are widely shared, the way students are expected to behave in class can differ – this practical understanding is, to an extent, community specific.

As argued, communities must be more than a set of people, but must involve social practices. These social practices are of course interconnected with each other. Within a community, some practices will be more central than others (Sewell, 1992; Swidler, 2001). Swidler argues, for example, based on the study carried out by Biernacki, that the way in which wages were calculated had an effect on laborers' conception of labor and many aspects connected to labor (Biernacki, 1995; Swidler, 2001). Thus, some key practices will enforce norms that are present and shape other practices in the community (Swidler, 2001). The most important examples of this are cultural norms, which are also enforced through practices and, moreover, only exist in practices. Consequently, the culture of a community should primarily be identified as the practices which involve and maintain these (cultural) norms, values and traditions.

1.1.2 Community membership

Now we have conceptualized communities, we can also ask what makes someone a member of such a community. This related question is an important one for multiple reasons. Firstly, in the debate over multiculturalism, it has been argued that it is impossible to give rights to communities, because it is impossible to clearly outline who is a member and who is not (Kukathas, 1992). The same kind of critique has also been voiced against community consent (Davis, 2000). Secondly, this question is not just a philosophical, conceptual issue, but very much a debated question in our political reality. This is especially clear in debates about membership of indigenous communities. Who is and who is not a member of such a community, since being a member sometimes gives people certain rights and/or status. In those cases, it is important to be able to draw a line between legitimate and illegitimate claims to membership. Although I will not completely resolve the issue of community membership here, nor the practical problem just mentioned, I want to suggest a way to think about community membership based on the previous conceptualization of communities.

If social practices are key in distinguishing non-communal groups from communities, it seems natural to presume that social practices also have implications for how we should determine membership of a community. This presumption is strengthened when we try to determine membership on the basis of the other two criteria mentioned at the beginning of this section – common characteristics and self-identification. It seems clear that subjective self-identification alone is not enough to determine community membership. There is more to being part of a community than identifying yourself as part of it. A subjective approach to membership is also unsatisfying in the case of disagreement – when someone identifies herself as part of a community, but the rest of the community members do not think she is. It seems unrealistic to hold that the former person is always right. Basing membership on a common characteristic is likewise problematic, since it could conceive people as members who do not identify themselves as such. Furthermore, as Horowitz has pointed out, even seemingly objective and rigid criteria like ethnicity are open for change (Horowitz, 1975).

A combination of the two – someone is a member of a community if she identifies herself as a member and possess certain characteristics that are the basis of the community – falls short as well, since this implies that someone can be a community member without engaging in any community practices. Interaction with other community members seems necessary to be part of that community. Of course, not any interaction in the community practices suffices, since you can obviously interact in community practices without being a member. However, it is way harder to engage in community practices in the right way, i.e. in a way that is right based on the norms of the practice. This requires practical understanding (Schatzki, 2003). This kind of understanding cannot be gained by studying alone, since such an approach would be confined a third-person perspective. To understand how to seamlessly participate in a practice requires more. It requires having a grasp of this practice, which includes all the implicit rules and the perspective taken within this practice. To gain such an understanding, acting within the practice is necessary, since only in that we can gain the first-person perspective needed to fully grasp all the dimensions of a practice. So, along with self-identification as a member and possession of the group characteristics, practical understanding should determine community membership. By including practical understanding as a requirement for membership, membership is tied to active and correct participation in the community practices.

Moreover, while a lack of self-identification or common characteristics do not necessarily negate community membership – e.g. a person who is included by an ethnic community and participates in all important social practices but does not have the ethnicity of the community could still be considered a member – a lack of practical understanding does undermine community membership. As argued above, it is strange to think that someone can be a member of a community without being able to participate in the social practices of that community in a right or acceptable way. This does not mean that members have to be participate in every practice in a community, but, as Swidler pointed out, some practices are more central to a community than others (Swidler, 2001). It seems therefore fair to say that community members should have the practical understanding to be able to act within those practices.

Admittedly, by basing community membership in practical understanding of community practices, not all problems around membership claims are solved. It can be asked what level of practical understanding is needed to be a member and of which practices. A full practical understanding of all practices that reside in a community seems too demanding to base membership on it. Practical understanding of the key community practices – i.e. those practices that involve norms that are central to the community – could offer a way out, but that begs the question which practices are central to a community.

In light of this, a more dynamic conception of community membership seems appropriate. Membership of a community can change over time, and people can feel more or less connected to a community. This would require a further elaboration on the concept of community membership. Additionally, who is a member and on what grounds must be informed by the actual practices of a community and is therefore to a certain extent community specific. Because answering the question of the value of communities does not require an exact delineation of who is a member, I will not investigate the question of membership any further. This will become relevant when asking who is represented by community consent. Although this is an important and difficult question for community consent, I will not discuss this question in this thesis. Still, I hope that I have convincingly argued that it is promising to focus on practical understanding of community practices, in addition to having a common characteristics and self-identification with the community, when determining community membership.

1.2 The value of communities

I have argued that social practices are an important feature to distinguish communities themselves as well as their members. Now I want to turn to the value that communities provide for their members, which is based on the value they have for people's identity and autonomy. As we will see, community practices are also important for this value. This argument will be based on Taylor's multiculturalism and Kymlicka's liberal approach to cultural rights. Although these accounts differ in important aspects – Kymlicka emphasizes cultural communities as an instrumental good to gain individual autonomy, whereas Taylor sees culture and community mainly as intrinsic goods – there are, I think, important connections between the values they attribute to communities. Communities help us to answer the questions of who we are and what we value. As Kymlicka and Taylor show, communities provide a background which is important for answering both of these questions.

These two questions are undeniably connected. Part of who I am is answered by what I value, and both are needed in order to understand and form our own identity (Taylor, 1989). Because I want to highlight the reflexive nature of identity and want to use identity more specifically in my discussion of the value of communities, I will refer to "knowing who you are" as *self-understanding*. Since what we value is part of who we are, it can be asserted that this distinction is inappropriate. Although I admit that there is no hard distinction between what we value and who we are, I think it is helpful to make this distinction to highlight the two different ways in which a community is important for its members. So, I will make a distinction between an identity-constituting and value-conferring feature of communities, but keep in mind that both are ultimately part of our self-understanding. In other words, it will be argued that communities are needed to understand ourselves.

I will proceed to discuss community as identity-constituting and as value-conferring respectively. The first part of this section will explain how communities give us a background of meaning which enable us to understand our relationships to others and, consequently helps us to understand who we are. The second part will explain how communities provide us with a conception of what is valuable and fulfilling in life to which we can relate ourselves. Only when we have such a context, we can answer what we value, which is needed to make autonomous choices. Thus, without a community we cannot begin to answer these questions. In the following section I will discuss these arguments in more detail.

1.2.1 Identity-constituting

To understand how a community is important for personal identity, some discussion on personal identity is required. What I want to highlight is that our identity is not created by ourselves isolated from everyone else (Taylor, 1989, 1994, 1995b). As Taylor argues, our identity is formed in relation to others. Through interacting with others (e.g. our parents, friends, or teachers) we define who we are and who we want to be. The question "who are you?" will partly be answered in terms of the relations I have or the roles I take on, both formal and informal. This means that who we are can only fully be answered when taking into account our relations with others, which Taylor refers as "the significant others" (Taylor, 1994, p. 32).[5] These significant others are not only important for the formation and development of personal identity, but also for maintaining who you are. Part of who we are is defined by the relations we have. If these relations would change, it would change who we are. Because of

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[5] Taylor borrows the term "the significant other" from George Herbert Mead. It is important to note that, though he uses the same concept, he disagrees with Mead's account of individual identity on the ground that Mead fails to account for the individual in the formation of identity.

this, recognition of this relation by the other is of great importance. When the relationship you have with significant others is not recognized by them, your identity is harmed. When a significant other does not recognize you in the way you would expect them to recognize you, the conception of yourself changes accordingly. This makes recognition from others of fundamental importance for your identity.[6]

Now we see the importance of relations for identity, we can also see the importance of communities for personal identity. This is because it is only against a background of meaning that our relations can have meaning.[7] This is well explained in Searle's discussion of "institutional facts" (Searle, 1995). Institutional facts only exist because we have rules about these facts which we all follow, i.e. constitutive rules. The clearest, and his most used, example is money. A piece of paper with "ten euro" on it only has value because we treat it as such. If we stop treating this piece of paper as valuable, its value will cease to exist. Note that part of this meaning is not only that this bill is worth ten dollars, but also how you relate to it, e.g. how you use it. Thus, the meaning of money as something valuable is constituted by the social practices involving money. Social practices enforce these constitutive rules. Because everyone acts as if this piece of paper is valuable, you will be expected to do as well. In other words, actions in which money is not regarded as valuable are considered wrong in the current practices that constitute money. And because you are expected to do so, and everyone does so, you will be pushed to do so as well.

In a similar way, social practices give meaning to our relations. Take the example of a teaching practice. As previously noted, how one is expected to behave as a student or teacher is governed by the norms of the teaching practice. If one day all students stopped treating their teacher as a teacher, the teacher is no longer a teacher and the teacher-student relationship ceases to exist. This construction of meaning is true for all our relations: the meaning of our relations is created by the constitutive rules that are embedded in our social practices. As I have argued, communities differ in the kind of practices and the kind of norms in those practices. If personal identity is tied to certain relations, it is also tied to the community practices that provide the meaning to these relations. The community enables us to understand who we are and our relations to others.

Note that this background of meaning is not only needed to create a meaning for our relations, but also to maintain this meaning. If people would stop acting in accordance with the rules that constitute the meaning of "president", the (previous meaning of the) role "president" ceases to exist. Since

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[6] As I will discuss below, this recognition is not only important for individual identity, but also for collective identities.

[7] Taylor builds on Wittgenstein and seems to hold that all things only have meaning against the background of a language. Because I do not have the expertise to discuss this debate I will focus on the meaning of *institutional facts*. Although this makes the claim weaker, I think it also demonstrates the necessity of a background of meaning.

constitutive rules can only give meaning to institutional facts when they are collectively endorsed, the background of meaning can only be created collectively. It is only because we have a common understanding of this social relation that the social relation exists as such. In other words, this background of meaning is not reducible to individual understanding: the understanding has to be a shared one. This is why Taylor calls this background an irreducible social good (Taylor, 1995a).

1.2.2 Value-conferring

An understanding of who we are is not only formed by the relations we have, but also by what we value and what choices we (want to) make. This brings us to the second part of self-understanding, namely what we value. Here, the background offered by communities is again necessary (Kymlicka, 1989, 1995; Taylor, 1989). This is because our cultural background, provided by a community, gives us some sense of what is valuable. "[I]t's only through having a rich and secure cultural structure that people can become aware, in a vivid way, of the options available to them, and intelligently examine their value (Kymlicka, 1989, p. 165)." Culture provides, as Kymlicka calls it, "*a context of choice* (Kymlicka, 1989, p. 166)." Only within this context of choice we can evaluate choices and thus make autonomous choices. This does not mean that we take our cultural standards unreflectively as our own. However, it is only from our cultural background that we can start reflecting on our values. From these standards we can start our own reflection on what is valuable. We can take our own standpoint on what is valuable, but this standpoint can only be taken in relation to a wider background of meaning, in this case a background of value.

To be clear, this idea of communities as value-conferring does not necessarily commit us to an anti-realist meta-ethical position – i.e. that values only exist ontologically in community practices. The value-conferring nature of communities can be interpreted as an epistemological point: it is only within a context of choice that we can develop an understanding about what is valuable. This is because these values can only be encountered within our social practices. Regardless of whether values ontologically exist independently from our social practices, it is within these social practices that values are practically realized. Values only exist in this practical sense (not in an ontological sense) in social practices. For example, treating others as equal only practically exists when people are indeed treated as equal. Furthermore, a practice also enforces the norm of treating others as equal through various means, like creating expectations and rules. Within these social practices treating others as equal is seen as right. This does not necessarily mean that this is also morally right – although I am of course strongly inclined to say it is –, but it means that we can only get acquainted with this value within a social practice. The values held within a community are realized within social practices.

Since most values can only be realized within social practices, it also follows that fulfilling what we value can only be done collectively.[8] The things you value – e.g. experiences, practices or a way of life – can only be valued within social practices. “I may value the fulfillment that comes from authentic self-expression, or the experience that arises from certain works of art, or outcomes in which people stand with each other on equal footing of frankness and equality. But all this is only possible against the background of a certain culture (Taylor, 1995a, p. 136).” This is not an instrumental relationship, e.g. authentic self-expression is made possible by certain culture arrangements and therefore culture is important to realize this value (Taylor, 1995a). Rather, these valuable goods like authentic self-expression and the experience of having these goods only exist as part of a culture. The individual experience of value is inseparable of the cultural practices which realize them. The experience of a free liberal society, which is valuable for a lot of people, is part of the Western culture. Since these values cannot be reduced to an individual experience but only makes sense as part of the social practices that make up the culture, this is an irreducible social good.[9]

It could be argued that there are people that “break free” from their traditional context and invent new values for themselves. In other words, that they don’t need such a collective background to be autonomous. However, this is always based on or in reaction to the old background. These people do not come from nowhere but develop their own ideas of a good life based on the background they came from. The new values which are created can only be understood in relation to the old ones from which they were developed. Furthermore, as said, most of these values can only be realized collectively. Even if someone would come to a picture of what is valuable, most of these values can only be enjoyed within social practices.

As already mentioned, communities as value-conferring have an important relation to the value of autonomy (Kymlicka, 1989). To be autonomous we need some conception of what choices we want to make. In other words, we need to have some qualitative position from which we can make choices. Consequently, we need to have a position on what a fulfilling life is, of what something’s being valuable is. As I have argued, what is valuable can only be learned within a background created by a community. Or more precisely, it can only be learned within a cultural background. Because of this link with autonomy Kymlicka has famously, and I think correctly, argued that even liberals who prioritize individual autonomy over other values have to recognize the value of communities.

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[8] It is not unthinkable that someone would value a solitary life in nature. This conception of a good life is however an exception which most of us do not desire.

[9] Note that we have now seen two distinct ways in which something can be an irreducible good (Taylor 1995a). The background of meaning is irreducible to individuals because it rests on a common understanding, which is essentially shared. Secondly, the things we value and our experience of them are inseparable from the social practices which create them and therefore irreducible to the individual experience.

Not all communities necessarily possess a background of values needed for autonomy. It is possible to imagine a community with practices in which no substantive position on what is valuable is taken. The previous discussion already mentioned that people need a *culture*, and Kymlicka and Taylor both focus on cultural communities instead of communities in general. Neither of them gives an explicit definition of cultural communities. At the same time, in both accounts cultural communities are taken to possess some conception of a good life. This is also in line with the value they possess for autonomy. Some conception of the good life is needed to function as a starting point for our personal reflection on what a good life is. What is therefore important for autonomy is not whether something is a "community", but whether the community offers a conception a good life as a background which is important for autonomy. This does not have to be explicit. As discussed in the section on communities, it has to be present in the social practices of the culture, because these practices are where the norms of a culture are created and enforced. Because it are those communities that are value-conferring, which is an important part of the value of communities, the rest of my argument will concern cultural communities. In other words, communities that have cultural practices in which offer resources for their members to understand themselves – i.e. who they are and what they value. The question to be asked is how this value of cultural communities provide a reason in favor of community consent.

1.3 Community consent

To answer this question positively, two steps must be made. First, it has to be shown that biomedical interventions can potentially harm communities and, secondly, that the best or even only way to reduce this harm is to involve communities. I will consider two possible lines of argumentation that could answer both points. First, I will consider direct harms to community members due to biomedical interventions. I will argue that this harm does not necessarily provide reason to support community consent. Then I will discuss how biomedical interventions could potentially harm people's self-understanding directly or through disrupting social practices and therefore harm communities and their members. This, I will argue, is the main reason to enable community consent in biomedical interventions. Finally, I will end by refuting a possible counter argument that has been made against Taylor and Kymlicka.

1.3.1 Direct harm to the community

One of the most prominent examples of harm connected to biomedical interventions is stigmatization. This harm can arise for community members individually or for the community as a whole. An example of the first case is the stigmatization that can result from participation in HIV research (Nyblade, Singh, Ashburn, Brady, & Olenja, 2011). Examples of stigmatization directed at the community as a whole can be found in genetic research in ethnic communities (Davis, 2000). Ashkenazi Jews, for example, have voiced concerns about genetic research in their ethnic community, arguing that it could foster discrimination for the community as a whole (Lehrman, 1997; Rothenberg & Rutkin, 1998). It is obvious in both cases that stigmatization can cause direct harm to community members. Based on the previous discussion, it can also be argued that this direct harm is not the only problematic aspect of stigmatization. In the case of individual stigmatization, members are stigmatized within their own community. So, on the one hand, the community possesses a deep value for its members. On the other, the stigmatized members are harmed within their own community. On the community level, stigmatization also attaches harm to membership of a community: in this case people are stigmatized because they are member of a community. Therefore, membership of that community becomes less desirable for these stigmatized people. In both cases, people are caught between putting up with stigmatization or losing membership in their community.

Based on this, multiple theorists argue for community engagement and community consent by arguing that it could minimize the risks of harms related to biomedical intervention (Dickert & Sugarman, 2005; King et al., 2014; Lavery et al., 2010; MacQueen et al., 2015; Tindana et al., 2007). The main idea is that, since they make up the community, community members would know best how a biomedical intervention could harm their community as well as the best way to avoid these harms. As King et al. write: “what constitutes a risk, and which risks are deemed to be acceptable, and by whom, may not be obvious to remote researchers and their IRBs [Institutional Research Boards], who may be unfamiliar with the ethically significant features of the specific research context (King et al., 2014, p. 2).” According to this argument, community consent must be included in community engagement since community members would know the stigmas existing within the community, as well as the ones about the community. Giving them power to decide about the research is the best way to avoid these direct and indirect harms.

However, it is questionable whether this approach successfully defends community consent. Firstly, it could be doubted whether community members are indeed aware of the stigmas that exist in their community. From the perspective of community members, stigmas could be the existing norms that are just as normal as other (non-ethically debated) norms that govern their practices. This is not only true for the example of stigmatization. Even though community members have a better understanding of the community than researchers, there is no necessary connection between this practical understanding and an understanding of potential harms and their acceptability. In other words, communities themselves are not necessarily in the best position to identify potential harms and determine which risks are acceptable. And even if we assume that they do have the best knowledge of which risks are prevalent in their community and which of those risks are acceptable, this still does not justify community consent. Community consultation which only involves information exchange could also achieve the same risk minimization. Although we should think about ways to avoid these potential harms of biomedical intervention, community consent is not necessarily the way to do this.

1.3.2 Disruption of community practices

Because of the restrictions community consent could put on individual autonomy (a problem which I will discuss in the third chapter), a stronger case for community consent is desirable. The second line of argumentation, which is more in line with the value of communities as argued for above, can offer this. This value of communities for members' self-understanding is realized in the (cultural) practices of the community. Therefore, a more promising line would be to see how research, and in particular standard, individual informed consent, could undermine members' self-understanding directly or by disrupting the community practices which offer resources necessary for self-understanding. I will elaborate on how practices and self-understanding could be disrupted in this section. I will end by arguing that this kind of disruption provides a strong reason for community consent.

Within biomedical interventions, potential research participants are traditionally approached on an individual basis and informed consent is also an individual form of consent. However, as Tindana et al. describe, as noted in the introduction, such an approach might not match the cultural beliefs about consent in a community (Tindana et al., 2006). Such a non-individualistic conception of consent is expressed by other communities as well. DeCosta et al., for example, describe how many members of an Indian village hold that decisions about research participation should be based on consultation of family members (DeCosta et al., 2004). Thus, members of this community seem to hold a different conception of consent, which does not correspond to the individualistic conception of informed consent normally employed within biomedical research.[10] This conception is also applied in community decision-making practices. For example, some communities could have a more collective form of decision-making or attach a lot of value to the judgement of their community leader when making a decision. Demanding individual informed consent in those communities involves the risk of demanding a change of community practices (e.g. demanding a decision-making practice without involving the community leader). As argued, community practices – through the norms and relations within those practices – can be central to people's self-understanding and disrupting them would be harmful.

But research does not have to change a community practice to undermine that practice. Ignoring community practices can already be undermining, as this would show an absence of recognition of these practices and the norms residing in them. As Taylor argues, like recognition by significant others of your relation with them, recognition of your cultural identity is important for your identity (Taylor, 1994). I think this also applies to the case of biomedical interventions. If biomedical interventions

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[10] Note that this, in itself, says nothing about the moral rightness or wrongness of that consent process.

would ignore certain community practices or things essential to those practices, like cultural beliefs, they would not acknowledge these cultural practices as equally worthy compared to the conceptions implicit in the research, like a Western conception of autonomy. This lack of recognition could undermine trust in these practices without altering or undermining the practices directly and, consequently, affect the self-understanding of community members.

Furthermore, individual consent can promote norms that conflict with the norms within the community. This could directly affect the self-understanding of community members. An example is the stance people take towards other decision-makers. As we will see in the next chapter, many community members have pointed out the importance of trust for community consent. Informed consent, on the other hand, requires a more critical attitude to the information, as well as the people involved in the consent process. Potential subjects are required to rationally deliberate and, in that deliberation, critically evaluate information, e.g. advice from others. Thus, demanding individual informed consent implies a duty to be critical. Such a critical position might not be compatible with the trust that is central to the decision of some community members. It seems impossible to be very critical or suspicious of a person, and trust that person at the same time. Informed consent could undermine existing norms and relationships, by imposing a norm to be critical.

Let me illustrate this with two examples taken from different studies on different aboriginal communities. The first example comes from an Inuit-Metis community (an aboriginal community in Labrador, Canada) (Bull, 2010). In research carried out by Bull, an elder of this community says:

> I am one man. One Metis man who is connected to the universe in many ways. I am connected to my past by my relations with the grandmothers and grandfathers. I'm connected to the future through my children and grandchildren. I do not stand alone in this world. […] We cannot separate ourselves from that and assume that we can make it in this life. (Bull, 2010, p. 17)

This shows a more relational conception of "the self" as connected to other relatives, which seems to be important for this person's identity. Such a conception is not supported by the standard individualistic approach to informed consent. As said before, in standard informed consent the individual alone must decide, independent from other family or community members. So there seems to be a conflict between the self-understanding of this aboriginal elder and the assumptions around identity employed in standard informed consent. Assuming that this relational conception of the self is shared throughout the community, it would be bad to employ a practice with a more individualistic conception of the self in this community. This could have a direct effect on members' self-understanding as well as the practices in which such a relation conception is assumed.[11]

That communities are concerned about protecting their decision-making practices is shown by a study in other aboriginal communities (Fitzpatrick et al., 2017). Fitzpatrick et al. describe the conceptions on research in aboriginal communities in Fitzroy Valley (Australia). They point out that the standard form of informed consent, which embraces an individualistic idea of decision-making, is not compatible with the conception of decision-making that these aboriginal communities have, which is more concerned with family and community. This more central role of others in the decision-making can, for example, be found in the requirement to include community elders in the research protocol and ask them for permission to conduct research. As one community leader says: "I think it's important to acknowledge that elders have that cultural authority and that they can make decisions for the whole of the Fitzroy Valley (Fitzpatrick et al., 2017, p. 12)." As said before, in standard informed consent, the individual alone has to decide, independent from other family or community members. Asking permission to ask an individual to consent would also conflict with the individual's authority to decide underlying this form of consent. In this way, individual informed consent is incompatible with the more collective focused conception of decision-making and the related practices. We can see how restricting consent to the decision of the individual and ignoring existing decision-making practices (such as the role of elders) could undermine the conception of decision-making in this community and the decision-making practices related to that.

Remember that a social practice is not isolated from others but stands in a web of intertwined practices. This is most clear in the way that norms of one practice influence the norms functioning in others. Furthermore, what we call cultural norms are norms shared in different social practices within a cultural community. Disruption of political and consent practices can therefore have consequences beyond these practices.[12] Take the role of community elders in aboriginal communities mentioned above (Fitzpatrick et al., 2017). If researchers were to ignore their role in the community and approach every member individually, they would undermine their authority. This undermining of their authority also undermines the meaning of "community elder". Since elders play an important role in the community, the undermining of their role as community elder could affect a variety of community practices and other members. I do not argue that this will necessarily happen, but we can see how

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[11] Although Bull argues that aboriginal communities have a need for collective decision-making in medical research, she does not explain whether this conception of the self and the importance collective decision-making are related.

[12] Because of this interconnectedness, other practices could also make up for the disruption of a (decision-making) practice. Although this weakens the argument for community consent, it must be noted when practices are more central to a community, it will be less likely can fully make up for the disruption of this practice. The argument here is therefore stronger when the practice is less replicable.

disrupting a decision-making practice could have harmful effects outside that practice. A similar argument could be made in the case of other community leaders or traditional gender roles, which are sometimes central to decision-making practices. Social relations, the conception of social roles, and cultural norms could be affected by imposing a different in decision-making practice.

We can now see how the case for community consent arises from the value of communities and its practices. The background offered by communities is created through social practices and disruption of those practices can disrupt the values and meanings created by those practices. By changing the meaning of social relations and roles in the community, and the norms governing those, biomedical interventions disrupt the self-understanding of community members. This does not mean that every community with consent and political practices that differ from the ones usually employed in biomedical interventions necessarily has a right to be involved in decisions about the intervention. Here, the role of community consent is to avoid potential disruption in key practices. Although individual informed consent does not necessarily disrupt community practices, I have argued that it has the potential to do so. If this would occur, it would undermine community members' self-understanding. Because this risk provides a reason for community consent, communities that want to argue for community consent based on this reason need to demonstrated that *the community has practices around autonomous and political decision-making that are incompatible with the standard procedures for biomedical interventions, and which are central to the community in such a way that disrupting those practices would have an effect on a variety of other community practices and, consequently, on the self-understanding of community members.*

Note that this the argument based on the value of communities does not imply a certain form of community consent. In most documented cases, this community consent will most of the time take the form that is described by Tindana et al.: first asking permission to the appropriate authorities within a community (e.g. community leaders and heads of households), then asking individual informed consent to potential research subjects (e.g. Fitzpatrick et al., 2017; Molyneux, Wassenaar, et al., 2005; Tindana et al., 2006). Furthermore, a number of studies also point out that the role of medical professionals in community consent goes beyond asking permission to enter (Fitzpatrick et al., 2017, 2019; Molyneux, Peshu, & Marsh, 2005). This mainly involves informing community members and involving them in decisions that concern the research throughout the project. Thus, typical community consent is more in line with shared decision-making, than a just asking one-time permission.

Weijer and Emanual have argued that community consent does not absolve researchers from their duty to get individual consent (Weijer & Emanuel, 2000). "Properly understood, community consent is an additional protection; a study may not proceed without informed consent from both the community and the individual research subject (Weijer & Emanuel, 2000, p. 1144)." The common form of community consent seems to adhere to this by still requiring individual consent. Note however, that the argument of this chapter does not warrant these restrictions on community consent in favor of individual consent. Based on the argument, if a collective decision-making practice is central to a community and an addition of individual consent to these practices would have a high risk of disrupting these practices, there is a strong reason to only have community consent. As said, this is not the form of community consent that is commonly described, but the argument based on the value of communities does not offer the resources to rule out every form of community consent which excludes individual consent – however, this could be done based on other reasons.

1.3.3 Contextualizing community protections

Before concluding, I want to point out one argument that has been made against multiculturalism. For this criticism it is important to know that the conclusions that Kymlicka and Taylor draw are mainly society-wide – by which I mean that the protections they defend are mainly meant to protect against societal and institutional developments that put pressure on the community (Kymlicka, 1989, 1995; Taylor, 1994). Both mainly target pressures from the majority culture on cultural communities and use pressures from Western liberal cultures as main example. Although Kymlicka takes a liberal approach to community protections, he agrees with Taylor that it is indefensible to claim that liberalism can be neutral towards culture. As Kymlicka argues, states cannot escape making difficult cultural choices about, for example, language. "The state unavoidably promotes certain cultural identities, and thereby disadvantages others (Kymlicka, 1995, p. 108)." For Taylor the problem of neutrality goes further than political decisions that must be made within a liberal society. According to him, the liberal tradition itself results from Western culture. "Liberalism is not a possible meeting ground for all cultures, but is the political expression of one range of cultures, and quite incompatible with other ranges (Taylor, 1994, p. 62)." Based on this, the two theorists argue for protections of cultural communities. Although they emphasize different forms of protections – Taylor promotes strong collective rights to organize around collective goals and recognition, whereas Kymlicka focusses more on weaker collective rights for cultural communities like rights to political or economic resources – they both defend protections against societal pressures that result from the majority culture.

According to Kukathas, protecting against these societal pressures assumes a wrong conception of communities (Kukathas, 1992). "The primary reason for rejecting the idea of group claims as the basis of moral and political settlements is that groups are not fixed and unchanging entities in the moral and political universe (Kukathas, 1992, p. 110)." Both the boundaries as well as the nature of communities change over time. Horowitz points out, for example, that ethnic identities change over time and with them the nature of the communities (Horowitz, 1975). So, the argument goes, why should we protect communities from a process that is part of the normal development of communities? Furthermore, even if we could resist cultural change, doing so “restricts the opportunity of minorities within the group to reshape the cultural community, whether directly or through interaction with those outside the group (Kukathas, 1992, p. 114).” Because multiculturalists employ this incorrect static conception of cultural communities, they restrict opportunities instead of fostering them.

I do not aim to defend Kymlicka and Taylor. Instead, I want to point out that such a critique is not applicable in the case of community consent. This is because community consent aims to protect communities against potentially disruptive effects of biomedical interventions, which are different from the threats that Taylor and Kymlicka wish to protect communities from. Firstly, protections like community consent are used against biomedical interventions that come from outside the community. These interventions are more direct than the societal and institutional changes from which Taylor and Kymlicka wish to protect communities. Therefore, protection from effects of biomedical interventions does not protect against normal changes, but against changes that result from active interventions that directly target the community. Secondly, whereas Kymlicka and Taylor defend more indeterminate protections, like community rights, the community consent is restricted to decisions about the biomedical interventions which are time restricted. Although they can run over a long course of time, biomedical interventions have a more defined endpoint. Because of this restricted focus of the protection, community consent is still compatible with a dynamic picture of communities. As we will see in chapter 3, I will even argue that openness to change of community practices (through Hirschman’s “voice”) from inside the community is a requirement for community consent (Hirschman, 1970).

Conclusion

In this chapter I have provided a reason for community consent based on the value of communities for their members’ self-understanding. I want to emphasize that it is only one reason. This means, firstly, that there might be other reasons for community consent, of which I mentioned a couple; like the ethical importance of having a say in health-related matters, as Pratt and De Vries argue. At the same time, I have argued that these reasons are weaker compared to the one given in this chapter, since they start from different considerations than the value of communities. This means that the decision-making can be on other levels than on a community level. This chapter, on the other hand, builds from and tries to explicate the strong intuition that there is something special about communities, which gives us strong reasons to involve communities in the decision-making about biomedical interventions.

Secondly, as already mentioned in the introduction, the reason I give in this chapter is only prima facie. In other words, it is possible that other reasons override the protection of self-understanding by community consent or put restrictions on community consent. As described in the introduction, one of these reasons is the restrictions community consent can put to individual informed consent. In practice, this mainly results in limiting the autonomy of women. Thus, even though this chapter made a strong case for community consent, there is at least one strong reason against it. In the next two chapters I will consider this objection and hope to decrease the tension between individual consent and community consent.

Chapter 2

Trust, Trustworthiness and Community Decision-Making

The previous chapter argued that the value of communities provides an important reason for allowing decision-making practices that deviate from the regular form of informed consent. Examples are shared-decision making practices where e.g. spouses are included in decisions about research participation. Another example is asking community leaders to consent before asking potential subjects. As said, I do not claim that any of these practices are morally superior to standard informed consent. Nor do I hold that the right form of decision-making is culturally relative, i.e. that which form of decision-making is the morally right one depends on the community in which the decision is made. The claim defended in the first chapter stated that the value that community practices have for members' self-understanding gives strong reason to respect community decision-making practices in biomedical interventions when not respecting those practices risks disrupting decision-making practices that are central to the community.

Although I think this provides a strong reason for allowing different forms of decision-making and consent, different decision-making should not directly be allowed in biomedical practice based on this argument. As said, the first chapter only gives a prima facie reason in favor of community decision-making, not an all-considered judgement. Furthermore, there are strong reasons to reject decision-making practices that differ from standard decision-making (i.e. individual informed consent) in the medical context. One of the strongest reasons against community consent is the restrictions on individual autonomy that can arise from community consent. The main goal of traditional informed consent is to allow a potential subject to decide for themselves whether they want to participate, i.e. to decide individually by which they make clear that they want to participate in the research on a voluntary basis. What is problematic about community consent, from this perspective, is that it can overrule or restrict individual decisions. Since individual informed consent is an important and central part of contemporary bioethical guidelines, this conflict between community and individual consent is very problematic

It is this conflict that I want to discuss in the next two chapters. The third chapter will consider how community consent can still be allowed considering that power relations can significantly influence people's acceptance of community consent. In this chapter, however, I will take a more ideal approach and assume that community consent is based on trust in other decision-makers. This assumption will be supported by several studies that have pointed out the importance of trust in (community) consent. I will argue that when interpersonal trust is present in community consent, this form of decision-making can satisfy the requirements for autonomous action: understanding, intentionality, and non-control. Autonomous action is held to be the main justification for (individual) informed consent. Therefore, if trust-based community consent is able to satisfy the requirements that make a choice autonomous, community consent is not as objectionable from the standpoint of informed consent.

I will start by discussing the standard conception of informed consent and the underlying idea of autonomous action. I will examine the three conditions of autonomous action as defended by Faden et al.: *intentionality*, *understanding*, and *non-control* (Faden et al., 1986). After that analysis of autonomous action, I will discuss the role of trust in community consent. I will start by pointing out that, in practice, trust is seen as an important value in community consent, since it both gives reason to consent as well as trusting others judgement when consenting. This will be followed by a conceptualization of "trust" and "trustworthiness". Based on that conceptualization I will argue that when community consent involves trust and trustworthy people, it can satisfy all three conditions of autonomous action and therefore be in line with the idea of informed consent. I will end by arguing that trust and trustworthiness are essential to satisfy these conditions. In other words, without these community consent cannot be based on autonomous action.

2.1 Informed consent and autonomy

Historically, the practice of informed consent has been motivated by malpractice and abusive research, most notably the Nazi experiments during the Second World War and the Tuskegee syphilis experiment. In both cases, research subjects were enrolled in studies without their explicit consent. In other words, they were part of an experiment without having chosen to be so. To avoid these kind of malpractices, informed consent is meant to ensure that all subjects participate in medical research voluntarily.

The first of the documents meant to govern research with human subjects was the Nuremberg Code, which was a reaction to the horrors of the Nazi experiments ("The Nuremberg Code (1947)," 1996). Multiple guidelines followed, like the Belmont Report and the Declaration of Helsinki (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; World Medical Association, 2013). It is helpful to give a more detailed impression of informed consent guidelines: let us therefore focus on The Declaration of Helsinki of the World Medical Association, which is currently the main ethical guideline on human research (World Medical Association, 2013). This declaration has an extensive section on informed consent, but I want to draw attention to the following points:

> 25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or

> community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.
>
> 26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. […] (World Medical Association, 2013, secs. 25–26)

I want to highlight three things here, which will illustrate the commonly held conception of informed consent. Firstly, point 25 states that consent has to be given voluntarily. Note that the Declaration connects this voluntariness to individual decision-making. In other words, to guarantee the voluntariness of consent, it has to be given, in the end, by the individual alone. Here, we can see, again, the tension between informed consent guidelines and community consent. Secondly, point 26 says that potential subjects must be informed about the research. This does not mean that all possible information has to be disclosed, but "rather, they [potential subjects] need to know how their lives, and what is important to them in their lives, are likely to be affected, both positively and negatively, by participating in the research (Brock, 2008, p. 609)." There are different standards that determine what this entails, but this discussion is not of direct relevance here. Note, however, that an understanding of all aspects of a proposed biomedical research is not required to have an adequate understanding necessary to give consent. Finally, the Declaration of Helsinki also emphasizes that the people consenting must be "capable of giving consent". What this exactly means is unclear and there are a lot of questions to ask about this requirement. Chapter 3 will give a more elaborate discussion on the capacity needed to consent. For now, there is no reason to assume that people in community consent are more often incompetent than those giving individual consent. We can therefore set aside a discussion about this condition.

Together, disclosure, voluntariness, and competence make up the requirements for informed consent and they are widely recognized to be so by both guidelines and the bioethical literature (Brock, 2008; Faden et al., 1986; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; "The Nuremberg Code (1947)," 1996; World Medical Association, 2013). As we will see, the first two requirements follow from the account of autonomous action that provides moral justification for the informed consent practice. These requirements of informed consent can be interpreted in a legalistic manner, in which consent is a legal or institutional requirement for research involving humans (Faden et al., 1986; R. Young, 2009). However, here I will focus on informed consent as an ethical requirement.

To see why informed consent is ethically required, we have to examine the justification of informed consent. This justification of informed consent has been discussed most extensively by Faden, Beauchamp and King in their book *A History and Theory of Informed Consent* and I will mainly rely on their account (Faden et al., 1986). In line with the bioethical consensus, they defend informed consent based on the value of autonomy. Very generally, autonomy is taken to be self-governance: people should be free to determine their lives according to their own plans (Beauchamp & Childress, 2001; Faden et al., 1986). Informed consent is meant to enable potential research subjects or patients to make such an autonomous choice about the medical intervention proposed by a researcher or their physician. Although autonomous actions and being an autonomous person are obviously connected, the two are not the same (Faden et al., 1986). An autonomous person is someone who leads an autonomous life, thus, plans her life according to her own will. In contrast "[a] fully or ideally autonomous action is an intentional action that is fully understood and completely noncontrolled by the influences of others" (Faden et al., 1986, p. 238). You do not have to be an autonomous person to conduct an autonomous action. Informed consent is primarily to facilitate an autonomous action (i.e. an autonomous choice). Therefore, I will focus, like Faden et al., on autonomous actions instead of what makes a person autonomous.[13] To examine this concept of autonomous action, I will look at the three conditions that together form the definition of autonomous actions as outlined above: intentionality, understanding, and absence of control.

Firstly, for an action to be autonomous, it has to be willed by the agent. If agent A performs act ϕ, without intending to ϕ, it is hard to uphold that this action is a form of self-governance. An act which is accidentally performed by an agent is not necessarily in line with what that agent wants or plans to do and therefore Faden et al. argue that an autonomous action must be an *intentional action*. This is an "action *willed in accordance with a plan*, whether the act is wanted or not (Faden et al., 1986, p. 243, italics are theirs)." Actions can be willed in various ways according to them. An action can be willed for its own sake, e.g. A wants to ϕ, because he likes ϕ-ing. An act can also be willed instrumentally. Here Faden et al. make a distinction between instrumental willing and tolerating. If A ϕs for the sake of Y, but does not object to ϕ-ing, A instrumentally wants to ϕ. If A performs ϕ for the sake of Y in spite

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[13] Mackenzie points out that making an autonomous choice does not imply that a person is autonomous (Mackenzie, 2014). Because the account of autonomous actions aims to protect people's autonomy, an underlying account of an autonomous person would be required. Although Mackenzie is right in pointing out that an autonomous choice does not imply full autonomy, I will assume that Faden et al. correctly limit their discussion to autonomous actions. In this account, the purpose of informed consent is to ensure that people make an autonomous decision about research enrollment and making people autonomous in general is beyond its scope.

of not wanting to ϕ, A tolerates ϕ. What is important in all these examples is that an autonomous action requires that that action is intended by the agent, i.e. the action is in line with the plan of the agent. This plan does not have to be a comprehensive plan which includes the whole life of an agent. A plan could also be very minimal as something that the agent is striving to achieve, in either the short- or long-term, in his or her action.

The second condition, *understanding*, is strongly connected to intentionality. If an act is to be wanted it should also be understood. Without having an appropriate comprehension of what an action entails, it is impossible, according to Faden et al., to really want to act in that way. This could seem confusing, because an act based on an incorrect understanding can be intentional. A can want to ϕ, even though she does not understand what ϕ-ing entails. However, the intention to ϕ does not refer to the act actually undertaken, since the agent does not know what that act is. For example, if A incorrectly mistakes ϕ-ing for χ-ing, she may intentionally do ϕ, but on the basis that this is χ-ing. Thus, the intentionality refers to χ and not to the actual action, namely ϕ. Therefore, the understanding of an act is essential for intentionality and, consequently, for acting autonomously.

There are different ways in which an act can be understood. For informed consent two things are important: firstly, it must be understood by the potential subject that she is consenting. In other words, she has to understand what it means to consent. Secondly, a potential subject has to understand what she is consenting to. This refers to the relevant information that informed consent requires. Thus, to make an autonomous choice, an agent needs to know *that* she is choosing and *what* she is choosing. Note that this understanding can come in degrees. The question therefore is not whether an agent understands everything about a choice but understands enough to make this choice autonomously. What “understanding enough” means is a difficult question, which is, as said, debated in the context of informed consent. However, as I will argue bellow, the potential research subject does not have to have such a deep *understanding what* (i.e. understanding the study and its implications for which the subject can enroll). I will therefore leave this question aside.

The last condition for autonomous actions is *non-control*. This is defined by Faden et al. as freedom from controlling influences. Not all influences undermine autonomous action. A good argument, for example, can have a significant influence on the course of action someone is going to take, but this does not make the argument a form of unwanted control over this action. By unwanted control, Faden et al. mean two forms of control over actions which can be morally bad: *coercion* and *manipulation* –

and by non-controlled they mean the absence of these two.[14] “Coercion occurs if one party intentionally and successfully influences another by presenting a credible threat of unwanted and unavoidable harm so severe that a person is unable to resist acting to avoid it (Faden et al., 1986, p. 339).”[15] This threat has to be irresistible to avoid for the person coerced, because it would otherwise qualify as manipulation. Furthermore, because in their conception coercion implies control by presenting negative consequences, offers cannot be coercive.[16] This analysis of coercion is quite uncontroversial and in line with the literature on coercion (including Nozick’s influential conceptualization of coercion), and we can therefore accept this conceptualization without a more thorough discussion (Nozick, 1969).

Manipulation is harder to define. Because manipulation is used to refer to a variety of different examples, the definition of manipulation is debated, as is whether and when it is morally wrong to manipulate. Faden et al. define “manipulation as any intentional and successful influence of a person by noncoercively altering the actual choices available to the person or by nonpersuasively altering the other's perception of those choices (Faden et al., 1986, p. 354).” Thus, manipulation is an attempt to influence an action, which is less controlling than coercion but more controlling than persuasion. This can be done by reducing options with threats or rewards, deceiving someone, or bypassing reasoning through psychological manipulation. Whether this influence is wrong depends on the context in which it is used. However, other conceptions of manipulation are defended as well. Noggle conceptualizes manipulation more in line with lying and defines “manipulative action as action done with the intent to lead astray” from what the manipulator beliefs are the ideal beliefs, desires, or emotions for the one manipulated (Noggle, 1996, p. 49). In this definition, manipulation is always wrong, since people are intentionally brought to a less-ideal stance. It can be distinguished from innocent persuasion, where people are pushed in the direction of what is thought to be ideal for them. Others connect manipulation with circumventing our reasoning (Sunstein, 2016). As Sunstein defines it: “an effort to influence people’s choices is manipulative *to the extent that it does not sufficiently engage or appeal to their capacity for reflection and deliberation* (Sunstein, 2016, p. 82 italics are his).” Since this leaves

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[14] As we will see in chapter 3, there are more controlling influences than coercion or manipulation by another party. For example, economic situations or social practices can restrict people’s freedom to choose significantly. However, here I will assume that Faden et al. are right that “[n]atural, environmental, and circumstantial threats, such as those presented by disease, are not in the relevant sense *controlling* (Faden et al., 1986, p. 345).” Consequently, although I do not entirely agree with their conclusion, I will hold that choices in these situations are autonomous.

[15] Note that since coercion is based on a threat, being coerced and being unfree are not the same (Nozick, 1969). If you’re threatened to hand over your money or being killed, you are coerced into giving the money but free to not do so. Or someone can be locked up and therefore being unfree to go out of that room, but not being coerced into staying in that room. At the same time, your freedom to ϕ is of course restricted when you are coerced to not-ϕ.

[16] Offers can be disguised threats or forms of manipulation but are not coercion.

open what goal manipulation is meant to serve, in this theory, manipulation is not necessarily morally wrong.

This leaves us with multiple theories on both the conceptualization and the wrongness of manipulation. I give an extensive examination on the (correct) conceptualization of manipulation and I do not think it is necessary to do so. Instead, I want to highlight two important differences between manipulation and coercion, on the basis of which we can distinguish the former from the latter. Firstly, coercion will involve significant control of someone's actions, whereas, in all three accounts, a manipulator does not have this amount of control over the manipulated. It is an attempt to influence someone's actions through various methods, which is far less controlling than coercion. Secondly, it is worth pointing out that, in contrast to coercion, a person being manipulated will not always know that he is manipulated. This is because coercion involves an irresistible threat (Faden et al., 1986). To be effective, such a threat should be known by the coerced, otherwise the coerced does not take this threat as a reason to do what is asked. Manipulation, on the other hand, does not necessarily require this knowledge. Although manipulation can involve threats, many forms of manipulation can influence people without them having any knowledge of these influences. Some forms even require ignorance on the part of the manipulated. An example of this is deception, in which someone is led to a false belief through e.g. disinformation or withholding information. For such a strategy to be effective, a person should not be aware of the manipulation. These differences are not meant to give an exhaustive overview of all differences between coercion and manipulation, but the ones highlighted will be important in the upcoming discussion.

Although I do not wish to take a position in the debate over the wrongness of manipulation, what is important is that even if manipulation can be used for good purposes, manipulation can, in any case, also influence people in a way which undermines autonomy. Therefore, it would count at least somewhat against community consent if people would be more susceptible to manipulation, and of course coercion, in this decision-making process. Thus, the question is whether the people engaged in community consent will be more vulnerable to manipulation. It is this question that I will try to answer below.

Together the conditions of *intentionality*, *understanding*, and *non-control* define autonomous action. It is this idea that informed consent is meant to enable and protect: ensuring the possibility for people to make an autonomous choice about biomedical interventions, including biomedical research, on their own body. This idea of autonomous action is implicitly individualistic due to the conditions of non-control and intentionality. Although they do not directly require an individualistic account of consent, they are certainly thought to be more compatible with individual consent than with forms of community consent in which decisions are made together or by someone else. Theoretically, freedom from control seems more easily ensured in individual informed consent, because it requires that the final decision to consent is made by an individual alone, without, for example, their partners. When, on the other hand, a decision to consent is made after deliberation with a partner, it less easy to determine whether the final choice is indeed in line with what the potential subject wants. Additionally, intentionality seems best ensured when a decision is made by yourself instead of by someone else. This individualistic conception is also implicit in Faden et al.'s account of informed consent, which is based on this idea of autonomous action: ""informed consent" is analyzable as a particular kind of action by individual patients and subjects: an autonomous authorization (Faden et al., 1986, p. 276)."

We also saw this individualistic conception of consent in the Declaration of Helsinki and it can be found in other guidelines as well (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978; "The Nuremberg Code (1947)," 1996; World Medical Association, 2013). This individualistic conception of informed consent clearly conflicts with forms of community consent, which require non-individualistic procedures like consent of community leaders or consultation with partners of potential subjects. Since informed consent and autonomy are taken to be central to biomedical research on humans, this provides a strong reason against community consent. Consequently, it seems natural to conclude that, although community consent is valuable for community members, medical professionals should hold on to standard informed consent, or abstain from conducting research in communities which value community consent.[17] However, it would be better if we could resolve this tension between autonomous informed consent and the value of communities; and I think this is, to a certain extent, possible, as I will argue in the remainder of this and next chapter.

Before arguing that community consent is compatible with autonomous action, I want to make two comments on my choice to use Faden et al.'s justification for informed consent based on autonomous action above another justification. Firstly, since there are different accounts of autonomy and because there is no consensus on what autonomy entails, I admit that the conception of autonomy discussed will not be accepted by everyone and is incomplete. The individualistic focus – which we found in the Declaration of Helsinki and is implicit in the condition of non-control – is not recognized by all philosophers and it is certainly not the only conception of autonomy (Mackenzie, 2014). A different conception of autonomy could have implications for our current informed consent practice, and

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[17] As I will argue in the next chapter, refraining from conducting research in a certain community is also an undesirable option, since it denies communities potential valuable medical findings and future members medical care.

perhaps raise new requirements. Lomelino, for example, argues for community engagement in international research based on a relational account of autonomy (Lomelino, 2015).

Another important objection to focusing on autonomous action follows from the defense of cultural communities in the first chapter. As argued, these communities are value-conferring and these values are needed to make autonomous choices (Kymlicka, 1995). If we want to promote and protect autonomy, we also have to protect the communities and practices from which the values that enable us to be autonomous arise. This is not done within the conception of autonomy employed here, since its focus is restricted to a (one time) autonomous action. But when we follow Kymlicka's argument, informed consent would be internally inconsistent, since it could undermine the sources of value needed for informed consent over the long term.[18] Therefore, it can be argued, that informed consent should be based on a conception of autonomy that explicitly recognizes the value of communities for autonomy. This would also enable a more direct argument for community consent.

Although I am sympathetic to both lines of argumentation – as said, the latter even follows from the defense of community practices, including consent, in the first chapter – I will leave them aside in this chapter. The main reason for this is that the justification presented by Faden et al. is still the most influential in bioethics and, as we saw, current guidelines presuppose this conception of autonomy. It is the conflict between community consent, and informed consent based on this conception of autonomous action I am interested in. Furthermore, if community consent can be justifiable within an individually focused decisional account of autonomy, we do not have to persuade opponents to accept other, broader conceptions of autonomy. I will therefore assume that the goal of informed consent is to enable an autonomous choice in a medical context and is restricted to that (autonomous) action. I will also assume that the above account of autonomous action provides the correct conceptualization of what such an autonomous choice entails.

Secondly, informed consent could also be justified based on other values. Most notably the value of well-being of the subject or patient (Buchanan & Brock, 1990). This line of argumentation is based on the idea that decisions about people are best made by themselves. If this is taken as the only reason for informed consent and autonomy, both only have instrumental value. However, Buchanan and Brock point out that this should be balanced against considerations of autonomy. Although I agree that a balance should be struck here – it can for example be questioned whether autonomy should be given priority in high risk, complex decisions if it does not lead to better choices – I will maintain that autonomy is the value that underlies the demand for informed consent. This is in line with the general consensus in both the literature and guidelines that autonomy, not well-being, provides the

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[18] I thank André Krom for pointing this out to me.

justification for informed consent. Furthermore, defending community consent with (individual) autonomy as the justification for informed consent seems to be a more difficult, and therefore interesting, task. If well-being would be the most important consideration for informed consent, community consent could be defended on paternalistic grounds (provided that better decisions are made in community consent) or grounded on the effect of self-understanding on well-being. I do not predict that these arguments will necessarily be successful. However, there appears to be a stronger conflict between individual autonomy and community consent than between well-being and community consent. It is therefore more interesting whether the former conflict can be resolved. Because of these reasons, I will hold that the most important foundation of informed consent is autonomy and focus on the conflict of this value with community consent.

2.2 Trust and informed consent

Based on the previous section, it could be concluded that community consent is incompatible with informed consent and should therefore be rejected. I think that this conclusion is wrong and would result in the loss of valuable community practices. Here, I want to argue that community consent can be argued to be compatible with autonomous action because of *trust*, which plays a vital role in both individually and community consent.

2.2.1 Prevalence of trust in informed consent

Before arguing that community consent can be in line with autonomous action, I want to look at the conceptions of consent held within communities that have non-individualistic decision-making practices. Though these conceptions can and will differ between communities, it is interesting to see that trust in both medical professionals as well as other community members plays an important role in consent. As Tindana et al. wrote about the conception of consent in the introduction case, the community in the Kassena-Nankana: “The issue of trust comes out strongly in these interviews. This runs through the chief’s trust in researchers and the community’s trust in the decision of the community leaders, which leads to a trust in researchers (Tindana et al., 2006, p. 4).” As I will show here, a similar role for trust in consent can be found in other communities.

It is important to distinguish the different roles trust plays in these forms of consent – even though they turn out to be related. First, many community members gave trust in the medical system or a particular medical center as *a reason to enroll in a study*. In Kassena-Nankana, for example, different subjects expressed that trust in both the chief and the researchers was their main consideration for giving consent (Tindana et al., 2006). The trust in researchers on which decisions would be made resulted from the approval of community leaders as well as past experiences with the NHRC. In the area of Kilifi (Kenya), Molyneux et al. found comparable opinions on informed consent (Molyneux, Peshu, et al., 2005; Molyneux, Wassenaar, et al., 2005). Trust in the Kenyan Medical Research Institute (KEMRI) was the main reason for many members to consent (Molyneux, Peshu, et al., 2005). This trust is based on knowledge of the KEMRI and their activities. However, it is necessary to note that this trust was not all justified, since many subjects based it on a therapeutic misconception – i.e. confusing medical research with medical treatment and therefore incorrectly holding the research as directly beneficial for the patient involved. Similarly, De Costa et al. describe that an important reason for enrolling was trust in the medical professionals conducting the research in Chhainsa, India (DeCosta et al., 2004). Thus, these show that trust, in medical institutions, is seen as an important reason to enroll.[19]

Implicit in "trust to enroll" is another function of trust that can be distinguished, namely trust as a reason to rely on or involve someone else's judgement. The connection between these reason giving functions of trust can be found in a statement from someone interviewed in the Kenyan study expressed: "KEMRI should take what they know is right. We know KEMRI is concerned so we cannot disagree to what they propose" (Molyneux, Peshu, et al., 2005, p. 1468). The same trust in the judgement of medical professionals was expressed in Chhainsa and Kassena-Nankana (DeCosta et al., 2004; Tindana et al., 2006). Therefore, that trust counts as a reason to enroll can be explained by the trust people have in the decisions of medical professionals. Thus, trust provides not only a reason to enroll, because people trust the judgement of medical professionals. This kind of trust gives a reason to hand over a decision to a medical professional, or to involve that professional in the decision.

A similar role for trust in community leaders was found as well. As one community member in Kassena-Nankana stated: "Well, why it is important to follow that process is that, many of us are not educated so if you go and explain to them (community leaders) then we will know that you are telling us the truth (Tindana et al., 2006, p. 4)." The same kind of reasoning can be found in another study of the KEMRI, which states that "[m]ost staff, parents and community leaders interviewed reported that it was essential to incorporate pre-existing decision-making structures such as district officers, chiefs and elders into CE strategies. These individuals reportedly helped build trusting relationships between researchers and community members because they are well recognised, trusted and respected" (Angwenyi et al., 2014, p. 8).[20] These examples imply that community members have trust in community leaders' judgement. This trust is an important reason to rely on their judgement and to

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[19] It is interesting to see that trust is also given as a reason to enroll in a study in more individual and information focused informed consent practices (Kass et al., 1996). Based on this, it could be argued that the requirements for understanding and individual choice in informed consent might be too strict. I will leave this aside, however, and focus on community consent.

[20] Angwenyi et al. focus on the perception of consent around research on children. I assume, however, that the involvement of children does not affect the trust placed in the community leader significantly.

want them involved in the decision-making process. Not all the studies outlined above focused on trust in community leaders and more research is needed to clarify the reasons for including community leaders and other members in decisions over enrollment. However, DeCosta et al. noted that "the majority of the community interviewed could decide about participation only after discussing it with other community members (DeCosta et al., 2004)." Trust will presumably not be the only reason for including other members in the decision-making process, e.g. power structures within the community will most likely influence who is included in the decision-making, but, as the examples of Tindana et al. and Angwenyi et al. show, trust in the judgement of community leaders can be an important reason for including them or relying on their judgement. Since I want to examine community consent, not reasons for enrolling in a research, it is this latter kind of trust – trust in others' judgement – that I want to explore as the basis for community consent. Keep in mind, however, the close connection between the two forms of trust, since trust to enroll can follow from trust as a reason to involve or rely on someone else's judgement when that judgement is positive.

2.2.2 Trust conceptualized

These examples give reason to think of trust as an important value for informed consent. However, thus far this has been descriptive. The cited research shows that trust is an important reason to both enroll as well as to rely on the judgment of others, like medical professionals and community leaders. The question I want to answer is whether trusting others to make a decision can result in autonomous decisions, which are required for informed consent. To do this, it is helpful to take a closer look at what "trust" is. More specifically, I will look at what "interpersonal trust" is, since that is the trust described above.

The conception of trust given here will be indebted to Jones, who is influenced by Baier but takes her conceptualization further (Baier, 1986; Jones, 1996). I choose to mainly rely on her account, because Jones, in my eyes correctly, emphasizes the mixed cognitive and emotional nature of trust. Accounts that conceptualize trust as only one of those two (assuming that such a distinction between emotions and cognitive beliefs can even be made) fail to capture the full nature of trust. Hardin, for example, defines trust as a cognitive state in which the truster has the rational expectation that the trusted will act according to the interest of the truster, because the trusted has an incentive to take the truster's interest into account (Hardin, 2002). In this way, trusting someone entails having a cognitive belief about that person's willingness to take your interest into account. However, this kind of conceptualization cannot explain blind trust: trusting someone without having adequate knowledge about that person and their motivation to take trust into account. Furthermore, even trust informed by rational beliefs seems to have an indispensable emotional aspect. I can belief that I have good reasons that someone will take my interest into account and still have the feeling that I cannot trust that person. Though a cognitive belief about the trusted seems to promote trust in that person, it is not enough.

Although trust is more emotional, overemphasizing this emotional aspect would also be wrong. There are indeed strong reasons to think that trust is an emotion. Lahno, for example, points out that trust, like other emotions, colors the way we perceive people and facts about them (Lahno, 2001). We are more favorable in a judgment about someone when we trust that person. This also enables us to make a distinction between trust and reliance. You can rely on someone based on purely cognitive belief. Trust, however, involves more, having the cognitive belief that someone is trustworthy involves a feeling that this person is trustworthy. However, although trust certainly has this emotional side, we should not neglect how trust is supported by cognitive beliefs about the trusted. Certain information about a person can make us lose our trust in him or her. Although we can of course blindly trust people, for most trust we need some reason to believe that they are trustworthy – I will unpack this concept below. Thus, an accurate conceptualization of trust needs to include both the cognitive as well as the emotional side of trust.

As said, Jones' conceptualization of trust does just that (Jones, 1996). According to Jones:

> [T]rust is composed of two elements: an affective attitude of optimism about the goodwill and competence of another as it extends to the domain of our interaction and, further, an expectation that the one trusted will be directly and favorably moved by the thought that you are counting on them. (Jones, 1996, p. 11)

This definition of interpersonal trust can be split in two elements: the first concerns the affective attitude and the second the cognitive expectation. Let's zoom in on both these parts, starting with "an affective attitude of optimism". It is important to see that this attitude of optimism is a directed form of optimism, namely at someone's competence and goodwill. Thus, trust involves optimism about the goodwill of the trusted towards the truster, as well as optimism about the competence of the trusted to do what the truster is expecting. This competence does not have to be a broad overall competence, but competence in the domain in which the truster expects the trusted to act for him or her. It also does not have to be a technical form, but can be moral competence, e.g. understanding what "respect" is and entails when interacting with people.

The second part concerns the expectation that the trusted will be motivated by the trust of the truster. Jones offers two arguments for this part. Firstly, she argues that trust is something which can feel as a burden. This is not because we do not want people to be optimistic about our goodwill towards them or our competence, but mainly because we feel a responsibility or duty because of the trust placed in us. In other words, when trusted we feel that we have to live up to the expectations of the truster.

Secondly, we would feel that our trust in someone is mistaken if that person is not motivated in any way by this trust. As Jones points out, when we trust a physician "we hope that what the physician takes to constitute acting with integrity and takes to constitute the interests of her patients will be, at least in part, shaped by the expectations of those patients (Jones, 1996, p. 10)."

As said, trust according to Jones is partly emotional and partly cognitive. Jones emphasizes that the emotional aspect is central to trust, since trust involves an attitude of optimism. In other words, without the feeling that someone is indeed trustworthy, it seems hard to trust that person. At the same time, cognitive beliefs help to establish, sustain, and increase trust. For example, judging whether someone is competent will be informed by beliefs about that person. Although these beliefs will be colored by emotions and will make our trust resistant to some facts about e.g. the person's competence, we cannot resist every fact about a person. Thus, except for blind trust, we need both positive attitudes about that person backed by some cognitive beliefs that that person is indeed trustworthy (i.e. of goodwill, competent in the relevant domain, and will be motivated by our trust) to trust someone.

Trusting someone will always involves taking a risk (Hardin, 2002). There is always a risk that the trusted will not do what the truster trusts them to do. Therefore, it is important that the trusted is also trustworthy. What does it mean to be "trustworthy"? Both Hardin and Jones take trustworthiness as being in some way responsive to the trust placed in you (Hardin, 2002; Jones, 2012). Of the two, Jones gives the most detailed definition of trustworthiness, but note that this definition is not directly in conflict with Hardin's definition of trustworthiness.[21] Jones defines trustworthiness as follows:

> B is trustworthy with respect to A in domain of interaction D, if and only if she is *competent* with respect to that domain, and she *would* take the fact that A is counting on her, *were* A to do so in this domain, to be a *compelling* reason for acting as counted on. (Jones, 2012, p. 70-71, italics are hers)

Thus, there are two main conditions for being trustworthy: being *motivated* by the trust placed in you to act in accordance with this trust and being *competent* enough to do so. Jones takes the fact that B takes the trust of A as a reason to act on this trust as a sign of goodwill. In this way, the three conditions of trust – optimism about the goodwill of the trusted, optimism about the competence of the trusted, and the expectation that the expectation that the trusted will be moved by your trust – come back in the definition of trustworthiness. An important implication of this conception of trustworthiness, is

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[21] They mainly disagree on what should motivate a trustworthy person, on which I will elaborate in the next chapter.

that trustworthy people must also be able to recognize when someone places trust in them (Jones, 2012, pp. 72–73). Without being aware of trust, people cannot be motivated to act on it.

As noted above, trust involves risk and being vulnerable to abuse of the person trusted. Trustworthiness is meant to overcome this risk, but what if the trusted is not trustworthy? What if the people trusted are incompetent? Or what if they do not want to act in accordance with the trust placed in them? The risk of untrustworthy people is admittedly a problem for trust-based consent. I will address this problem in the next chapter by pointing out ways in which trustworthiness can be promoted. Promoting trustworthiness will decrease the risk involved in trust-based decisions. In the upcoming analysis of trust-based informed consent, I will assume the trusted to be trustworthy.

2.2.3 Trust-based consent

How does this conceptualization of trust and trustworthiness help in the context of informed consent? Basing trusting someone else to make a decision seems to be incompatible with the individual nature of informed consent. However, I think this conclusion is false. Trust-based (community) consent can be just as autonomous as individual informed consent. In this section, I will argue that when a decision is based on trust and the others involved are actually trustworthy, community consent can satisfy the three conditions for autonomous action as defended by Faden et al.

Let us start by discussing the condition of *understanding*. As said, there were two ways in which informed consent required understanding. Understanding *that* you are giving consent and understanding to *what* you are consenting. There is no reason to suppose that the former form of understanding, *understanding that*, lacks in community trust-based consent. Even if a consent decision is made by someone else and is based on trust in that person, the truster has to know what she is trusting the other to do. Furthermore, since community members have a practical understanding of their decision-making practices, it can be assumed that they know they are making a decision. Thus, if trust-based consent would be problematic due to lack of understanding, it would be lack of *understanding what*.

This latter form of understanding is, however, not as necessary as Faden et al. think. Kongsholm and Kappel make a convincing case against the *understanding what* requirement (Kongsholm & Kappel, 2017). Many autonomous decisions in our daily life involve trust in others knowledge. To give a couple of examples: when we decide to lend someone a key to our home, we trust them to not sell our possessions. When we look at the weather report, we trust it (i.e. the meteorologists who made it) to provide us with correct information. Although this information is certainly relevant, we do not have to know this information ourselves to act upon it. To the contrary, it would be a very high standard to require a full understanding without trust for every action. It would be near to impossible to make decisions without moral or epistemic trust. It is, for example, impossible to require everyone to be an expert in meteorology to make decisions that involve the weather report.

In the same way, the people in communities do not have to understand the research or all possible implications of it. It would not only be near to impossible to have this kind of understanding on their own, it is also perfectly reasonable to trust the understanding of medical professionals and community leaders. Thus, *understanding what* does not have to be held by all people in an informed consent process. What is important is that the people trusted, such as the community leader or the medical professional, have this knowledge. In other words, when the people trusted to make a decision are indeed trustworthy (which implies that they are competent to do what their trusted to do), the truster does not have to have this understanding. Therefore, when based on trust and trustworthiness, we have reason to believe that community consent does not lack *understanding what*.

Secondly, a decision based on trust can still be *intentional*. This is best illustrated with an example of Kongsholm and Kappel:

> Suppose a good friend of mine has taken me to dinner at his favourite restaurant, where I have not dined before. […] my friend suggest that he orders us both his preferred dish. Knowing that he usually has a good taste and trusting that he would not order me something I would not enjoy, I promptly close my menu and acquiesce. (Kongsholm & Kappel, 2017, p. 435)

As they correctly conclude, we would not consider this a non-autonomous choice, even though the choice is made by someone else. I think part of the reason we have this intuition is because of the connection between trust, trustworthiness and intentionality. To see this, we first have to make a distinction between two specific types of intentionality at play. Firstly, there is an intentionality of the truster to hand over a decision (in this case to let the friend choose dinner). Call this intentionality$_1$. Secondly, the decision made has to be in the line with the will of the truster (the dish chosen has to be what the truster wants) to be intentional. Call this intentionality$_2$. Because of the trust of the truster and the trustworthiness of the trusted, we have strong reasons to believe that intentionality$_1$ and intentionality$_2$ are present.

First look at intentionality$_1$ and trust. If we trust someone to make a decision for us, we have an optimism that that person will be competent to make the right decision for us and will be motivated to do so. In other words, we have strong reasons to hand over the decision. We can see this in the example of Kongsholm and Kappel. The truster has a reason to let the friend choose dinner because the truster knows “that he usually has a good taste and trusting that he would not order me something I would not enjoy” (Kongsholm & Kappel, 2017, p. 435). Although trusting someone is not always enough reason to had over a decision – I might still want to make the decision for myself, even if I trust someone – when a decision is handed over and there is trust, we have strong reasons to think this is done intentionally$_1$. Therefore, trust-based community consent cannot only be intentional$_1$, the presence of a trust-relationship gives us more confidence that the decision-making process (e.g. handing over a decision) is in line with the intention$_1$ of the truster.

Secondly, if the trusted is trustworthy (which we assumed) we also have strong reasons to think that the decision made is intentional$_2$. If a person is trustworthy, that person is expected to act in line with the trust placed in her, and be competent to do so. This is the case in the example. The friend has good taste (he is competent) and would not order something the truster would not enjoy (is motivated to act in accordance with the trust place in him). Thus, the will of the truster is taken into account in the decision-making process. Furthermore, there is a strong reason to think that the dish chosen by the friend is in line with what the truster wants. In other words, the decision made by person A for B can still be in line with what B wants. Together this means that the decision-making process can still follow the intentionality$_2$ of a person, even if another person makes the decision. Again, this is not necessarily so – a trustworthy person could make a wrong choice – but a decision made by someone else can be intentional$_2$ and the presence of trustworthiness gives us strong reasons to think this is the case.

This last point might seem counterintuitive. How can a decision made by A be intentional for B? It can be argued then that you cannot intentionally ϕ if you do not ϕ yourself. Thus, "intentionality" would be used incorrectly in this last case, since actions can only be intentional for the person that performs the action. In this way, trust-based consent can never be intentional$_2$. However, this objection would mis the point of the argument. What the example above shows is that at least the underlying idea of intentionality$_2$ and the reason why it is required for autonomous action, can be present in trust-based consent. When the person trusted is indeed trustworthy, the decision-making process is guided by the will of the truster and therefore there is strong reason to think that the decision made is in line with the plan of the truster. Therefore, a trust-based decision can satisfy the condition of intentionality$_2$, the decision made can be in accordance with the will of the truster.

Finally, we have the condition of *non-control*. Both the decision to hand over the decision to enroll as well as the decision to enroll itself can be influenced by unwanted control. However, since the latter decision does not differ from individual consent in regard to its susceptibility to unwanted control, I will focus on control of the former decision. First consider *coercion*. There is no reason to think that a decision to hand over consent based on trust is more susceptible to coercion than individual consent. On the contrary, trust is less susceptible to coercion than decisions not based on trust. Coercion is based on a threat known to the coerced. However, trust cannot be the result of a threat, because, as multiple authors point out, trust is not something that can be willed (Baier, 1986; Jones, 1996; McMyler, 2017). ""Trust me!" is for most of us an invitation which we cannot accept at will – either we do already trust the one who says it, in which case it serves at best as reassurance, or it is properly responded with, "Why should and how can I, until I have cause to (Baier, 1986, p. 244)?"" Or to give a more extreme example: "Trust me or I will kill you!" Such a threat sounds absurd, because we cannot trust at will, even if we would like to. We do not control our trust like we control our actions.

Jones explains this with the emotional nature of trust (Jones, 1996). Emotions cannot be forced based on threats or inducements. People cannot be forced to feel happy. Likewise, people cannot forced to trust someone. Note, however, that this coercion-resistant nature of trust does not stand or fall with a conceptualization of trust as (partly) emotional. As McMyler points out, beliefs are also not subject to our will (McMyler, 2017). We cannot belief that P because we are forced to do so. So, even if Jones' conceptualization of trust turns out to be incorrect, and trust is, as Hardin argues, a cognitive attitude, trust is not something that can be coerced.

Trust is liable to the weaker form of control: manipulation. It is important that this not include all forms of manipulation. For example, more resistible threats, which are thought to be manipulation, cannot influence trust, since, as argued, trust cannot be influenced by threats. Other forms of manipulation can influence trust. People can, for example, be deceived into thinking that someone is trustworthy, without that person actually being trustworthy. Another example, particularly serious in relation to trust, is the influencing of people's emotions. A manipulator could try to make people fear another group (e.g. a particular minority), which would make it harder for the manipulated to trust them (Jones, 2019; Noggle, 1996). This is strengthened by the affective nature of trust, which shields us from certain evidence about the person we trust (Jones, 1996, pp. 11–14). "Trust restricts the interpretations we will consider as possibly applying to the words and actions of another (Jones, 1996, p. 12)." This feature of trust could intensify its susceptibility to this type of manipulation.

However, trust is not totally indifferent to evidence. As Manson and O'Neill argue, trust does not have to be blindly placed, but can be placed intelligently (I will call this *informed trust*) (Manson & O'Neill, 2007, pp. 159–167). Judgements of competence and goodwill can, and will most of the time, be informed by cognitive judgements based on evidence about that person. Thus, trust can indeed be manipulated, but we can also shield trust from manipulation. As will become clear in the next chapter, transparency about trustworthiness is an important way to do this (Manson & O'Neill, 2007, pp. 169–181).

In our present discussion, what is most important is that manipulation is not a problem exclusive to trust but can also distort information-based individual consent. Deception and disinformation are also a danger in information-based consent (Faden et al., 1986). Trust can indeed be manipulated, but there is no reason to think that trust is more liable to manipulation than individual consent, nor that community consent will involve more manipulation. We should always safeguard against manipulation, but this danger of manipulation is no reason to label trust-based (community) consent not autonomous.

Altogether a trust-based consent seems to satisfy the conditions of autonomous action. It can be based on *understanding that* and involve *understanding what*, although this last form of understanding does not have to be held by the truster. Furthermore, if the trusted (e.g. the community leader or medical professional) is trustworthy, we have reason to believe that *understanding what* is present. Trust based decisions can also be intentional. Trust of the truster will increase our confidence that community consent involves intentionality$_1$. And if the trusted is trustworthy, we have reason to think that the decision made will be intentional$_2$. Finally, trust is not something that can be coerced. They can be manipulated, however this is also the case for individual informed consent. We always have to be careful to avoid manipulation. Thus, trust-based community consent can involve *understanding*, *intentionality*, and *non-control*. The presence of trust and trustworthiness gives us strong reasons that this is also the case.

Applied to the case of the Kassena-Nankana district, this means that when women trust their gate-keepers and those gate-keepers are trustworthy, the decision of women to enroll which follows from the consent process is likely to be in line with their autonomy. To be more specific, the permission given or not given by a trustworthy gate-keeper is likely to follow the will of the woman for whom the decision is made. Furthermore, if she trusts the gate-keeper, it is likely that she wants that person to make a decision for her without being forced to. It can be objected that most of the time women are forced to accept the gate-keeping system. This is indeed a significant problem, which will be discussed in the next chapter. However, for now I want to point out that when community consent involves trust and trustworthiness, it is likely to be in line with the autonomous action model of Faden et al.

2.2.4 A higher standard for consent?

It could still be argued that informed consent in a medical context is a special case in which the bar for decisions is higher than the daily-life cases that have served as examples, because of the high risks and importance of medical decisions (Kongsholm & Kappel, 2017). The fact that we consider decisions based on trust to be autonomous in other (less important) contexts does not imply that decisions based on trust in the medical context are also autonomous, since there are important differences in the medical context. A decision to participate in a research should be held up to higher standards than other decisions. Therefore, one could argue that trust-based decisions cannot be seen as autonomous in the medical context.

However, as Kongsholm & Kappel point out, many decisions made in a context of medical health are trust-based and we would not consider them non-autonomous (Kongsholm & Kappel, 2017, p. 435). When we consult our physician and she prescribes a certain drug, we trust her to have the knowledge and competence to prescribe us the right drug. Furthermore, we trust her decision that this is the best treatment for us, and that this decision is not based on egoistic considerations like her own gain. It would be weird to say that deciding to take this drug would be a non-autonomous action, even though we completely base our decision on the judgement of our physician. Even in the medical context trust-based decisions can be autonomous decisions.

Secondly, it is not clear why an emphasis on individual consent is appropriate in medical decisions. On the contrary, trusting in the judgement of others that have more competence than you would be more reasonable, especially when those people are motivated to act in line with your values and plans. Note also that, from a descriptive standpoint, people do not always decide based on only rational deliberation, but will base their decision on trust even in a setting where individual consent is emphasized (Kass, Sugarman, Faden, & Schoch-Spana, 1996). If medical decisions require complete understanding and rational deliberation, a lot less people would be allowed to consent themselves. Thus, rejecting trust-based consent on the basis that (individual) rational deliberation is needed for medical decisions will exclude a lot of people from consenting. This is unnecessary, since trust-based consent can be an autonomous action.

Finally, there can be situations where trust can be more problematic than presented here. For example, when there exists (a history of) sexism or discrimination. Or when it is clear that decision-makers are not capable of making decisions for others. I agree that in those cases we should be cautious in granting community consent. In the next chapter, I will discuss the how trust and trustworthiness can be indicated in a community. In doing so, we can also protect suppressed people for being forced into a decision-making process against their will or protect them against untrustworthy (not motivated or competent) decision makers.

2.3 Community consent without trust?

I have argued that trust and trustworthiness enable autonomous decisions in community consent. Finally, we have to ask the question whether they are both necessary for autonomous action within community consent. We can answer this question by imagining a scenario in which one of the two is not present and ask whether the conditions for autonomous action – understanding, non-control and intentionality – can still be satisfied.

First the question whether trust is necessary for community consent to be autonomous. As argued, trust gives us reason to think that community consent is intentional$_1$ and non-controlled. So, the question is whether both conditions can still be realized in a situation without trust? Suppose that someone (A) does not trust B.[22] This can be for different reasons. It could be the case that A does not think B has any goodwill towards her. A could also think that B is not competent to make a decision about enrollment in a study. Or A thinks that B is not motivated to act in accordance with the trust placed in him. Or a combination of these reasons. In these circumstances, would A still choose to accept B's involvement in the decision-making process over research enrollment, even though A lacks trust in B, when A is free to decide whether B should be involved and the alternative of deciding alone is just as good?

It might be hard to imagine why A would want B involved in the decision-making, since A does not think, for one of the reasons outlined, that B will act in line with her will. Although a strong reason in favor of community consent is removed by removing trust, it is still possible that A wants B to make a decision for her.[23] For example, suppose that A does not want to hurt B's feelings and therefore decides to let B decide for her. This might be a very strange and incorrect reason for community consent, but in such a case the decision of A to hand over the decision to enroll to B is intentional$_1$ and without control. Thus, although trust gives a good indication that the conditions of intentionality$_1$ and non-control are satisfied, trust is not necessary to satisfy these two conditions.

Now the question of community consent without trustworthiness. Trustworthiness gave strong reasons to believe that the decision made in the consent process was intentional$_2$ and with *understanding what*. Can those conditions still be present when there is no trustworthiness? Suppose that A does trust B, but B is untrustworthy. As said, I will give a more in-depth discussion of trustworthiness in community consent in the next chapter, but here we can rely on the definition of trustworthiness as being *motivated* to act in line with trust and being *competent* to do so. Thus, in this scenario, B is not competent to decide about enrollment in a study, or not motivated to do so, or both. In this case, A will freely accept community consent, but B is not likely to be able or not want to act in the interest of A. This means that the decision made will probably not be in line with A's will. However, B could (coincidentally) makes a decision in line with A's will. Thus, trustworthiness is not necessary to make the consent decision intentional$_2$. Furthermore, note that competence is needed for

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[22] Note that lack of trust does not imply distrust (Baier, 1986; Jones, 1996). There is a neutral space between trust and distrust in which we do not have strong feelings about a person.

[23] Note that this is independent of the actual trustworthiness of B. Even if B is competent in the relevant domain(s) and would be motivated by trust placed in her, it would be wrong to force A to involve her in the decision about her consent to the research if A does not want to.

trustworthiness, but someone can be competent without being trustworthy. So, without trustworthiness, the condition of *understanding what* can also be satisfied.

Trust and trustworthiness turn out to be neither necessary for community consent. This does not, however, defeat the purpose of this chapter. Firstly, recall that trust is central in most community members' decision in favor of community consent. So, a focus on trust is in line with what many community members see as a central value of community consent. Secondly, although trust and trustworthiness are not necessary for autonomous decisions in community consent, they provide strong reasons to think that community consent is in line with autonomous action. Thus, a focus on trust and trustworthiness indicate that community consent is based on *intentionality*, *understanding*, and *non-control*. Therefore, although trust and trustworthiness are not necessary, a central focus on trust and trustworthiness in community consent is still appropriate.

Conclusion

Many (potential) research subjects noted trust in medical professionals or community members (e.g. leaders) as an important consideration in the decision to consent to research enrollment. In this chapter, I have argued that this importance of trust is more than a description of reasons that people take to be important. Trust and trustworthiness can take up the challenge of individual informed consent by satisfying the conditions for autonomous action. Trust gives reason to involve someone in a decision and therefore indicates intentionality$_1$. Trust also cannot be enforced by coercion and therefore indicates non-control (although manipulation is still possible). When the trusted is trustworthy we have reason to believe that *understanding what* and intentionality$_2$ will be satisfied.

The current chapter assumed an idealized situation in which people where trustworthy and community consent was actually based on trust. However, critics will point out that community consent is not purely trust based and will be supported by a power structure of that community. It is therefore unclear whether people freely agree to consult community leaders or their partner when making a decision about research enrollment. Furthermore, there is always the risk that the ones trusted turn out to be untrustworthy. The next chapter will discuss these worries and suggest ways how they can be addressed. It will try to answer the questions that were idealized away in that chapter.

Chapter 3

Indicating Trust and Trustworthiness in Communities

Based on trust and trustworthiness, community consent can satisfy the conditions of autonomous action, which justifies informed consent. However, as already pointed out in the previous chapter, community consent is not always purely based on trust. A lot of practices of traditional communities are enforced by patriarchal norms: norms which are reciprocally maintained by these practices. It is not only because of trust that people decide to include a community leader in the consent process, but also because of the power structures present in the practices of a community. Because of this, it is questionable whether community consent in practice is as compatible with autonomous decision-making as the previous chapter argued.

In this chapter, I will argue that communities that want to have community consent face two burdens of proof.[24] Firstly, they have to show that it is likely that community consent is based on trust. Secondly, they must show that the people trusted are likely to be indeed trustworthy. Although it is impossible to provide definitive proof, I will argue that certain practices, relations, and norms can promote trust and trustworthiness. By demonstrating that these practices exist in a community, this community can show that trust and trustworthiness are likely to play a role in community consent.[25, 26] I hope to show that communities can meet the two burdens of proof in this way.

I will start this chapter by discussing the conflict between community consent and individual autonomy in more detail. I will demonstrate this problem with the case of the Kassena-Nankana district and the feminist critique of multiculturalism. From this discussion follow the two burdens of proof that are central to the rest of the chapter. First, I will discuss the first burden of proof, namely showing that community consent is based on trust. I will argue that communities can show that people trust the others involved in community consent by showing that these people have a non-controlled choice to accept or reject this form of consent through exit and voice. Although a non-controlled choice cannot be accomplished in these circumstances, exit and voice are still valuable in offering an approximation of this choice. Second, I will discuss fostering trustworthiness. Based on an examination of the different conditions needed for trustworthiness, I will point out different ways of promoting trustworthiness. By having ways to promote trustworthiness in the community, we can increase our confidence that

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[24] In addition to burden of proof that followed from the argument in the first chapter: showing that community decision-making practices are central to the community and, consequently, to community members' self-understanding.

[25] I will refer to "communities" that face these burdens of proof to not single out one member who must show that the burdens of proof are met. In practice, this burden will most likely fall on community leaders.

[26] I focus on burdens of proof on communities. To be clear, these burdens on communities do not absolve medical professionals of their duties for ethical conduct in the consent process and the research.

the people trusted are trustworthy. This chapter will end by a discussion of informed trust, which connects trust and trustworthiness.

3.1 Trust and oppressive communities

In the previous chapter, I have argued that community consent, when based on trust, is defensible within a theory of autonomous action from which the demand of informed consent for research participation arises. However, an obvious argument against this defense of community consent is that community consent is, in many instances, not based on trust. In many communities, people do not have a choice whether to involve others, e.g. their husband, in decisions about research, but are forced to accept it based on coercive or manipulative mechanisms within the community.

This can be illustrated with the case of the Kassena-Nankana district in northern Ghana (Tindana et al., 2006). As described in the introduction, the political organization of this rural area in Ghana consists of a system of chiefs, who are always men, who all report to the chief higher in this hierarchy. Moreover, many women in this area are restricted by a “gate-keeping system”, which means that they have to ask permission to their husband or head of their compound (two or more families) for various activities including pursuing health services (Ngom et al., 2003). In the context of consent, this means that gate-keepers must agree with the women’s decision to take part in a biomedical intervention if they would want to enroll (Tindana et al., 2006). This gate-keeping power relation of women is not only enforced through cultural norms, but also strengthened by the spiritual and economic power these “gate-keepers” have (Ngom et al., 2003). Thus, it seems that women have no other choice than to ask permission to gate-keepers before performing any activity.

Based on the argument in the first chapter, if the decision-making practices or the norms involved in these practices are central to a community, there is a strong reason to take over these practices as part of the consent process for the research. This is also the case in the Kassena-Nankana district, where, as described in the introduction, community leaders and other gate-keepers are asked permission before conducting individual consent (Tindana et al., 2006). Though this procedure might be desirable to avoid potential disruption of cultural practices, it is based on the gate-keeping system which cannot be assumed to be based on trust. Women do not have a non-controlled choice to be part of this system but are forced to be part because of the different power structures in the community (such as the spiritual and economic powers held by men).

What is most troubling about this example, from the perspective of informed consent, is that this form of consent is not in line with autonomous action. Firstly, the non-control condition in the decision to involve others in the consent process is clearly violated. Secondly, because of the violation of the non-control condition, we are not able to say that this decision is intentional$_1$. This does not mean that it is always the case that these women do not trust their gate-keepers. The point is that we are not able to infer that from this case. Since there are systems of enforcement which force women into the gate-keeping relation regardless of whether they choose to, we cannot know from the outside whether any given gate-keeping relation involves trust or is solely based on force.

This conflict between women's autonomy and respecting cultural practices has been pointed out by different feminists in reaction to multiculturalist theories (Benhabib, 2002; Okin, 1998, 1999; Shachar, 2001). By granting group rights to cultural minorities, multiculturalists can support practices that suppress women based on their gender. These instances of suppression can severely limit the autonomy of these women, which is of course most troubling for liberal defenders of cultural rights like Kymlicka. Since these patriarchal norms also influence decision-making practices, the feminist problem is also applicable to community engagement and community consent, as has been pointed out by Davis (2000). In addition, including the gate-keeping system in a research protocol could be perceived as legitimizing by some members. Although I disagree with Davis contention that community consent rests on some form of moral relativism – as I have argued, it is coherent to hold that a practice itself is immoral and, at the same time, hold that this practice plays an important role in people's self-understanding – she rightly argues that community consent or other forms of decision-making could result in undesirable forms of suppression (Davis, 2000). "If it is ethically wrong for scientists to conduct research on African Americans without their consent and participation, or to exclude them from research without a good reason, why is it not ethically wrong to conduct (or forgo) research on women in a group whose "culturally appropriate authority" is solely in the hands of men (Davis, 2000, p. 43)?"

Based on this, Davis concludes that community consent "is a notion too deeply flawed to be given effect (Davis, 2000, p. 44)."[27] Although I agree that the autonomy-undermining structures existing in communities is troubling for community consent, I don't think that this is necessarily defeating. As I have argued, when based on trust, community consent can be in line with autonomous action, which means that community consent is not necessarily "flawed". Moreover, we should not dismiss the significant value community consent can have for community members, as argue for in the first chapter. Dismissing community consent from the start would imply that in some cases researchers have to impose a specific conception informed consent on a community, even if this conflicts with the values and understanding of such a community. Therefore, it would be preferable to find a way to enable people to make autonomous decisions and allow community decision-making practices at the same time.

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[27] Davis' paper concerns community consent in genetic research, but most of her criticisms of community consent are also applicable to other types of research.

As argued in the previous chapter, the gap between autonomous action and community consent can be bridged by trust and trustworthiness. Trust indicates a non-controlled and intentional$_1$ choice to consent according to the community decision-making practices. However, the case of the Kassena-Nankana district shows that we cannot assume that community consent is based on trust. This gives communities a burden of proof:[28]

(1) Communities have to show that it is likely that the people that consider enrolling trust the ones that are involved in the decision-making procedure (e.g. community leaders or gate-keepers) that is their form of community consent to increase our confidence that community consent is accepted without control and intentionally$_1$.

However, trust alone will not ensure that autonomous decisions will follow from community consent. As argued in the previous chapter, trustworthiness of the people trusted is also needed. Trustworthiness of the trusted increases the probability that a choice to participate is intentional$_2$ and based on understanding. Although the case above does not directly challenge the trustworthiness of people, it is clear that gender roles are an important factor determining the role of different people in the consent process. In other words, the fact that a husband is consulted in a consent process is more influenced by the fact that this person is the husband, than by whether or not this person is trustworthy. Furthermore, even if gender roles are not of influence on who is involved in the decision-making, it is important to make sure those people are indeed trustworthy to meet the conditions of understanding and intentionality$_2$ of autonomous action. Thus, communities face a second burden of proof:

(2) Communities have to show that it is likely that the people that are involved in this decision-making procedure are indeed trustworthy to increase our confidence that decisions reached in community consent are based on understanding of the intervention and will be in line with the intentionality$_2$ of the potential research subjects.

In this chapter, I want to address both these burdens of proof and suggest ways in which communities could meet them.[29]

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[28] Although the burdens of proof fall primarily on the communities, I do not want to rule out any obligations of researchers to help communities meet these burdens of proof. Since both community consent, and trust and trustworthiness could make some research conduct more ethical, it could be argued that researchers have a duty to help communities meet these burdens of proof. However, further research is needed to fully develop this argument.

[29] Note that these conditions do not involve the condition of *understanding that* you are consenting. This is because this understanding is not undermined by the coercive forces in a patriarchal community, as described in the example. I will therefore assume that everyone involved in community consent has this *understanding that*. This assumption is, as said earlier, strengthened by the idea that all community members have a practical understanding of the (decision-making) practices.

3.2 Trust and acceptance

I want to start with the first burden of proof: how can we know that community consent is based on trust? As argued in the previous chapter, trust is an indication of non-control and intentionality$_1$ in community consent. Therefore, showing that community consent is based on trust would increase our confidence that people intentionally$_1$ and without control accept community decision-making. Therefore, the first burden of proof communities face when community consent is demanded, is to show that their decision-making practices, which differ from the standard individual informed consent, are based on trust.[30]

The most obvious way to ascertain whether trust is present, much used in (social-science) research, is conducting a survey or interviewing people (Lewicki & Brinsfield, 2012; Welter & Alex, 2012). So, we could take a straightforward way to measure trust in a community: communities could show trust by letting members express their trust in decision-makers. There are, however, a couple of downsides to this method. Firstly, there is a gap between trusting someone and saying that you trust someone. The expression of trust indicates the former but does not prove that people indeed trust decision-makers. Although people cannot be coerced into trusting others, they can be coerced (or manipulated) into saying that they trust others. It is plausible that surveys would give a more reliable view of trust than observation from a third-person perspective, but there is no guarantee that people's answers reflect their actual attitude. Moreover, this method is time-consuming and labor intensive, since it requires active questioning in a community. This work could be increased by the high illiteracy that is typically present in more traditional communities, which would rule out written surveys and demand oral interviews (DeCosta et al., 2004; Fitzpatrick et al., 2019; Molyneux, Wassenaar, et al., 2005; Tindana et al., 2006). Although I do not necessarily reject this method of identifying trust, it is helpful to look for additional and easier ways of identifying trust.

I want to propose a way of indicating trust on a more community level, instead of conducting surveys and assessing trust for every individual. To see this, we have to recall what trust aimed to show: intentionality$_1$ and non-control in the decision to hand over consent (or to involve someone else). So instead of trying to demonstrate that community consent is trust based, we can also aim to show intentionality$_1$ and non-control in community consent. There is no necessary connection between trust and non-controlled and intentional$_1$ acceptance of community consent (e.g. we can trust people's decision-making, without wanting them to make decision for us). However, as argued in the last

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[30] Note that this only asks whether trust is present or not. So, for this burden of proof, it would not be problematic when trust could be based on e.g. incorrect information. At the end of this chapter, I will suggest how in this context a desirable way of trust placement (i.e. informed trust) can be promoted. Here, however, the focus is on the existence of trust, not its source.

chapter, there is a relation between trust and an intentional$_1$ and non-controlled decision to involve others in the decision to enroll, since trusting that person decide for us gives a reason in favor of wanting this. Moreover, when community members don't trust the people making decisions in community consent, they lack a strong reason to intentionally$_1$ and without coercion or manipulation accept community consent. Assuming that the *understanding that* is present (see footnote 29), the presence of *intentionality$_1$* and *non-control* would show that the decision to accept community consent is based on an autonomous choice.

Note that this focus on the choice to accept community consent (i.e. intentionality$_1$ and non-control) is not a full departure from the idea of trust-based consent. As argued, there is a strong relation between trust and such an autonomous choice, which works two ways. Trust-based community consent indicates, intentionality$_1$ and non-control. At the same time, when community consent is accepted intentionally$_1$ and without control, it is likely that the people making the decision are trusted. Although trust will still play a role in the upcoming discussion, I will mainly focus on intentionality$_1$ and absence of control in acceptance of community consent to avoid the confusion of the different concepts and their relations. This is also the more straightforward way to what we want communities to show: an autonomous choice of community members for community consent.

The best way to show intentional$_1$ and non-controlled acceptance of community consent is to give people the option to reject it. If people have this option but do accept community consent, we know that this choice is not controlled and we have strong reason to believe that it is intentional$_1$.[31] In the literature on multiculturalism and the feminist critique, there are two prominent positions on how to give people the option to reject and thus show acceptance. These suggestions map on Hirschman's model of *exit* and *voice* (Hirschman, 1970). Both try to ensure that people are not coerced or manipulated into accepting a certain arrangement (in our case a decision-making practice). Some authors, mainly traditional liberals, suggest that people should have the right to *exit* their community or practices. If that right is guaranteed, and they do not make use of it, we can assume they accept the decision-making practices in their community. Most feminists, on the other hand, support a wider set of rights and procedures in which people have a say over the practices in their community, i.e. *voice*. If people are enabled to voice their concerns but abstain from doing so, we can assume they accept the decision-making practice. I will now discuss both exit and voice, and the problems they face. We

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[31] I want to emphasize that this is only an indication of intentionality$_1$, not proof of this. I can of course make a non-controlled choice to ϕ, but not have the intention to ϕ (e.g. due to lack of understanding). However, assuming that people know what community consent entails (which is plausible since community members have a practical understanding of community practices), a non-controlled choice for community consent is a strong indication that this choice is intentional$_1$.

will see that the two do not exclude each other, but, on the contrary, are complementary measures to ensure non-controlled acceptance of community consent.

3.2.1 Exit

Although Hirschman's model is focused on the relation between consumers or members, and companies, it provides a helpful insight into the meaning of voice and exit (Hirschman, 1970). To start with exit: "Some customers stop buying the firm's products or some members leave the organization: this is the exit option (Hirschman, 1970, p. 4)." This exit must, according to Hirschman, be seen as a sign of dissatisfaction with the product or the organization. When consumers stop buying a product, it implies that these consumers are dissatisfied with the product compared to the other options. A similar case can be made about communities and members. When members exit their community, it means they are dissatisfied with the community (i.e. with some or all its practices).

Many liberals have used this category of exit normatively in the debate over multiculturalism (Galston, 2002; Kukathas, 1992, 2012; Raz, 1994; Spinner-Halev, 2000). In other words, exit is not only a phenomenon that indicates dissatisfaction with a practice or community, but, according to liberals, people should have a right to do so. This idea of the right to exit follows directly from the traditional liberal value of individual freedom, which is of course strongly connected to the liberal ideal of the autonomous person. Exit rights ensure the freedom of the individual to exit certain practices or, in the case of multiculturalism, certain groups. As Kukathas, one of the more prominent liberal defenders of exit rights, argues: "individuals should be free to associate: to form communities and to live by the terms of those associations. A corollary of this is that the individual should be free to dissociate from such communities (Kukathas, 1992, p. 116)."[32] Thus, exit is supposed to guarantee choice over group membership needed to protect the autonomy of people.

Exit rights are relevant for our discussion on community consent in both ways. They help to indicate non-controlled and intentional$_1$ acceptance of community consent and enable an autonomous decision to participate in or leave the community practices, which is (normatively) required for autonomy. How, then, should it be applied to this context? It would be incorrect to interpret this right to exit as a right to withdraw from a research trial. Someone could want to withdraw from a study without rejecting the community decision-making process. Rather, exit rights in our present context should be implemented on two different levels. It could be the right to exit the decision-making

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[32] There is a philosophical debate over what the freedom to associate entails. For example, it can be asked whether and to what extent this gives a right to exclude people from such an association (White, 1997)? Or what the limits of this right are (Alexander, 2008)? However, this right is recognized as a universal human right in these philosophical debates as well as in official documents (Council of Europe, 2010 art. 11; United Nations General Assembly, 1948 art. 20)

practice, i.e. not being part of the community consent. Or, an exit right could be interpreted as a right to leave the community. Although this last form is significantly more drastic, it could sometimes be the only option for a community when decision-making practices are central to the community – which is required by my argument for community consent. These two forms of exit rights are of course not necessarily mutually exclusive.

However, as several authors point out, exiting a community involves significant costs (Barry, 2001; Okin, 2002; Weinstock, 2005). Because of the nature of communities as value-conferring and identity-constituting, leaving a community could seriously harm a (former) member's self-understanding. One could argue that exit of the community is not necessary for exit rights to work in this context. Community members could exit the community's decision-making practice, not the community itself. However, based on the central value of such a community practice – which is the reason community consent is considered in the first place – this exit will still involve significant costs for the people exiting. Moreover, it can be questioned whether it is possible to exit a decision-making practice, without having an effect on your relations within the community. Take the example of the women in the Kassena-Nankana district and the gate-keeping system. In those communities, this gate-keeping system is an important step when making a decision. Furthermore, this system will also be an important part of the relation between men and women in the community. It is therefore hard to see how a woman leaving this part of community consent would not have any effect on her relationships within the community, such as the relation with her husband. Thus, even if exit is solely applied to the community consent practice, there are significant exit-costs.

These exit costs restrict the freedom of people to exit, because they make the option to leave undesirable and therefore push people towards staying. Although a decision to accept community consent based on not wanting to leave can still be intentional$_1$ and non-controlled in the conception of Faden et al., it is not the kind of motivation we want for acceptance of community consent. To counter the worry of suppression of autonomy as described in the Kassena-Nankana example, we would need a choice for community consent, motivated by a positive support for community consent, such as acceptance based on trust in the decision-makers. The solution might seem that communities should aim to reduce these kinds of pressures. However, the exit costs that come with leaving community decision-making practices are inherent to the kind of communities and practices considered here: because these decision-making practices are valuable for communities, we have reason to consider including them in the consent process. At the same time, because these decision-making practices are valuable for communities, exiting them will have high costs. Thus, exit rights do not suffice as a way to indicate an intentional$_1$ and non-controlled choice.[33]

Another approach to enable choice over community decision-making practices is required, which brings us to voice. This step is not just an argumentative one, but, as Hirschman points out, one that follows the real choices made by members or consumers (Hirschman, 1970). With high exit costs, people tend to stay in a community – they will be loyal, as Hirschman calls it – and find another way to express their discontent over an arrangement (e.g. a decision-making practice) and aim to change it. The different ways in which they do so are bundled together under voice. It are those mechanisms that we have to investigate next.

3.2.2 Voice

Voice is an umbrella term that refers to different ways in which members (in this case of a community) can voice their concerns in order to achieve change (Hirschman, 1970). Thus, when contrasted with exit, voice aims to change practices from within instead of exiting the practice. Within the category of voice, there is no restriction on how this done. Although there is a lot of philosophical debate on what the best way is to empower people to express their concerns and achieve change, for reasons that are clarified below I will not single out one form of voice as most appropriate to show acceptance of community consent. Instead, I will rely on Hirschman's broad definition of voice:

> as any attempt at all to change, rather than to escape from, an objectionable state of affairs, whether through individual or collective petition to the management directly in charge, through appeal to a higher authority with the intention of forcing change in management, or through various types of actions and protests, including those that are meant to mobilize public opinion. (Hirschman, 1970, p. 30)

From this definition a broad spectrum of "voice" follows, which can comprise different models to enable voice, which do not necessarily exclude one another. Voice could achieved by having deliberative practices, as both Benhabib and Deveaux propose in the debate on multiculturalism and oppression of women in (some) cultural communities (Benhabib, 2002; Deveaux, 2005). It could also be enabled by giving the possibility to adhere to a legal authority outside of the community (Shachar, 2001). Or voice could have an activist interpretation, in which people have the freedom and power to protest the existing state of arrangements through different methods (Walzer, 1993). The effectiveness of different forms of voice will partly depend on the context, in this case the community.

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[33] This does not make exit rights pointless, as will become clear below.

This does not mean that whenever some form of criticisms is allowed, people have an option to voice. In her deliberative democratic approach, Deveaux proposes three conditions which in my opinion apply for all forms of voice (Deveaux, 2005). Firstly, everyone should be *free to voice*, i.e. they should not be oppressed not to make use of the voice mechanism. This is in line with the non-control condition of autonomous action. Secondly, everyone should have *equal opportunity to voice*. So, the ability to voice should not be coupled to e.g. specific roles or positions. Thirdly, *the outcomes of voice should be revisable*, which means that the decisions or change reached through voice should be open to revisit. People should be free to change their opinion and voice this, even though they initially accepted a certain decision, and the decision reached should be open to change. This list of conditions is not exhaustive. A more thorough discussion of voice would be needed to come to such a list. However, I think the conditions outlined by Deveaux provide a good basis to think about when voice shows non-controlled acceptance of a practice. It also shows that, although the category of voice is broad, not every mechanism would suffice.

Although I have pointed out some examples of voice and some requirements to evaluate these, I left open how exactly voice should be enabled. This has the advantage of allowing for different voice measures. Thus, voice can be different in different communities, depending on the context. And communities are free to give their own shape to voice. This avoids demanding a form of voice that might conflict with community practices, most notably an overly individualistic form of voice. If voice would be such an overly individualistic mechanism, the problem that individualistic informed consent forms for some communities would not be solved but substituted for a new problem, namely the imposition of an individualistic voice measure. Fortunately, voice does not have to be individualistic, but can take other forms as well. An example of a specific method of decision-making, which includes voice, as described by Fitzpatrick et al. can illustrate this (Fitzpatrick et al., 2019). An aboriginal community in the Fitroy valley (Australia) reached consensus over a decision in a circle:

> This appeared to came about through one person starting to make a statement about a topic, then the next person repeating part of the last few words in agreement and adding it their point of view or knowledge on the subject. The last part of their sentence might then be echoed by the first person or another until silence occurred. Those who did not agree would then have space to speak at this point. (Fitzpatrick et al., 2019, p. 7)

This decision-making circle was employed for various topics related to the research. In this already existing practice, community members collectively came to a decision. It is noteworthy that consensus was not always reached. This implies this practice does not force people to come to a consensus and people are not forced into agreeing with every outcome. In this practice, community members are enabled to voice their complaints during this process. Thus, a collective form of decision-making can also enable people to have voice. This shows that communities can shape their own voice measures and we should give them the freedom to do so. Whether these measures are sufficient should be judged on a case-by-case basis, in order to take the context of the community into account.

Like exit, voice can both function as indicating non-controlled and intentional$_1$ acceptance of community consent, as well as a normative requirement for communities. On a normative level, it has been argued that people should have a say in practices or decisions that affect them. This has, for example, been defended by deliberative democrats, but this could also be achieved through other forms of voice than deliberative forms (Benhabib, 2002; Deveaux, 2005). Although this idea as voice as a normative requirement for communities seems to rest on a more comprehensive conception of autonomy than one restricted to autonomous action assumed here, this aligns with the non-control condition of autonomous action. By enabling people to protest current form of a practice that affect them and try to reshape those practices, voice can help to decrease controlling influences existing in those practices. Furthermore, according to this normative standpoint, people should be able to do so without coercion or manipulation. At the same time, voice can indicate an intentional$_1$ and non-controlled acceptance of community consent. When people have the opportunity to voice but refrain from doing so, they accept community consent. Since this acceptance is based on non-controlled voice, the choice to participate in community consent is non-controlled. Furthermore, when community consent is accepted without such control, there is reason to believe this is the intention of people. Together, this increases the likelihood that acceptance of community consent is an autonomous choice. In this way, voice has, like exit, both a normative and indicating function.

Compared to exit, voice is less costly. Although voice could involve costs – for example, voice requires people to criticize existing norms which could have social consequences – and some forms of voice more than others, it has a significantly lower cost than exit. Whereas exit involves leaving a community and, consequently, losing the value that communities possess, voice can be employed from within a community. However, since voice does not involve such a determined action as leaving, the success of voice is far less guaranteed (Hirschman, 1970). When possible, exiting will always lead to escaping the control of a practice. It is less certain, on the other hand, that voice will lead to changing a practice. Furthermore, since voice is performed from within a community, it will be governed by the norms in that community, which could restrict the freedom to voice (I will elaborate on this point below).

Even though voice has these problems, voice is preferable to exit as a way to enable and show an autonomous choice over community consent. Voice can already exist in a community or be integrated in existing practices and it has relatively low costs. However, this does not mean that exit rights are not valuable. On the contrary, I think both exit and voice should be promoted. Even though there are exit costs, it would be wrong to keep community members in a community against their will. Therefore, they should always be given the opportunity to leave their community. Moreover, exit rights make voice more effective. As pointed out by Hirschman, the threat of exit makes voice more powerful (Hirschman, 1970). "The chances for voice to function effectively as a recuperation mechanism are appreciably strengthened if voice is backed up by the threat of exit, whether it is made openly or whether the possibility of exit is merely well understood to be an element in the situation by all concerned (Hirschman, 1970, p. 82)." Without such a threat, the need to listen to voice and change practices decreases significantly. Thus, voice is most important as providing choice over community practices, because exit has high costs in these cultural communities. At the same time, exit complements voice and will make voice more effective. Together, exit and voice offer a choice over community practices. They are, therefore, both needed to increase our confidence that members accept community decision-making practices without control and intentionally[1].

3.2.3 Exit, Voice, and Acceptance

Unfortunately, people are not always free to exit or voice. On top of the exit costs already mentioned, there are obstacles for members in a community to exit or voice, some of which are coercion or manipulation. Let me give some examples to illustrate how community members can be restricted in their choice. First of all, members can be pressured in different ways to not exit the community or its decision-making practices. For example, people can be coerced through physical force, as interviews with women in Harare (Zimbabwe) on informed consent make clear (Nyika et al., 2009). Many women told that they could expect emotional, financial, or physical punishment if they would go against their husband's will in the informed consent process. Secondly, social practices and norms can also push people into accepting a certain practice. They could raise certain expectations which members feel they must meet. These norms can influence how they think and discuss the existing practices. As Young points out in a discussion of deliberative democracy: "[i]n a society with longstanding and multiple structural inequalities, some such discourses are, in terms derived from Gramsci, "hegemonic": most of the people in the society think about their social relations in these terms, whatever their location in the structural inequalities (I. M. Young, 2001)." Finally, as theorists in the debate on adaptive preferences point out, members sometimes internalize these norms as their own preferences, even though the situation that created these preferences is unjust and the adapted preferences conflict with the more deeply held preferences of the person that holds them (Benson, 1991; Cudd, 2006;

Elster, 1983; Nussbaum, 2001).[34] In our present context, adaptive preferences would mean that women accept their subordinate role and incorrectly prefer that men have a say in all important decisions.[35] Thus, even though they do not really prefer it, they think they prefer a gate-keeping system and would not make use of their ability to voice or exit this system. These are just some examples which point out some of the different forces within a community inhibit exit of or voice against a community practice. Since some of these influences are coercive or manipulative, acceptance of community consent in the presence of the option to exit or voice is not without control. This also implies that we cannot know whether this acceptance is inentional$_1$. This means that the presence of exit and voice does not show an autonomous choice for community consent (when accepted), because the choice to exit or voice is not without control. And even if all restrictions put up by communities do not arise out of one party coercing or manipulating another (which Faden et al. think is necessary to count as a relevant controlling influence), these kind of restrictions on people's choice to exit or voice are still worrying. Like in exit costs, acceptance of community consent would not be based on embracing community consent.

It seems therefore that we should require that communities counter unwanted influences in order to establish a high level of non-control in exit and voice mechanisms. However, it is questionable to what extent a community can get rid of these influences. Although some forms of control could be mitigated, like physical and economical forces, others, like social norms, are harder to remove. As argued in the first chapter, a practice is constituted by behaving a certain way and therefore enforcing norms. Getting rid of these norms, ultimately means getting rid of this practice. In this way, it is not possible to enable people to criticize or leave a practice free from these social norms, since those norms constitute the practice that people must choose about. Moreover, as pointed out above, exit will always involve costs that restrict people's freedom to exit. Since the communities considered have a value for their members, exiting a community will always imply loss of this value. Because of this exit and voice can most of the time not fulfil both their normative as indicating function to enable (free) acceptance of community consent.

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[34] This should be distinguished from reshaping preferences based on the available options, which is not always harmful or immoral. How to distinguish the two is, however, debated (Christman, 2014; Colburn, 2011; Elster, 1983). Fortunately, we do not have to draw this line. We only have to hold that adaptive preferences exist, which is far less controversial.

[35] When people have incorrect preferences is debated. There are roughly two positions in that debate. The substantive account holds that there are some thing people should want, even if they do not have a preference for them (e.g. Nussbaum, 2001). The second is called the proceduralist position, which states that a preference is adapted when it would be refuted after reflected upon by the individual who holds the preference (e.g. Christman, 2014). But, independent of how we would determine the "incorrectness" of people's preferences, they all agree that people can be wrong about their own preferences because of adaptation caused by suppression. Since this is all what is needed here, I will not take a position in this debate.

Based on this inability to create a (complete) free choice for community consent, requiring a high level of non-control in exit and voice will result in two possibilities. On the one hand, research would require significant changes in many communities to allow for the kind of individual freedom to choose, which could result in the kind of conflict between individual choice and community practices which we aim to avoid. On the other, we could refrain from doing research in communities which cannot or do not want to accommodate free individual choice to this extent. This would avoid the risk of community disruption but would exclude these communities from potentially valuable research. Additionally, it could also deprive communities from other valuable things that being involved in medical research could bring, such as education of community members (Tindana et al., 2011).

Since holding on to this high standard for exit and voice is not an attractive option, should we then abandon exit and voice? This is also undesirable. First, note that the controlling forces in a community are not limited to exit and voice, but part of the community and practices. Therefore, other ways to indicate intentionality$_1$ and non-control, or trust will probably face a similar problem. We already encountered similar problems in the discussion of using surveys to identify trust, which can also be influenced by forces in the community. Furthermore, although to a lesser extent, trust and exit can still fulfill both their indicative and normative function. As normative requirements, both still provide a choice over practices. Even if that choice is not completely free from coercive or manipulative influences, it can still be a valuable option. A limited choice is still better than no choice at all. Something similar holds for the indicating function of exit and voice. Although more restrictions to exit or voice makes it harder to indicate non-controlled and intentional$_1$ acceptance of community consent, there will still be some indication of both if exit and voice are presence. Furthermore, the more freedom people have to exit or voice, the more confidence we have that this acceptance is non-controlled and intentional$_1$. Thus, even though exit and voice are imperfect, they are still both valuable as normative and indicative requirements in community consent.

For exit and voice to fulfill these functions, some level of freedom to choose for exit or voice should be present. What the threshold level of freedom would be for exit and voice to be useful is a very difficult question, which I am not able to answer now. To some extent the answer to this question will be the same for all communities. In other words, what level of non-control in exit and voice we generally demand. At the same time, the answer to this question will depend on the context. These are factors such as the form of community consent – e.g. the more decision-making authority is given away, the more freedom to exit and voice is required – and the research under consideration – high risk research would require more freedom to exit or voice. Since I do not have the time to give a thorough discussion of this level of freedom required and the factors determining it, I will have to leave this discussion aside here. What I hope to have argued here is that exit and voice can still be useful as a way to indicate some level of a non-controlled and intentional$_1$ decision to accept community consent.

We have to admit that the defense of community consent based on trust presented in the previous chapter does not always correspond to the practice. Trust is not the always the reason that people accept community consent and, furthermore, people are not always free to choose for community consent. For similar reasons, we must conclude that the choice to involve others in a decision about research enrollment is not always an intentional$_1$ and free from control. Although this is of course a bad thing, it would be incorrect to claim that exit and voice can completely solve this. At the same time, some exit and voice can already resolve some of the conflict between community consent and individual autonomy. But rejecting a very strict form of exit and voice is not necessarily a defeat. It allows us to make realistic demands to communities. Communities have to show that they allow for a certain level of freedom to exit or voice. They do not have to achieve complete freedom for their members to exit or voice.

How does this help to answer the first burden of proof? Since I have discussed exit and voice in relation to intentionality$_1$ and non-control, we can best start by answering this question with these concepts. Because of the restrictions to exit or voice that exist in most communities, exit and voice do not show that the choice to involve others in a decision to enroll in research is always non-controlled and intentional$_1$. They do, however, show a level of non-control and intentionality$_1$ in a consent practice. Furthermore, the more freedom community members have to exit or voice, the more acceptance of community consent indicates non-control and intentionality$_1$. Because trust has a similar relation to exit and voice, the same can be said of trust. In practice, acceptance of community consent when there is the opportunity to exit or voice does not demonstrate trust, but do show a certain level of trust in community consent. The more freedom people have to exit or voice, the more confidence we can have that community consent is based on trust. So, although exit and voice have no necessary connection to trust, I have argued that they can be used to indicate trust, as well as intentionality$_1$ and non-control. Besides this indicative function of exit and voice, they also enable autonomous choices over community practices. This makes exit and voice preferable to, for example, surveys to identify trust in communities.

3.3 Trustworthiness

Now that I have suggested how communities could meet the first burden of proof, I want to address the second one: how do we know that the people trusted in community consent are indeed trustworthy? To answer this question, we first must take a closer look at trustworthiness and the conditions that make someone trustworthy. Based on these conditions, I will argue that practices and relations can foster trustworthiness and informed trust. Therefore, communities that want to have community consent must show that these kinds of structures exist or can be installed in their community.

Despite the role played by trust in medical professionals in community consent, I will limit my focus to the trustworthiness of community members. This choice is motivated by the fact that trustworthiness of medical professionals is not part of the burden of proof of communities. What communities have to show is that there is reason to believe that the ones making decisions in communities are trustworthy. This does not mean that the trustworthiness of medical professionals is not of importance for (community) consent, but in the context of this chapter it is more interesting to explore how communities can show the trustworthiness of their members. Note also that trustworthiness of community members in relation to community consent is less covered in contrast to trustworthiness of medical professionals, which has been discussed more widely, especially in relation to accountability and professionalism (e.g. Cruess, Cruess, & Steinert, 2016; Manson & O'Neill, 2007; O'Neill, 2004).

3.3.1 The conditions of trustworthiness

In the previous chapter, I already discussed the concept of trustworthiness. I now want to elaborate on that definition to give a more detailed picture of trustworthiness and specify the conditions of trustworthiness. This will help us to think about ways to show trustworthiness in a community.

As discussed previously, the definition of Jones, on which I rely, stated two main elements for trustworthiness: being *competent* to act as expected and being *motivated* to act in this way by the trust placed in you (Jones, 2012). Before going into detail about these two conditions I want to point out a third, more implicit condition for trustworthiness, which follows from the conditions of competence and motivation: trustworthy people have to know that trust is placed in them and know what is expected by the trusted. If the trusted lacks this knowledge it is hard to be motivated by the trust and to act in line with what is expected by the truster.[36] Note that this third condition of *knowledge of trust* does not necessarily require explicit communication of trust placement. In many cases trust can be assumed. For example, when given a key, we know that we are trusted not to misuse that key by robbing someone. In the same way, community leaders presumably know that they are trusted to make the right decisions for their community without explicitly being told so. Because this

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[36] This condition relates to a problem addressed in the previous chapter: the therapeutic misconception. In those cases, research subjects and medical professionals have a different conception of what is expected from them. However, as previously argued, the therapeutic misconception is problematic for all forms of consent and I will therefore leave the therapeutic misconception aside.

knowledge of trust condition is quite straightforward, I now want focus on the other two conditions, starting with *competence*.

Since people's competence varies in different areas, the condition of competence should be specified according to the domain in which the truster expects the trusted to act. In our discussion, the trusted should be competent to be involved in a decision about enrollment in a study. Thus, a trustworthy person should have *decisional competence*. This form of competence has been widely discussed in the context of in individual informed consent (Appelbaum & Grisso, 1988; Beauchamp & Childress, 2001; Berg, Appelbaum, & Grisso, 2006; Buchanan & Brock, 1990; Faden et al., 1986). Decision-making competence has a different interpretation, which I will not all discuss here. Instead, I will rely on general criteria of competence derived from the influential account of Buchanan and Brock (Buchanan & Brock, 1990).[37] They identify three criteria for competence: (1) potential research subjects or patients) must be able to *understand and communicate* about the research, (2) they must be able to *reason and deliberate* about their decision, and (3) they must have some *values or a conception of the good* to base a choice on (Buchanan & Brock, 1990). Similar criteria (though in different formulations) can be found in other accounts as well (Appelbaum & Grisso, 1988; Berg et al., 2006). The level of competence required is not a general standard that can be applied to all cases. Some decisions require higher competence, e.g. better capacities to deliberate and reason, than others. For example, a higher level of competence is needed when people want to enroll in a more complex and riskier study in comparison to a low-risk research, which is easy to understand. This means that a decision about competence must be research specific. Consequently, a person can be competent to make one decision, but incompetent to make another.

If we assume Buchanan and Brock's conception is correct, how can this be applied to the context of community consent? The first and second criteria for competence can be directly applied to community consent. A person involved in decision-making should be able to understand the research, communicate, and be able to reason about it. It seems that these criteria do not change within community consent, even though a decision is made for another person. In both individual and community consent, a basic level of understanding and rationality is needed to make a decision. However, remember that when consent is based on trust and trustworthiness understanding of the research can be shared by the different people involved in the decision to enroll, including the medical professionals (Kongsholm & Kappel, 2017). Thus, although some basic capacity to understand and

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[37] Note that it is not directly problematic for my discussion of trustworthiness if Buchanan and Brock's conception of competence turns out to be incorrect. The question is how competence, needed for trustworthiness, can be identified. A different conceptualization of decisional competence does not change this question. Furthermore, assuming that Brock and Buchanan are not completely wrong in their conceptualization, it will not fundamentally change the answer to this question.

communicate is required, trustworthy people do not necessarily need to have a high level of understanding when other, more knowledgeable people, like medical professionals, are involved as well.

Since the decision made concerns the truster and not the trusted, the condition of value and conception of the good live changes accordingly. Instead of having a conception of their own values, the decision-maker needs an adequate understanding of the values and plans of the truster. This kind of understanding of the values of the truster by the trusted is necessary to increase the chance that the condition of intentionality$_2$ for autonomous action will be fulfilled. Without it, it cannot be ensured that the decision made is in line with what the potential research subject wants. Because I want to emphasize this criterion, I will distinguish it from the other criteria for decisional competence (i.e. understanding and reasoning capacities) and refer to this understanding of the truster's values as *cultural competence* (Marshall, 2008).

The remaining condition for trustworthiness is that of *motivation*: trustworthy people have to be motivated by the trust placed in them (Jones, 2012). The trustworthy takes the trust placed in her as an important reason in favor of acting in line with the expectations of the truster. If a person is not motivated by our trust, we would not trust that person. Although other reasons can motivate someone to act in accordance with trust, it is important that the trust you place in people is at least taken as a reason to act in this way. Otherwise someone could be trustworthy independent of she relates to the trust placed in her. This means that a person that acts in line with the expectation of the truster, but for egoistic reasons would be considered trustworthy. It is, however, questionable whether the term "trustworthy" is really applicable to a person only motivated by self-interest.

I agree with Jones that trust as motivating is needed for (what I will call) "genuine trustworthiness". However, I think the focus in the context of decision-making should be trustworthy behavior instead of this "genuine trustworthiness". Although the two are certainly connected – trustworthy people will display trustworthy behavior – people who are not trustworthy in the genuine sense can still behave trustworthily. From the perspective of community consent, it is less important whether the person is motivated by the trust itself or not. In the end, we want to promote trustworthy behavior. By trustworthy behavior I mean behavior that is in line with what someone is trusted to do. Thus, what behaving in a trustworthy manner means depends on what one is trusted to do. In our present discussion, this would be to help a person to make a decision about research enrollment in a way that is in line with that person's will. To display trustworthy behavior, a person does not have to be motivated by the trust itself. As a result, a trustworthy person could be motivated by egoistic reasons – even though that may sound contradictory.

This shift from genuine trustworthiness to trustworthy behavior is close to Hardin's conception of trustworthiness: "trustworthiness is just the capacity to judge one's interests as dependent on doing what one is trusted to do (Hardin, 2002, p. 28)." In line with his rational conception of trust, he also spells out the motivations to be trustworthy as rational motivations. For example, Hardin argues that thick relationships motivate people to act trustworthily because they value the relationship and do not want to lose it (Hardin, 2002, pp. 21–23). Furthermore, people do not want to suffer from a bad reputation caused by their untrustworthiness. Although I do not want to deny the cognitive side of trust and trustworthiness, I want to emphasize (again) that these concepts have an important emotional side. We can, and are, also motivated emotionally to be trustworthy. For example, most of us do not behave trustworthily towards our family and friends because we reasoned that such behavior is needed to continue the relationship we value. Rather, our motivation to do so is more emotional, e.g. we behave trustworthily towards our friends and family because we love them. Even if being untrustworthy would not change our relationship, we would still behave in a trustworthy manner. It is important to not overlook neither the rational nor emotional motivations for trustworthy behavior.

Altogether we have three conditions for trustworthiness. Firstly, a trustworthy person should be *competent* to act according to the expectations of the truster. In the context of community consent this means that a trustworthy person has a level of competence to decide about research enrollment in general and knows the person who considers enrolling well enough to be able to take the values and plans of that person into account. Secondly, the trusted should be *motivated* to act in line with the trust. Although I agree with Jones that genuine trustworthiness requires that a person is motivated by the trust placed in him, I argued that trustworthy behavior is the main requirement in community decision-making. Therefore, we can leave unspecified what kind of motivation is needed to satisfy this condition. Lastly, implicit in both these conditions is the condition of *knowledge of trust*. The trusted has to know that someone placed trust in her, even if this trust does not directly motivate her. Otherwise she will be unable to even consider acting in accordance with this trust. Furthermore, she must of course know what she is trusted to do in order to do what is expected of her.

3.3.2 Promoting trustworthiness

To be trustworthy, a person must be motivated to act as expected, have a knowledge of trust placed in them, and have both decision-making and cultural competence to be included in trust-based consent. Judgements about trustworthiness are to an extent subjective. This is because trust is placed from a first-person perspective. How much trustworthy a person has to be (e.g. how competent a person should be), to be trusted can differ from person to person. However, this does not mean that we cannot demand a level of trustworthiness. A basic level of the conditions outlined can be assumed to be necessary for trustworthiness, even though some people might not require these conditions to be fulfilled to trust them (e.g. in blind trust there is no knowledge whether these are fulfilled). It is therefore meaningful to assess trustworthiness from a third-person perspective.

It would be natural to just straightforwardly assess the trustworthiness of individual community members based on the conditions outlined. Although such an individualistic approach might be taken, this has clear practical problems. Most importantly is the amount of time and work needed to assess all community members involved in decisions. It is also difficult to give definitive proof of someone's trustworthiness beforehand, since even the most trustworthy people could sometimes behave untrustworthily. The most we can do, is to show that it is likely for people to behave in a trustworthy manner. The best way to do this, I suggest, is not by demonstrating the trustworthiness of every individual, but by showing that the community as a whole promotes trustworthy behavior. I will discuss all three conditions for trustworthiness – *knowledge of trust*, *competence*, and *motivation* – in turn and suggest ways in which a community could promote them. By having these mechanisms in place, a community could show that members are likely to be trustworthy. I do not aim to give an exhaustive list of trustworthy promoting mechanism. Rather, the examples I give illustrate some ways in which trustworthiness could be promoted and, consequently, show the diverse mechanisms that could serve as indications for trustworthiness within a community.

Knowledge of trust – the trusted being aware of the trust placed in them – seems to be the condition which is relatively easiest to promote in a community. Here communities need to show that there is communication and comprehension of trust and what is trusted between the truster to the trusted. This could be shown by, for example, pointing to communication practices in which trust is expressed, e.g. a general assembly, or specific procedures which ensure communication of trust. These practices do not have to be present in a community before the start of the research of which community consent is part. A community could also implement these practices at the start of the research. Since knowledge of trust does not have to be explicit, this could also been shown by pointing out norms in decision-making practices. For example, it could be shown that decision-makers are expected to behave and behave as if they are trusted by the people for whom they are deciding. In this way, implicit knowledge of trust could be shown.

The second condition of *competence* has to be split into *decisional* and *cultural competence*. As said, the level of decisional competence depends on the decision to be made. However, some basic level of decisional competence could and should be ensured, which includes skills such as some basic understanding, communication, and reasoning skills. In most cases, we can assume that people will possess these skills, since they can be learned and are needed in a variety of activities outside of this specific consent context. Still, communities could point out formal or informal educational practices in which these skills are learned. By pointing out these practices, we have more reason to believe that community members have a general level of decisional competence.

Besides decision-making competence, community consent also requires cultural competence. To be trustworthy to make a decision, a person trusted should know the values and the plans of the truster. It might be hard to show that a trusted knows a truster well enough for every instance. Furthermore, since cultural competence concerns personal values, plans, and conceptions of the good, it is hard to describe this without referring to actual people. However, the shared cultural practices, including the values and norms of those practices, implies that a great extent of values are shared within the community – though they might differ in their relation to those values. Furthermore, thick relations between people are also an indication for cultural competence. This is especially helpful when those relations are the basis of the community consent, e.g. relations between community leader and the potential research subjects, or husband and wife. Although these inferences can of course be incorrect, I think looking at cultural practices, showing a shared practical understanding of the practices and pointing out the relations between community members, is a helpful way to show that possession of cultural competence is likely.

The last condition for trustworthiness is the *motivation* to behave trustworthily. Like the other conditions, we should focus on the likelihood of people being motivated to be trustworthy, instead of their actual motivation, since the latter is difficult to determine from a third-person perspective. This means that, although people can be motivated by internal reasons alone to act in a trustworthy manner, the focus will be on external sources of motivation, since those can be identified from a third-person perspective. Because these external sources (I will refer to them as “motivational mechanisms”) can take a variety of forms, this variety also allows different communities to motivate trustworthy behavior in different ways.

Both Jones and Hardin point out that trustworthiness can be increased through motivational mechanisms (Hardin, 2002; Jones, 2012). Hardin’s discussion is especially helpful, since he elaborates on different motivational mechanisms (Hardin, 2002). He divides them in three categories. First, there are thick relationships we have with e.g. friends and family with whom we have ongoing relations. These ongoing close relations create incentives to be trustworthy because people do not want to lose these relations due to acting untrustworthily. Additionally, people can be motivated to act trustworthily through social and institutional constraints. I take Hardin to use the former for informal mechanisms and the latter for more formal ways of incentivizing. Social constraints are created by social relations other than close personal relations. For example, in a community where people see being trustworthy as a social norm, community members could get strong, negative reactions when behaving untrustworthily. Apart from these social costs, people would tend to behave more trustworthily in such a community, because they consider being trustworthy as normal. Finally, as said, Hardin points out that norms of trustworthiness can be implemented through formal institutions. An example of this is when an organization installs a body to monitor people and hold them accountable for untrustworthy behavior. In this way, accountability creates an incentive to behave trustworthily, as has been pointed out by Manson and O'Neill (Manson & O'Neill, 2007).

As Jones points out, another way to promote trustworthy behavior is to reduce incentives that conflict with trustworthiness (Jones, 2012). By eliminating structures that push people to not behave trustworthily, people will be less tempted to behave untrustworthily and therefore act more in line with trust. For example, praising or rewarding households for enrolling in a research could promote decisions to enroll members of that household, even if this is not in line with what these members want. Because it is harder to show which conflicting motivations are eliminated in contrast to pointing out which exist, we should look at whether conflicting incentives are created within a community when assessing the motivational condition. When there are structures that incentivize untrustworthy behavior, this counts against meeting the burden of proof.

There are of course other ways in which trustworthiness can be shown and promoted, and this discussion is not meant to be exhaustive. Rather, I hope to have pointed out some general ways in which the three conditions of trustworthiness could be promoted. As I said in the beginning of this section, a community that wants to implement community consent must be able to demonstrate that their decision-making practice will most likely involve trustworthy people. I have suggested that the best way to do so, is to show that trustworthiness is fostered within their community.

3.3 Informed trust

I have argued that by providing exit and voice we can increase our confidence that community consent is accepted without control and intentionaly[1]. Although the presence of exit and voice opportunities do not necessarily prove trust, they are an indication for trust. And the more freedom people have to exit or voice, the more exit and voice opportunities will indicate trust. At the same time, I have argued that the likelihood trustworthiness – consisting of knowledge of trust placed, competence, and motivation) – can be increased by having different mechanisms in place that foster these three conditions, most notably the condition of motivation. In this way, the second burden of proof can be met. I want to end by pointing out how a community can promote informed trust. This trust, as opposed to blind trust, is based on information about the trusted. In other words, promoting informed trust would promote trust in trustworthy people. This is not needed for the burdens of proof itself, it shows how these two burdens of proof (which aim to show trust and trustworthiness) can be connected.

Insofar community members have a choice who to trust – which is, as the example at the start of this chapter showed, not always the case – it is important that they place trust in trustworthy people. So, what has to be promoted is *informed trust* which is based on information about trustworthiness. This can be contrasted with *blind trust*, in which trust is placed unreflexively. Although chances of trusted people being indeed trustworthy increase in a community where trustworthiness is promoted, it is still valuable to promote a reflective way of placing trust. Manson and O'Neill have discussed informed trust (which they call intelligent trust) in informed consent and suggest that transparency about trustworthiness is essential for this form of trust (Manson & O'Neill, 2007). I will build on their discussion and argue that providing information about trustworthiness is a useful way to promote informed trust in a community. First, I want to point out a couple of obstacles for informed trust to emphasize the need for the promotion of this kind of trust. These underline why it is important to promote informed trust.

I will outline two influences on judgements of trustworthiness and trust placement, which seem unreliable and not trustworthy-tracking. These examples are not meant to be exhaustive, but they give an idea of the kind of problems for informed trust. The first is inherent to the dual nature of trust, namely its emotional side. As Jones points out, trust can be influenced by emotions (Jones, 1996, 2019). For example, when you love someone, you will interpret evidence about their trustworthiness in a more positive light then when you hate that person. Your judgement of trust will be biased by emotions, including the emotional nature of trust. When trusting someone, that person is "viewed through the affective lens of trust that those who trust are – usually cheerfully, and often on the basis of the smallest evidence – willing to risk depending on the one trusted (Jones, 1996, p. 12)." Thus, emotions, including trust, influence our placement on trust and bias our judgement of trustworthiness.

Secondly, Jones points out as well that our judgement of competence, which is as explained an important part of judgements of trustworthiness, can be biased. An example of this is gender bias: "Given how sexism shapes what we take to be signs of competence, we should be wary of our tendency to trust when an etiology of that trust tells us it is as likely to be caused by mannerisms of privilege as by marks of trustworthiness (Jones, 1996, p. 21)." Although there is not much research in gender bias on judgements on decisional and cultural competence in traditional communities, it is reasonable to expect that (especially decisional) competence would associated with masculinity when leaders in a community are almost always male.

These two examples show that judging who to place one's trust in is not always based on a well-reasoned judgement about trustworthiness. There are two ways to counter this. A community could try to diminish biases or other unwanted influences on trust judgements by directly targeting them. For instance, it could create an environment in which biases are of less influences. However, some forms of influences cannot be totally removed. An important example of this are the role of emotions which is inherent to trust judgements. As put forward by Jones, emotions will color our trusts judgements and how we interpret the information about the trustworthiness of people. Even if we would want trust without emotions, banning out emotions and demanding a completely rational placement is not possible, because of the inherently emotional nature of trust.

Although I do not want to rule out the former way of countering incorrect trust, I want to focus on a different way, namely promoting informed trust. This can be done by providing information about the (potentially) trusted. To indicate trustworthiness, information has to be provided about the conditions of trustworthiness. For example, decisions made earlier could demonstrate whether a person is generally motivated and competent to trust. This kind of information about someone's trustworthiness can be gained through personal relations, which might be more prevalent in the cultural communities we have in mind (Hardin, 2002). However, this is not always the case and there are other additional ways to provide information about trustworthiness. For example, communal practices in which decisions or actions are communicated and explained, on the basis of which community members can assess trustworthiness.

Note that information does not necessarily result in informed trust. Our emotions, including trust, will still color how we interpret the information provided. However, it does make information about the trusted available. This information enables community members to make an informed trust decision. Furthermore, by giving information, there is an increased chance that people will be moved by this information and trust intelligently. When there exists a large and accessible body of information about trustworthiness, it is harder to ignore this information. Even Jones acknowledges that, although trust in a person will color how future evidence about the trustworthiness of that person will be interpreted, "this resistance to evidence is not limitless" (Jones, 1996, p. 16).

Note that providing information does not necessarily have to be accompanied by the same critical stance that is required by individual informed consent (see section 1.3.2). This kind of "duty to be critical" could undermine the very trust relationship it is supposed to support. There is space between providing information and creating suspicion that will destroy trust. Here it is also important to promote both informed trust and trustworthiness. If only informed trust was promoted, there would be a greater need to take a critical position to towards the trusted, since there would be more risk in judging someone trustworthy. In other words, there would be more reason to be suspicious of other decision-makers. This is not only problematic because it would undermine trust relationships in decision-making, but also because it would undermine general trust in a community. Mechanisms to promote trustworthiness defended above will decrease the need for this critical attitude. When trustworthiness is promoted, there is less reason to suspect someone to be untrustworthy. So, to promote informed trust, the promotion of trustworthiness is important as well.

Conclusion

This chapter started with the case of Kassena-Nankana district in which the gate-keeping system requires women to ask permission to male community members before consenting to a research. In such a situation, which is not unique for these communities, it is questionable whether women really support the decision-making processes within a community. From this example followed two burdens of proof. Firstly, communities have to show that community consent is based on trust to show that people are not forced into community consent practices. Secondly, communities have to demonstrate the members making decisions in community consent are trustworthy. I have pointed out mechanisms for both, which could show the likelihood of trust and trustworthiness being present in community consent. In both cases, the examples given are not exhaustive, but these are promising ways to demonstrate trust and trustworthiness. I have ended by pointing out that providing information about trustworthiness can promote informed trust. Since informed trust will increase the possibility of trusting trustworthy people, this links the two burdens of proof.

Some implications for informed consent guidelines of the last two chapters can already be spelled out. Most importantly, that community consent is conditional on demonstrating the presence of trust and trustworthiness in a community. In other words, before an institutional review board or other ethics committee would authorize community consent process in a community, communities have to show that their practices are based on trust and trustworthiness. If communities cannot meet these requirements, the value of community consent does not weigh up to the risk of suppression of individual autonomy. There are of course a lot of details that still have to be articulated – e.g. what level of confidence for trust and trustworthiness is required? – some of which I already pointed out in this chapter. However, the conditional nature of community consent already provides some direction to address the conflict central to this thesis: that between individual autonomy and community consent.

Conclusion

This thesis started with the case of community consent by the NHRC in the Kassena-Nankana district. The NHRC asked permission to different gate-keepers within communities in that district before asking consent to individuals (Tindana et al., 2006). I have argued that there is a strong reason in support of shaping informed consent according to community decision-making practices, because of the value these practices can hold for community members. At the same time, I have acknowledged the (potential) problems of these practices, because of the restrictions they can put on individual autonomy. To bridge this gap, I have argued that trust and trustworthiness can ensure autonomous decision-making in community consent. Furthermore, I have argued that communities must and can show that both trust and trustworthiness are present in their community and their decision-making practices.

It might be noticed that many arguments throughout this thesis have (sometimes implicitly) relied on an individualistic standpoint. For example, the value of communities is explained by referring to the value they have for community members. Consequently, community consent is not defended to protect the community for the sake of the community, but to protect the community for its members. This could result in the same conclusions, but there is an important difference in the starting point of the justification. Similarly, I have maintained that community consent should not overrule the individual autonomy of community members. It must be compatible with the individualistic conception of autonomous action defended by Faden et al. (1986). The reason for this individualistic starting point is both pragmatic and ethical. It is pragmatic because this individualistic outlook is widely held by bioethicists. This pragmatic motivation is most clear in the use of autonomous action as the basis for informed consent. At the same time, I think this is also a correct ethical standpoint. Communities cannot be valuable without being valuable for people and when they restrict individual autonomy, the value they have for those individuals decreases.

Some theorists, those defending a more communitarian outlook for example, could object that this individualistic starting point does not do justice to the value of communities, which goes beyond how individuals value it. Consequently, a Western, individualistic outlook is still imposed on communities. In response, it is important to realize that we cannot impose any self-understanding on people.[38] It is true that communities and their practices are valuable for people and this gives us a strong reason to protect those practices. However, those practices only have value if they have value for someone. This value is defined here in terms of self-understanding. A community cannot force this self-understanding on its members. In other words, we cannot say that a community practice such as community consent

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[38] I owe this point to Joel Anderson.

is valuable and therefore protect and enforce it without referring to the self-understanding of community members. And since this is the self-understanding of an individual, the individual standpoint taken in this thesis is appropriate.

The question also arises whether the argument in favor of community consent made here is also applicable to the Western sphere. The focus of this thesis has been on more traditional non-Western communities, since it is in that context in which the request for community consent commonly arises. In Western countries, the individual outlook of informed consent is less controversial. However, it would be interesting to see whether the Western decision-making practices do align with this conception. As pointed out in the first chapter, our identity and values are partly formed by the people and practices around us. Although a more individualistic conception of the self is commonly held within Western societies, identity is still created in dialog with others (Taylor, 1989, 1995b). It can be questioned whether the individualistic approach to informed consent matches the decision-making practices that shape people's self-understanding in Western societies. For example, different papers have already pointed out that the way patients/potential subjects conceive their relationship with medical professionals in medical decisions does not always match the individualistic informed consent model. When deciding to consent, potential subjects have expressed the importance of trust in their physicians and the role of medical professionals in the decision-making process based on this trust (Boisaubin, 2004; Kass et al., 1996). Thus, their conception of their relationship with medical professionals influences the decision-making practice, which can, on its turn, enforce (this conception of) their relationship. What must be asked is whether this and other (e.g. involvement of family) decision-making practices are so important for people's identity and values that holding on to an individualistic informed consent process would undermine their self-understanding. More research needs to be done the nature and importance of different decision-making practices in Western societies to answer this question. Such research is not only important to clarify the conception of decision-making held in Western countries, but could also strengthen the case for other forms of decision-making in informed consent, such as a shared decision-making model (Charles, Gafni, & Whelan, 1997, 1999).

Finally, to conclude this thesis allow me to comment on potential guidelines for human research ethics and community consent. Although there is still a lot work to do in relation to community consent and I do not claim that this thesis has covered everything around community consent and its relation to individual autonomy, it is useful to ask what the implications of this conclusion are on current ethical guidelines. Let me go back to the Declaration of Helsinki to point out some directions (World Medical Association, 2013). As can be read in chapter 2, the most recent version of this declaration includes a statement on including others, such as community leaders or family in informed consent:

> Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees. (World Medical Association, 2013, sec. 25)

At the same time, the Declaration seems to uphold an individual focused conception of informed consent by requiring that a person “freely agrees” and fails to address the tension between the two. A further specification seems needed to do this, as well as to specify the conditions under which consultation of community leaders and family members is appropriate. As said, this thesis only discussed one line of argumentation and further research is necessary to fully spell out ethical guidelines around community consent. However, based on this thesis we can conclude that future ethical guidelines governing research with human subjects (of which the Declaration of Helsinki is only one) should (implicitly or explicitly) address the following questions:

(1) What is the role and importance of community decision-making practices, which deviate from standard informed consent, for community members’ self-understanding and could those practices potentially be disrupted by standard informed consent?

(2) Is the community able to show that these community decision-making practices likely to be based on trust and trustworthiness?

Based on the first question, some (not all) cases can be distinguished in which community consent can offer important protection to community practices. The second question helps to answer whether community consent which restricts individual autonomy is justifiable, since, based on trust and trustworthiness, the community members choose autonomously for this practice and their autonomy is upheld in the decision about consent following from this practice. In contrast to what the Declaration of Helsinki implies, a form of community consent in which there is no individual informed consent could be justified based on those questions. The burden of proof to answer both questions falls on communities. However, this does not mean that medical professionals do not have a duty to help to answer these questions. Since appropriate community consent would bring us closer to ethical research conduct, community consent is something medical professionals should support when they can.

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