THE SOCIAL DIMENSION OF INFORMED CONSENT PROCEDURE IN BIOETHICS:

A KANTIAN INTERPRETATION

MASTER THESIS

Ya-Yun Kao

Supervisor: Marcel Verweij

Erasmus Mundus Master Program in

Applied Ethics

Utrecht University

The Netherlands

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Abstract

This thesis argues, along the line proposed by Neil Manson and Onora O'Neill in their book *Rethinking Informed Consent in Bioethics*, for what may be called a "paradigm shift" wherein informed consent is conceived as a "waiver" of certain fundamental rights and their correlative obligations, and as a "speech act" that can only be meaningful against the background of these rights and obligations. I believe this new way of looking at informed consent can help us to better address ethical challenges recently raised by the establishment of large or even national human genetic biobanks, and by secondary research uses of left-over biological samples. I will begin, in Chapter 1, with a critical examination of the so-called "principle of respect for autonomy," which Tom Beauchamp and James Childress hold to provide the "primary justification" of informed consent; and I will argue for the need to reconceive informed consent in a way which severs it from personal autonomy as its justification—a way which is exactly what Manson and O'Neill propose. In Chapter 2, I will look into the moral foundation of this new conception and hold that Kant's Formula of Humanity can serve as such a foundation. Finally, with a fuller picture of Manson and O'Neill's conception at hand, I will suggest, in Chapter 3, how the above-mentioned challenges can be met in ways that are more reasonable than those which bioethicists like Beauchamp and Childress could offer.

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Introduction

In both clinical and medical research settings, informed consent by patients or research participants has been typically regarded as both necessary and sufficient for ensuring that intended invasive interventions such as surgery or clinical trials will proceed in an ethical manner. Without informed consent, an invasive intervention may well be considered as wrongfully causing injury or even killing when it fails. It has long been acknowledged that the moral justification of such an important practice lies in the fact that it protects the so-called "personal autonomy" of patients and research participants. In their canonical book *Principles of Biomedical Ethics*, Tom Beauchamp and James Childress incorporate this moral concern underlying the requirement of informed consent into what they call the "principle of respect for autonomy." They claim that "respect for autonomy does provide the primary justification of rules, policies, and practices of informed consent."[1] To ensure that informed consent does protect the personal autonomy of patients and research participants, it has been emphasized by bioethicists such as Beauchamp and Childress that clinicians or researchers ought to provide patients or participants with sufficient information and make sure that they are not (unwittingly or, what is worse, intentionally) exercising undue influence. By itself, the requirement of informed consent does seem to protect personal autonomy as an important moral value. Nevertheless, concern for this moral value seems to me to have been over-stretched to such a point that it loses its true spirit. As it turns out, the informed consent form has become unbearably lengthy, complex, or even unintelligible. No wonder that some critics question whether a patient or participant who is a lay person to medicine can really comprehend complex medical terms and information provided in the informed

[1] Beauchamp and Childress 2009: 118.

consent form. Moreover, under the influence of illness and emotional disturbance caused by it, such as fear, stress and frustration, it is also doubtful whether a patient or participant can understand in an appropriate, undistorted way what is stated in the informed consent form.

Worse still, the requirement of informed consent faces challenges raised by secondary research uses of biological samples and information originally obtained and stored through proper informed consent procedure, and by the establishment of large-scale human genetic biobanks, especially those designed for the purpose of prospective epidemiological studies in the future. According to the hitherto standard conception of the informed consent procedure as both necessary and sufficient for the protection of personal autonomy, further informed consent (or, in short, re-consent) by the original donors is indispensable in the case of secondary research uses of left-over biological samples. Nevertheless, such requirement for re-consent may be impossible to satisfy when the original donor is dead, becomes incompetent, or simply cannot be located. It may also be impractical if it imposes significant financial and administrative burdens on researchers. The most recent, 2008 version of the Declaration of Helsinki tries to meet this challenge by leaving it to a research ethics committee to decide whether re-consent is needed in a particular case. Accordingly, if the committee comes to the conclusion that re-consent is not needed, it can approve or disapprove the proposed secondary research usage of left-over samples on behalf of the original donors. This solution, according to the standard conception mentioned above of the informed consent procedure, can only be considered at most as a "second-best" option. However, as I will argue in Chapter 3, if we conceive informed consent differently, in a way suggested by Neil Manson and Onora O'Neill in their book *Rethinking Informed Consent in Bioethics*, the second-best option mentioned

above will turn out to be actually the most reasonable option, whether or not re-consent by the original donors is impossible or impractical.

The challenge raised by the establishment of large or even national biobanks comes from the infeasibility of (specific) informed consent at the initial stage of recruitment. As the Helsinki Declaration understands it, informed consent is *specific* to a given research project with a specific purpose and procedure, and with specific potential risks and benefits that go with the project. But in the case of a human genetic biobank that is to serve *prospective* medical studies, the matter is totally different: when collecting samples for such a database, it is as yet unknown for what research projects these samples will be used in the future. Therefore, people deliberating on whether or not to participate in a biobank of this kind cannot be provided with adequate and specific information about exactly how their samples will be used in the future, nor for this reason can they give (specific) informed consent.

To rectify the current tendency of the informed consent procedure toward formalism, Manson and O'Neill call our attention to, and elaborate a great deal on, the *background* against which the informed consent procedure takes place and makes sense. They propose a new way to conceive informed consent as a "waiver" and a *context-dependent* "speech act." The informed consent procedure is not merely, as it has long been taken by many to be, a process of passing a filled-out form with abundant information to the patient or participant and asking him or her to read it and then sign on it. What matters is (mutual) *communication*, a kind of norms-laden "speech act," between two parties: patients and clinicians, or participants and researchers. More crucially, Manson and O'Neill put much emphasis on the fact that the informed consent procedure is to take place and make sense against a *normative background of rights and their correlative obligations*: "Informed consent has a role

only where activity is already subject to ethical, legal or other requirements."[2] To view informed consent as a "waiver" means that it is required *when and only when* there are fundamental rights and obligations to be temporarily waived for specific medical purposes.

However, although they admirably bring out the background of fundamental rights and obligations against which the informed consent procedure operates and makes sense, they do not touch on the moral foundation of that background. They argue for the need to view informed consent against such a normative background; as to what important rights and obligations are to be included in the background, they offer a short list, saying simply that they assume it to be unproblematic that the rights and obligations cited as examples are what "nearly all ethical outlooks and legal systems will converge [on]."[3] Though their assumption may well be true, it does not enable us to see why those items on the list are to be regarded as rights and obligations, why they are fundamental or generally inviolable, and how, given their fundamental status as rights and obligations, they can be reasonably waived at all. In my view, all these questions can only be answered if we go deeper into the moral foundation of the background that Manson and O'Neill speak of. In Chapter 2, I will argue that Kant's Formula of Humanity can serve as such a foundation.

My chief task in what follows is, in a nutshell, to re-examine the informed consent procedure, along the line proposed by Manson and O'Neill, in order to better address the above-mentioned challenges raised by secondary research uses of biological samples and information originally obtained and stored through proper informed consent procedure, and by the establishment of large human genetic biobanks. Manson and O'Neill's new model of the informed consent procedure looks

[2] Manson and O'Neill 2007: 72.
[3] Ibid.: 74.

very appealing to me. By directing our attention to a rich normative background behind the procedure, their model enables us to uncover convincing *rationale*, stemming from Kant's Formula of Humanity, in support of some familiar institutional designs for regulating the procedure. And it helps us to come up with further institutional designs to address the above-mentioned challenges more satisfactorily than if we adhere to the hitherto standard model. My thesis will begin by critically examining the most prominent espousal of this standard model by Beauchamp and Childress.

Chapter One

Informed Consent and Its Justification

1.1 The principle of respect for (personal) autonomy

It has been widely assumed that the reason why informed consent needs to be obtained in cases of medical treatment and research is that it is both necessary and sufficient for the protection of an important moral value, namely, the personal autonomy of patients and research participants. In their canonical book *Principles of Biomedical Ethics*, Tom Beauchamp and James Childress incorporate this moral value into the so-called "principle of respect for autonomy" (hereafter abbreviated as "PRA"). They claim that "respect for autonomy does provide the primary justification of rules, policies, and practices of informed consent."[4] This claim is crucial to their account of the role played by PRA in biomedical ethics, and is for this reason worthy of our careful examination. The first question we must ask about this claim is: what conception of personal autonomy underpins PRA? Beauchamp and Childress explicitly hold that their conception of personal autonomy applies to actions instead of persons, and the following statement of theirs gives us a succinct account of how they have conceived personal autonomy as applied to actions: "We analyze autonomous action in terms of normal choosers who act (1) intentionally, (2) with understanding…, and (3) without controlling influences that determine their action."[5]

However, Richard Dean, a recent Kant scholar examining personal autonomy as it figures in bioethics, points out that in their elucidation of PRA Beauchamp and Childress actually vacillate between two conceptions of personal autonomy.[6] At first

[4] Beauchamp and Childress 2009: 118.
[5] Ibid.: 101. As to the claim by Beauchamp and Childress that their conception of personal autonomy applies to actions, see ibid.: 100.
[6] Dean 2006: 200-204.

they characterize it as exemplified in one's choosing in accordance with "self-chosen plan," when they say, "Personal autonomy encompasses, at a minimum, self-rule that is free from both controlling interference by others and from certain limitations such as an inadequate understanding that prevents meaningful choice. The autonomous individual acts freely in accordance with a self-chosen plan.…"[7] Negatively speaking, personal autonomy is freedom from others' control and undue influence, and positively speaking, it is choosing (and subsequently acting) in accordance with one's "self-chosen plan." Dean labels this conception of personal autonomy as the "more robust" conception which construes personal autonomy as "the power to make decisions in accord with one's overall ends and plans."[8]

This more robust conception reminds us of models advocated by Harry Frankfurt and Gerald Dworkin of personal autonomy as what we may call "second-order endorsement." According to them, personal autonomy is to be conceived as a capacity to rationally reflect on, and then identify with, one's first-order desires through second-order ones (which are desires to have this or that first-order desire). It might seem that Beauchamp and Childress also follow such models in thinking about personal autonomy if Dean is right in attributing the more robust conception to them. However, Beauchamp and Childress have in fact explicitly rejected such a conception on the ground that it is "beyond the reach of normal agents and choosers."[9] In *A History and Theory of Informed Consent* Beauchamp and Ruth Faden voice similar concern when they point out that "the importance of the principle of respect for autonomy would itself be diminished, because its utility in guiding moral conduct in everyday interactions would be reduced."[10] In other words, for Beauchamp and

[7] Beauchamp and Childress 2009: 99.
[8] Dean 2006: 203, see also 199-204.
[9] Beauchamp and Childress 2009: 101.
[10] Faden and Beauchamp 1986: 265.

Childress, personal autonomy understood as choosing in accordance with one's overall ends and plans demands too much: I might decide to donate blood and then sign the informed consent form simply because many of my friends do so when we go shopping and see a sign asking people to donate blood. I may never have reflected on my action as to whether it accords with my "self-chosen plan." Would this then disqualify my action as autonomous? Would my action not be something that deserves respect by others? Instead of embracing such a demanding, more robust conception of personal autonomy, Beauchamp and Childress settle on a "thinner" one, which they explain by the succinct account quoted at the outset of this chapter, namely, that normal choosers, in order to exercise their capacity for autonomous choice and action, must "act (1) intentionally, (2) with understanding…, and (3) without controlling influences that determine their action."[11] As far as autonomous choice and action are concerned, this thinner conception does not require one to choose or act in accordance with considered values or "self-chosen plan," nor does it require one to choose or act through rational reflection.

It might appear that Beauchamp and Childress have not adhered to this thinner conception all the time: two pages later they appear to fall back on the more robust conception of personal autonomy when they say, "To respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their personal values and beliefs."[12] Dean would regard the statement quoted here as expressing the more robust conception,[13] and would therefore count this as another

[11] Beauchamp and Childress 2009: 101.
[12] Ibid.: 103.
[13] Commenting on a statement by Beauchamp and Childress which is similar to the one last quoted in the text, Dean says: "The rationale for requiring that physicians give adequate information before obtaining consent is to allow patients to make choices that fit with their overall desires, goals, and attitudes. This is the real requirement and intuitive force of the principle of respect for autonomy, and it accords with most explicit formulations of that principle. Tom Beauchamp and James Childress, in the virtually canonical *Principles of Biomedical Ethics*, state, 'To respect an autonomous agent is, at minimum, to acknowledge that person's right to hold views, to make choices, and to take actions based

instance of Beauchamp and Childress's oscillation from the thinner conception to the more robust.

This reading of the statement in question by Beauchamp and Childress is problematic, however. It overlooks their emphasis that their concern is about autonomous choices rather than autonomous persons.[14] Beauchamp and Childress may well point out here that the more robust conception applies only to autonomous persons because it emphasizes the autonomy of an individual who "acts freely in accordance with a self-chosen plan," and that such a conception is over-demanding, as shown by their criticisms of the model proposed by Frankfurt and Dworkin. It seems that Beauchamp and Childress can consistently contend that there is only one conception of personal autonomy, specifically the thinner conception, that underpins PRA.

Yet, in my view, this only half-clarifies the matter about the kind of personal autonomy involved in PRA. We have so far seen Beauchamp and Childress speak of (A) acting and choosing in accordance with one's "self-chosen plan" (as depicted by the more robust conception) on the one hand, and (B) acting and choosing in accordance with one's "personal values and beliefs." Leaving aside the fact that Beauchamp and Childress associate the kinds of acts and choices involved here with autonomous agents, there is an important difference between (A) and (B): Choosing (or acting) in accordance with a "self-chosen plan" is different from choosing in accordance with one's "personal values and beliefs." The former not only indicates choosing in accordance with my *plan*, but also implies that such a plan is what *I* decide to incorporate into my values and beliefs and to identify with as *my* plan. Such incorporation and identification involve reflection on the plan as to whether it accords

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on personal values and beliefs'" (Dean 2006: 200).

[14] Beauchamp and Childress 2009: 100.

with one's values and beliefs, and whether it is really what one wants to set to oneself as one's own plan. On the other hand, choosing in accordance with one's "personal values and beliefs" does not require one to have reflected in a similar way on these values and beliefs. To illustrate the difference I have in mind between (A) and (B), let us consider this example: Annie refuses blood transfusion in accordance with her religious belief as a Jehovah's Witness. Her choice to refuse blood transfusion is based on her personal religious belief (together with values associated with it), which she may have never reflected on as to whether it is what she really wants whole-heartedly to commit her life to. It might be the case that her being a Jehovah's Witness results from her upbringing and her parents' influence, and that she has never considered the question as to whether she really wants to be a Jehovah's Witness. Suppose this is indeed the case with Annie. Then does this imply that a clinician has no reason to respect her choice not to accept blood transfusion? Beauchamp and Childress would certainly point out that such a choice, made in accordance with one's personal values and beliefs but without any prior reflective evaluation of these values and beliefs themselves, is still autonomous and thus deserves respect according to PRA.

Let us say of Annie's choice that it is "minimally rational" insofar as it was made by Annie in accordance with her values and beliefs, but that it is not only minimally but also "*reflectively* rational" if it was made by her in accordance with values and beliefs *that she had reflected on and identified with as her own*. Suppose Annie is not an autonomous agent conceived according to the more robust conception (as applied to persons). Then, even though Annie cannot, under that assumption, make reflectively rational choices (since she lacks the requisite reflective capacity in being a non-autonomous person), she can still make *minimally* rational choices. Thus, we may ask, should Beauchamp and Childress not include this feature of being minimally

rational in their thinner conception of personal autonomy (as applied to actions and choices instead of persons)?

At first sight the thinner conception only requires one to act intentionally, with understanding, and without undue influence. It says nothing about acting in accordance with one's personal values and beliefs. However, if we attend carefully to the requirements proposed by the thinner conception, we can see the connection. The reason why we discuss different conceptions of personal autonomy is to find out which of them underpins PRA. Why do we want to talk about PRA? PRA is used to remind clinicians or researchers that they have a *moral obligation* to respect the personal autonomy of patients or participants. Whereas it seems that the different conceptions discussed above of personal autonomy emphasize conditions that patients or participants must meet if they are to enjoy the respect they deserve, those conceptions should be read as proposing demands for clinicians or researchers to comply with in order to pay due respect to patients or participants. Thus the thinner conception can be read as requiring clinicians or researchers to offer adequate information (so that patients or participants can choose with proper understanding) and to refrain from exercising undue influence; and the point of such requirements may be said to be no more than that they give patients or participants a chance to choose in accordance with their personal values and beliefs, if not also with their "self-chosen" plan (if they are reflective enough to have any such plan). An example would illustrate this point: in the case of Bang v. Miller Hospital, the patient Bang consented to prostate surgery without being told that an inevitable consequence of that surgery is sterilization. Beauchamp and Childress comment that "Bang's failure to understand this one surgical consequence compromised what was otherwise an adequate understanding and invalidated what otherwise would have been a valid

consent."[15] What is the problem? Is Bang's original consent invalid simply because the clinician did not provide adequate information? Lack of adequate information is only a superficial reason; what is really troubling in this case is that such a mistake deprived Bang of opportunities to make a choice that conforms to his *values and beliefs.* Obviously he believed that the operation would not make him sterilized. He may be the kind of person who gives great value to having children or simply enjoying sex, which is unfortunately no longer possible for him. Viewed in this light, one can say that without recognition that the autonomous choice made by patients or participants ought to accord with their personal values or beliefs, or that it ought to be (at least) minimally rational for them, clinicians or researchers would have little reason to abide by PRA by providing adequate relevant information to the patients or participants.

Thus, if I am right, the conception of personal autonomy proposed by Beauchamp and Childress should be rephrased as follows: An autonomous action or choice is one that is done (1) intentionally, (2) with understanding, (3) without undue influence, and (4) in accordance with one's personal values and beliefs. Let us call this a "minimally rational" conception of personal autonomy as applied to actions and choices. It is this conception that Beauchamp and Childress should take to underpin PRA. The reason why such a conception is called "minimally rational" is that in order to act or choose autonomously, one needs to exercise one's rational capacity for understanding options and making decision about which among them is preferable in accordance with one's values and beliefs; and such a (minimal) exercise of practical rationality is less demanding than that required by the more robust conception of personal autonomy. Hence, the minimally rational conception may be said to provide clinicians and researchers with more compelling reason than the more robust

[15] Ibid.: 127-128.

conception for abiding by PRA, since significantly more of ordinary people are capable of making autonomous choices according to the former conception than according to the latter.

The minimally rational conception may also be compared with what may be called a "mere choice" conception, which holds that a person makes an autonomous choice as long as she does so freely, *regardless of whether or not her choice accords with her personal values and beliefs*. Perhaps more of ordinary people are able to make autonomous choices as mere choices than as minimally rational choices. But the mere choice conception does not provide clinicians and researchers with more compelling reason than the minimally rational conception for abiding by PRA. This is so simply because "mere choice" may be arbitrary and therefore offers little legitimate moral ground to demand others to abide by PRA if PRA requires respect for mere choice.

Nevertheless, the minimally rational conception itself faces difficulties. The biggest difficulty concerns whether this conception can be properly held to be the source of a moral principle. If PRA is to be one of the *fundamental* principles in bioethics as Beauchamp and Childress intend it to be, and if the personal autonomy that it involves is of the "minimally rational" kind, then it is hardly plausible that PRA as a "moral principle" *always* deserves our compliance.[16] For, even if a choice is minimally rational, it may be risky or morally wrong; hence it alone can hardly justify the moral bindingness of the respect required by PRA for personal autonomy. In other words, if underpinned by the minimally rational conception of personal autonomy,

[16] One might object to the argument here as problematic, because according to Beauchamp and Childress PRA is neither the sole nor the most important principle. There is no need for PRA to *always* demand compliance from clinicians and researchers. Sometimes considerations based on the principle of beneficence, for instance, may outweigh PRA. But even if this is the case, how should we proceed with the weighing? Behind the four principles suggested by Beauchamp and Childress, is there any more fundamental, higher-order principle which could be used as a guideline for the weighing?

PRA would have difficulty in persuading clinicians and researchers always to fulfill the moral obligation required by PRA to respect decisions made by patients or participants. For example, Beth who has inflammatory breast cancer was advised to undergo chemotherapy followed by mastectomy may refuse to do so because she does not want to go through all the painful process and because she firmly believes that breasts are an essential part of her identity as a woman. Even though her understanding of the proposed treatment is adequate and there is no undue influence, her personal values and beliefs go strongly against it. Suppose further that she is so stubborn that neither her family nor her physician could persuade her to accept the proposed treatment. Should her physician respect her decision? If PRA is to be a *fundamental moral principle*, it seems that at least in some cases it requires the more robust conception of personal autonomy to underpin it. In Beth's case, for example, she must *rationally reflect* on and wholeheartedly endorse her belief that breasts are inseparable for her identity as a woman if her physician is to respect her decision based on that belief.

Besides the above difficulty, even the conditions specified in the minimally rational conception of personal autonomy are not always easy to satisfy. Take "proper understanding" as an example. Risk is an unavoidable element to be conveyed to patients and participants. Yet, as Beauchamp and Childress indicate, "risk disclosures commonly lead subjects to distort information and promote inferential errors and disproportionate fears of some risks."[17] If so, it is hard to maintain that patients and participants are commonly able to attain proper understanding of the proposed intervention; it must therefore be admitted that their decisions do not usually count as autonomous. Beauchamp and Childress seem to have made room for this problem by admitting that personal autonomy as they conceive it may be exemplified to greater or

[17] Beauchamp and Childress 2009: 130.

lesser degrees by people's actions and choices.[18] So they might reply that even if patients and participants do not usually attain proper understanding of the proposed intervention, this at most shows that their decisions made on the basis of inadequate or partial understanding are typically not "fully autonomous," but that they can be autonomous nonetheless, even if to a lesser degree. Still, the problem I am raising has to do not so much with inadequate or partial understanding, as with distorted or misguided understanding that tends to result from people in illness making decisions under conditions of physical pain, fear, anxiety, dependency on others, and so on. If this is indeed often the case, the question is not so much whether patients and participants can achieve as much as possible the kind of proper understanding that is required for their making autonomous choices as conceived by Beauchamp and Childress, but whether it is appropriate to require clinicians or researchers to abide by PRA at a time when they know well that their patients or potential participants may fall prey to the kind of distorted or misguided understanding as a result of stressful physical and psychological conditions. Abiding by PRA under such circumstances seems even to run counter to the professional obligations such as beneficence and non-maleficence clinicians and researchers have in the first place toward their patients or participants.

Thus, even though the minimally rational conception may sound more plausible than both the more robust (or reflectively rational) conception and the mere choice conception, it must face two challenges: first, the minimally rational conception of personal autonomy does not seem to carry sufficient moral weight to underpin PRA if we take seriously the role PRA is supposed to play as one of the fundamental principles in bioethics; second, there is significant likelihood for patients and potential participants who are in especially stressful conditions to fall prey to distorted or

[18] Ibid.: 101.

misguided understanding, so that it may not be appropriate to require clinicians and researchers to abide by PRA.

1.2 Personal autonomy and informed consent: Manson and O'Neill's criticisms

The above discussion is intended to show that PRA as conceived by Beauchamp and Childress rests on shaky foundations. Even though Beauchamp and Childress are aware of recent criticisms made by Manson and O'Neill of "autonomy in bioethics" and of the informed consent requirements, they still insist that PRA is indispensable for the justification of informed consent requirements. They claim that "respect for autonomy does provide the primary justification of rules, policies, and practices of informed consent."[19] Is this claim tenable?

Manson and O'Neill argue that *conceptions* of rational autonomy which have hitherto been used by many to justify informed consent practices either justify too much or too little.[20] The underlying belief shared by advocates of rational conceptions of personal autonomy is that if informed consent is a result of rational choice, then it must be regarded as reasonable. By suggesting that some conception(s) of rational autonomy justifies too much, Manson and O'Neill mean to hold that there are some cases in which informed consent is rational according to the conception but is intuitively (or widely regarded as) not reasonable. Consensual torture or masochistic practices, consensual killing and consensual cannibalism are best examples. One's

[19] Ibid.: 118.

[20] Manson and O'Neill claim that "[i]nformed consent is seen as justifying invasive interventions by ensuring that patients or research subjects not merely choose or decide whether to accept such interventions, but make *informed, reasonable* or *reflective* choices to do so: only then can their choices be seen as reflecting their rational autonomy. This line of thought risks justifying both too much and too little" (Manson and O'Neill 2007: 70). Although this claim explicitly says that conceptions of rational autonomy risk justifying "both too much and too little," I suggest that we can read it as saying that *some* conception(s) of rational autonomy may justify too much (such as the one proposed by Beauchamp and Childress) and *some* may justify too little (such as those proposed by Frankfurt and Dworkin), and still others may justify "both too much and too little." Even if there turns out to be no single conception of rational autonomy that risks justifying "both too much and too little," I believe this does not necessarily undermine my suggested reading here.

"consent" to being tortured, killed, or eaten may be made with proper understanding, without undue influence, and even in accordance with one's values and beliefs. But it would hardly be accepted by any "civilized" society as reasonable. On the other hand, by suggesting that some conception(s) of rational autonomy justifies too little, Manson and O'Neill mean to hold that there are some cases in which informed consent (or refusal) is intuitively (or widely regarded as) reasonable but does not count as rational in the sense defined by the conception. As the example of Annie suggested in the previous section shows, her refusal to receive blood transfusion is widely regarded as reasonable; nevertheless, according to the more robust or reflectively rational conception of personal autonomy, her refusal is not rational.

The conception of personal autonomy advocated by Beauchamp and Childress is also one of rational autonomy, since it requires that a patient or participant, if she is to give a valid consent, must exercise her rational capacities so that she can understand the proposed treatment or experiment and then decide in accordance with her values and beliefs. Although their conception does not risk justifying too little (it is, after all, "minimally rational," and is supposed by Beauchamp and Childress to be able to be satisfied by the majority of people through their ordinary actions and choices), it might risk justifying too much: for example, one might consent to an extremely dangerous experiment with little possible benefit to oneself, and do so with proper understanding and no undue influence; though such consent might be rational if one embraced highly altruistic, self-sacrificial values and beliefs, it is, arguably, unreasonable. It might be objected that this example is far-fetched because Beauchamp and Childress can easily reply that PRA is not the sole fundamental principle in bioethics, that researchers also abide by, say, the principle of nonmaleficence and therefore would not propose any such dangerous experiment to their participants. Granted that this is a legitimate objection, it nevertheless casts

doubt on the claim made by Beauchamp and Childress that PRA provides "the *primary* justification" of informed consent practices. Seen from the perspective of the participant, the list of options that she is asked to choose from in giving consent or refusal is already, before it is put to her for consent or refusal, a very limited list constrained by considerations such as those of nonmaleficence and beneficence; and such prior considerations may well strike the participant as undue paternalistic constraints on the exercise of her personal autonomy. Hence it seems doubtful how PRA could provide "the *primary* justification" of informed consent practices. The following question raised by Manson and O'Neill sounds instructive here: "Do appeals to autonomy in biomedical practice perhaps presuppose and rely on a residual paternalism that frames and protects the supposed exercise of individual autonomy?"[21] It seems that Beauchamp and Childress cannot coherently claim on the one hand that PRA provides the "primary justification" of informed consent practices, and on the other hand that the informed consent practices are appropriately constrained by certain prior considerations, such as those of nonmaleficence and beneficence, that limit the options to be offered to patients and participants.

1.3 A new perspective on the informed consent procedure

In the previous two sections we have seen, first, that PRA itself is not free from problems and, second, that PRA cannot provide what Beauchamp and Childress call the "primary justification" of informed consent practices *if* they concede that these practices already presuppose certain ethical constraints on the kind of medical interventions it is permissible to offer to patients and participants for their consent. Those who regard personal autonomy as the primary ground for justifying informed consent procedure put a lot of emphasis on two parts of the procedure, namely, the

[21] Manson and O'Neill 2007: 72.

cognitive, "informed" part and the volitional, "consent" part. For Beauchamp and Childress, such emphasis is exemplified as requirements on proper understanding and exclusion of undue influence respectively.[22] To allow room for a competent patient or participant to make her autonomous decision, clinicians or researchers ought to provide sufficient information and make sure that they are not (unwittingly or, what is worse, intentionally) exercising undue influences. Such an account is depicted by Manson and O'Neill as falling under a "conduit/container model" which, as pointed out above, fixes our attention on *one party giving information to the other and the other giving consent (or refusal) in return*.[23] Although this model is not wrong by itself, it nevertheless leads us to overlook the background against which the informed consent procedure takes place and, most importantly, makes sense. As the example of "dangerous experiment" that we saw toward the end of the last section shows, constraints on informed consent practice are not limited to those based on PRA only; the principle of nonmaleficence, for example, is also very important, which operates behind and prior to the act of informed consent and serves as a constraint on what kind of experiment could be proposed to participants. If I am right, this way of situating informed consent practice in its proper background or setting in fact suggests that Beauchamp and Childress cannot consistently claim that PRA is the primary justification of such practice, because they also admit that other moral principles may compete with PRA, or that PRA does not enjoy *the highest* priority among the four principles in biomedical ethics that they propose.[24]

In order to redirect our attention to the background against which informed consent procedure takes place and makes sense, Manson and O'Neill first remind us that informed consent procedure involves a kind of "speech act" involving two parties,

[22] Beauchamp and Childress 2009: 117-134.
[23] Manson and O'Neill 2007: 35-41.
[24] Beauchamp and Chidlress 2009: viii, 99, 140.

and the main function of the speech act is to communicate and adjust practical and cognitive commitments of the two parties to the speech act. They call this way of looking at informed consent procedure the "agency model."[25] For any communication qua speech act to be successful, it must proceed against the background of a set of operating rules. To see what such rules may be, we must first note that Manson and O'Neill propose to view informed consent as an act by means of which some fundamental normative requirements are "waived" by patients or participants: in short, for Manson and O'Neill, informed consent is best thought of as a "waiver." Not only must the informed consent procedure follow familiar epistemic norms for successful communication such as intelligibility, relevance and accuracy of the information to be communicated from one party (the clinicians or researchers) to the other (the patients or potential participants), it must also serve to help the other party to waive important ethical and legal norms that it would *otherwise* be a serious moral wrong to violate by means of the proposed treatment or intervention: "In consenting we *waive* certain requirements on others not to treat us in certain ways (sometimes this will include waiving rights), or we *set aside* certain expectations, or *license* action that would *otherwise* be ethically or legally unacceptable. Informed consent has a role *only* where activity is already subject to ethical, legal or other requirements."[26] Informed consent is required when and only when a clinician or researcher proposes to do what is regarded under normal circumstances or non-medical setting as ethically or legally wrong. One might then ask, what are these ethical and legal requirements?

Manson and O'Neill's reply goes as follows: "[W]e will rely on the fact that certain types of action will be prohibited in most jurisdictions. We assume, for example, that nearly all ethical outlooks, and nearly all legal systems, will converge in

[25] Manson and O'Neill 2007: 50-67.
[26] Ibid.: 72.

prohibiting action such as injury, torture, poisoning or killing. Further, nearly all legal systems will prohibit the use of force, fraud, duress and coercion, deception and manipulation, and nearly all ethical outlooks will condemn such action as wrong."[27] In short, these (allegedly universal) prohibitions, or obligations to refrain from doing certain things to other people, are supposed to be valid across different jurisdictions and different cultures and moral systems: they are supposed to be "very widely accepted and endorsed by an overlapping consensus among [people] with an extremely wide range of ethical, social and religious outlooks."[28] These prohibitions are not simply widely accepted; they are also so important that to violate any of them is to "violate fundamental rights of the person, as well as to flout or neglect a range of legitimate expectations."[29] Surgery is the most obvious example. *Without consent*, surgical operation amounts to injury, or, in some cases, torture or killing if it fails. We could view these prohibitions and their correlative rights against potential violators of them as constituting certain very fundamental moral requirements. Thus construed, the informed consent procedure is to be viewed as operating or making sense only against such a background of fundamental moral requirements. More importantly, viewing the informed consent procedure in this way suggests that clinicians and researchers also work against this rich normative background and are constrained by the moral requirements safeguarded by it. This in turn suggests that in their professional practices clinicians or researchers should abide by these fundamental moral requirements so as to avoid doing grave wrongs to their patients or participants. In other words, these fundamental moral requirements are the *moral obligations* they owe, other things being equal, to their patients or participants in order to respect and protect the correlative rights of the latter.

[27] Ibid.: 74.
[28] Ibid.
[29] Ibid.: 76.

One might ask: granted that these moral requirements are so fundamental, how could one ever *waive*, through informed consent, the correlative moral rights that are, qua fundamental rights, "*generally* inviolable"?[30] Manson and O'Neill address this question by pointing out that "in specific circumstances refusal to waive an important ethical or legal requirement for a specific purpose may itself lead to pain, injury, damage, distress and even to death."[31] Thus, it seems, in order to determine whether it is morally justifiable or permissible for a patient or participant to waive a particular right or requirement for a specific medical purpose in a particular case, the patient or participant must weigh between (a) waiving the right or requirement and thereby allowing the specific medical purpose to be achieved on the one hand, and (b) refusing to waive it and thereby disallowing the purposed to be achieved on the other hand. Manson and O'Neill seem to think that (a) would be justifiable if (b) would "lead to pain, injury, damage, distress and even to death" while (a) would prevent any of these undesirable consequences from taking place (even though it would involve the waiving of a fundamental right or requirement). As the above surgery example shows, consent to surgery requires the patient to waive her right to bodily integrity, and such waiving is justifiable because otherwise one would continue suffering great pain and would probably or even surely die.

Three important observations must be made about the weighing described above. First, given that medical practices take place against the background of (the above-mentioned overlapping) ethical and legal norms and standards, the weighing is something that should be done if a proposed invasive intervention does violate a fundamental right or requirement, such as the right to bodily integrity, set up by the background norms and standards. Second, since it is a *fundamental* right or require-

[30] Ibid.
[31] Ibid.: 74.

ment that is threatened by the intervention proposed, it is reasonable to hold that there should be a presumption *against* the intervention, and that (a) must therefore carry *sufficiently greater* moral weight in order to override (b). As the surgery example shows, such a greater weight might come from the prospect of the patient's pain being relieved and avoidable death being prevented by means of the intervention proposed. However, there may not, unfortunately, be a precise, well-defined boundary between what is "sufficiently greater" and what is not; hence, whether or not the waiving of a fundamental right or requirement carries sufficiently greater moral weight must often be a matter of particular judgment. Finally, even if the weighing is to be done on a case-by-case basis, this does not mean that it must be arbitrary. After all, the need for such weighing arises from a background of ethical and legal norms and standards; the weighing must therefore also find its own grounds of justification within such a background. In the next chapter, we shall explore more about the basis of this background.

To sum up, in this chapter I have tried to show, first of all, that PRA, one of the fundamental principles in bioethics, is problematic. Furthermore, such a principle cannot provide the "primary justification" of informed consent practice as Beauchamp and Childress intend it to provide. We have also seen that, as the "agency model" proposed by Manson and O'Neill shows, the informed consent procedure is better conceived as presupposing and operating against a background of ethical and legal norms and standards. In the next chapter I will explore and elaborate on this background by giving it a Kantian interpretation, along the line which O'Neill pursues in some of her writings and which, as we shall see, even Beauchamp and Childress themselves would acknowledge to bring out "the substantive basis" of PRA.

Chapter Two

Search for Moral Foundation

2.1 The need for a moral foundation

According to Manson and O'Neill's model of informed consent as a "waiver," and a context-dependent "speech act," informed consent is required when and only when fundamental rights are to be temporarily waived for some specific medical purpose. In other words, the informed consent procedure must operate against a rich normative background of rights and their correlative obligations (namely, those which bearers of rights can raise against others for compliance). As to what these important rights and obligations may be, Manson and O'Neill offer a short list and simply assume it to be unproblematic that the rights and obligations cited as examples are what "nearly all ethical outlooks and legal systems will converge [on]."[32] Though their assumption may well be true, it does not enable us to see *why* those items on the list are to be regarded as rights and obligations, *why* they are fundamental or generally inviolable, and how, given their fundamental status as rights and obligations, they can be reasonably waived at all. If we get clearer about these questions, we may have a better and deeper grasp at Manson and O'Neill's model, and we may then be able to see how it can provide a more persuasive way to deal with emerging difficulties that make traditional informed consent requirements hard to satisfy in contemporary biomedical research. However, in order to address the above questions, we will have to touch on theoretical issues in moral philosophy; more specifically, we will have to find a moral foundation or grounding for those fundamental rights and obligations.

[32] Manson and O'Neill 2007: 74.

Since Manson and O'Neill believe that the rights and obligations they have in mind are what "nearly all ethical outlooks and legal systems will converge [on]," presumably there will be many candidates for such a moral foundation. One possible candidate comes from Immanuel Kant's ethical theory. In *Autonomy and Trust in Bioethics*, O'Neill suggests that because Kant's ethical theory gives due emphasis on obligations that are indispensably correlative to rights, it is a better candidate for explaining the moral bindingness of rights than other ethical theories which attempt to base moral rights on some conception of the good.[33] However, O'Neill only singles out the Formula of Autonomy, one of Kant's three chief formulations of the so-called "supreme principle of morality," and she portrays the kind of autonomy involved in it as "principled autonomy" which, unlike the kind of personal autonomy that has hitherto concerned bioethicists, is "expressed in action whose principle [or the reason for which it is undertaken] *could be adopted by all others*."[34] Beauchamp and Childress are not unaware of this sense of "autonomy" as Kant uses the term, for they have pointed out that although Kant would support their "principle for respect for autonomy," he is "largely concerned with morally correct autonomous choices."[35] This reading of Kant is in tune with the view generally shared by contemporary writers on autonomy that whereas Kantian autonomy is more appropriately called "moral autonomy," recent theories of autonomy focus on something different or broader in scope than moral autonomy, and should be given a different name, such as "personal autonomy" or "individual autonomy." Beauchamp and Childress are aware

[33] O'Neill persuasively argues that a right without its correlative obligations lacks its moral bindingness; see O'Neill 2002: 76-82.

[34] Ibid.: 85. Kant's Formula of Autonomy goes as follows: "Not to choose otherwise than so that the maxims of one's choice are at the same time comprehended with it in the same volition as universal law"; see Immanuel Kant, *Groundwork for the Metaphysics of Morals*, translated and edited by Allen Wood 2002: 58. I will add to all citations from Kant a page-reference to the relevant volume of the standard Prussian Academy edition of Kant's complete works. The reference for the passage quoted from the *Groundwork* is p. 440 of volume 4, abbreviated customarily as 4:440.

[35] Beauchamp and Childress 2009: 104.

of this distinction, and they prefer to understand "autonomy" in the contemporary rather than the Kantian sense. Thus, to avoid begging their question, perhaps we should not, at least not directly, appeal to Kant's Formula of Autonomy in our entire critique of their system of biomedical ethics.

Fortunately, Kant has offered two other formulations of one and the same "supreme principle of morality," and according to him the Formula of Autonomy actually follows from them.[36] These two other formulations are the Formula of Universal Law and the Formula of Humanity (as an End in Itself), and the latter has been considered by Allen Wood as "the most substantive value thesis on which Kantian ethics rests."[37] Moreover, Kant relies heavily on the Formula of Humanity rather than the Formula of Universal Law for his systematic derivation of ethical duties in the *Metaphysics of Morals*.[38] I will therefore appeal to the Formula of Humanity (hereafter abbreviated as "FH") in my search for a moral foundation of the fundamental rights and obligations that are supposed to lie in the background against which the informed consent procedure is to be understood according to Manson and O'Neill.

Most importantly, even Beauchamp and Childress, whose PRA (i.e., principle of respect for autonomy) may appear to have nothing to do with Kantian ethics, explicitly admit that not only does FH serve as the "substantive basis" of PRA but it also has great and legitimate influence on bioethics. As they put it, "Kant's second formulation of the categorical imperative—that persons must be treated as ends and not as means only—can be, and often has been, interpreted as the substantive basis of

[36] As Kant points out: "The ground of all practical legislation…lies *objectively in the rule* and the form of universality, which makes it capable of being a law (at least a law of nature) (in accordance with the first principle), but *subjectively* it lies in the *end*; but the subject of all ends is every rational being as end in itself (in accordance with the second principle): from this now follows the third practical principle of the will, as the supreme condition of its harmony with universal practical reason, the idea *of the will of every rational being as a will giving universal law*." See Wood 2002: 49, and Kant, 4:431.
[37] Wood 2002: 164.
[38] Wood 1999: 139.

what, in Chapter 4 and throughout this book, we refer to as the principle of respect for autonomy. Kant's second formulation has been enormously, and justifiably, influential on contemporary biomedical ethics."[39] Indeed, in spite of many obscurities in Kant's exposition of his philosophical doctrine, the second formulation FH has rightly provided one of the most memorable passages in his writings, namely: "So act that you use humanity, whether in your own person or that of another, always at the same time as an end, never merely as a means."[40] Given their recognition of the importance of FH in contemporary bioethics, I believe Beauchamp and Childress will not find my appeal to FH objectionable, even though I will be using it to ground a new model of informed consent that is intended to show inadequacies of their own favored model.

2.2 Kant's Formula of Humanity

It must be noted that "humanity" as Kant uses it is a technical term for him. Thus, in *Religion within the Boundaries of Mere Reason*, we find him distinguishing three "original predispositions" (*ursprüngliche Anlagen*) in human nature: a human being has the predisposition to animality as "a *living being*," the predisposition to humanity "as a living and at the same time *rational* being," and the predisposition to personality "as a rational and at the same time *responsible* being."[41]

The predisposition to animality represents our impulse toward self-preservation, propagation of the species, and being in community with others; it is a tendency belonging to "physical or merely *mechanical* self-love, i.e. a love for which reason is not required."[42] The predisposition to personality, on the other hand, is "the susceptibility to respect for the moral law *as of itself a sufficient incentive to the power of*

[39] Beauchamp and Childress 2009: 349.
[40] Wood 2002: 46-47; see Kant, 4:429.
[41] Kant, *Religion within the Boundaries of Mere Reason*, translated and edited by Allen Wood and George di Giovanni 1998: 50 (= Kant, 6:26).
[42] Ibid.: 51, (= Kant, 6:26).

choice."[43] Wood puts it as follows: "Personality is our rational capacity to legislate for ourselves the moral law and obey it."[44]

The predisposition to humanity is, in general, the capacity to set ends through reason, and such a capacity "has no specific reference to morality."[45] In *Anthropology from a Pragmatic Standpoint*, Kant subdivides the predisposition to humanity into "technical predisposition" and "pragmatic predisposition."[46] The former indicates elementary use of rational capacity, namely, to manipulate things in order to satisfy one's desires or needs.[47] We possess rational capacity to adopt effective means to achieve whatever ends we might have. Drinking water, for example, is an effective means to quenching my thirst. The pragmatic predisposition, on the other hand, refers to another, *more specific* aspect of rational capacity which enables us "to form a concept of ends, and from an aggregate of things purposively fashioned to construct by the aid of his reason a system of ends."[48] As Wood interprets it, humanity as a pragmatic predisposition "enables us not only to set ends but to compare the ends we set and organize them into a system…. Hence humanity also involves the capacity to form the idea of our happiness or well-being as a whole. The pragmatic aspect of humanity is the basis of what Kant calls 'prudence' (G 4:416) and is therefore the ground of the actual principles through which we seek happiness, which Kant calls 'counsels of prudence' (G 4:418)."[49]

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[43] Ibid.: 52; see Kant, 6:27.
[44] Wood 2008: 88.
[45] Wood 1999: 118.
[46] Kant, *Anthropology from a Pragmatic Standpoint*, selected in *Toward Perpetual Peace and Other Writings on Politics, Peace, and History*, edited by Pauline Kleingeld and translated by David L. Colclasure 2006: 165-167, (= Kant, 7:322-324).
[47] Kant describes this rational capacity to manipulate things as follows: "Nature has by this means designed [a human being] not for merely a single manner of manipulating objects, but rather generally for all forms of manipulation, and has thus designed him for the use of reason and thereby marked the technical predisposition of his species or the predisposition of his species for skill in manipulation as that of a *rational* animal"; in ibid.: 166 (= Kant, 7:323).
[48] Kant, *Critique of Judgment*, edited by Nicholas Walker and translated by James Creed Meredith 2007: 255 (= Kant, 5:426-427).
[49] Wood 1999: 119.

The exercise of the pragmatic predisposition to humanity, in particular, expresses uniqueness of human being *as rational being*. In order to compare the ends to be set or chosen and organize them into a system, I need to know what matters more and what matters less for *me*. That is, as suggested by Terence Irwin, I as a rational being have "relatively stable concerns," derived from my "rational agency," which sets an ultimate criterion by means of which I am to set or choose ends for myself: "Something appears valuable to me, as a particular agent with relatively stable concerns, in so far as I connect it with my rational aims and their objects, and hence with my rational agency."[50] I choose an end not because I find it appealing in its own right, but because it fits into my rational life-plan, made up of my long-term concerns and goals, which expresses my conception of myself; and insofar as I choose particular ends in this way, I value myself. According to Irwin's interpretation, if I am to value myself, I must also acknowledge the duty that Kant says everyone has to cultivate one's own talents: "If I value myself, I must also (Kant assumes) value my abilities, and hence seek to realize them. Hence the capacity to set ends for myself supports the demand for cultivation of one's talents."[51]

Besides telling me which particular ends deserve to be brought about if I am "prudent" in pursuit of my happiness, this rational capacity (the pragmatic predisposition to humanity) also requires for its exercise, as a necessary condition for my being able to pursue my happiness, that I be able to resist satisfying whatever desires or impulses I might happen to have which would distract me from pursuing those ends. That is, it requires me to perform self-constraint to a certain degree. As Wood points out, this explains Kant's conception of "negative freedom": "Humanity thus also presupposes a kind of freedom, namely the ability to resist the immediate coercion of

[50] Irwin 2009:111.
[51] Ibid.: 44.

desires and impulses. Kant calls this the 'negative' conception of freedom (G 4:446, KpV 5:47-48)."[52]

Most importantly, to exercise the above rational capacity, I must *value myself as an* "*end in itself*" which deserves *respect*. Since the reason for me both to choose, compare and organize ends and to exert self-constraint in pursuit of them is *myself as a rational agent*, this suggests, as Kant puts it, that I am an "end in itself," as a member of *rational beings* whose "nature already marks them out as ends in themselves, i.e., as something that may not be used merely as means, hence to that extent limits all arbitrary choice (and is an object of respect)."[53] Immediately Kant explains this notion of "end in itself" through another two conceptions "objective end" and "absolute worth": "These are not merely subjective ends whose existence as effect of our action has a worth *for us*; but rather *objective ends*, i.e., things whose existence in itself is an end, and specifically an end such that no other end can be set in place of it, to which it should do service *merely* as means, because without this nothing at all of *absolute worth* would be encountered anywhere; but if all worth were conditioned, hence contingent, then for reason no supreme practical principle could anywhere be encountered."[54] My status as an "end in itself" derives from rational nature or humanity in the pragmatic sense, and this status does not require me to perform any particular kinds of action in order to attain it; rather, it is already rooted in the predisposition to humanity in the pragmatic sense as part of human nature. Furthermore, as involving "objective end," the claim that "*rational nature exists as end in itself*" indicates that it is *no means to any other ends*; that is, rational nature already exists in us as a "self-sufficient end" (*selbständiger Zweck*), and by itself

[52] Wood 1999: 119.
[53] Wood 2002: 46; see Kant, 4:428.
[54] Ibid.

alone possesses "absolute value" which demands respect.[55] In other words, my rational nature confers upon me a moral status as an "end in itself" which possesses absolute worth, and thus demands me to *respect myself (as a rational being)*.

In a society with limited resources everyone pursues his or her own well-being. It is very likely that my pursuit of my well-being is interfered with or blocked by others in pursuit of their own. Hence, as Irwin points out, "my own impulses are not the only possible source of exploitation and subordination [of my pursuit of well-being]; threats of subordination may also come from other people's desires."[56] How can I persuade others not to subordinate my pursuit to that of theirs? The key lies in rational nature as an *end in itself* which is possessed by all rational beings and which requires *respect*. As mentioned above, when Kant explains the conception of end in itself, he does not distinguish "I" from "others" and demand how others should treat me as a particular person; on the contrary, he indicates how all rational beings *as such* should be treated. Simply qua rational beings, others and I are guaranteed the same moral status as "end in itself." Hence the moral demand to respect oneself is "objective": "But every other rational being also represents his existence in this way as consequent on the same rational ground as is valid for me; thus it is at the same time an *objective* principle, from which, as a supreme practical ground, all laws of the will must be able to be derived."[57] Since rational nature by itself demands respect for it, to say that rational nature demands me to respect myself implies that I ought to respect others as well, given that they also possess the same rational nature as I do. This is precisely what Kant intends FH to assert: "Now I say that the human being, and in general every rational being, *exists* as end in itself, *not merely as means* to the discretionary use of this or that will, but in all its actions, those directed toward itself as well as

[55] Ibid: 46, 55; see Kant, 4:429, 437.
[56] Irwin 2009: 111.
[57] Wood 2002: 46; see Kant, 4:429.

those directed toward other rational beings, it must always *at the same time* be considered as an *end*."[58] Simply qua rational being, I possess *moral status as an "end in itself"* which grants me *moral rights* to be treated in ways compatible with my status as an end in itself; correspondingly, others have moral obligations to treat me in these ways, or at least to refrain from treating me *merely* as a means. Given that others are also rational beings, I have the same moral obligations to them. As Irwin puts it, moral rights demand people not to treat others in morally impermissible ways: "If persons are treated as ends, some moral limits are imposed on the permissible treatment of them; it follows that they have moral rights to be treated one way rather than another."[59] This then explains Kant's proviso on what he called the "principle of freedom" of every member of society as a human being for the constitution of a commonwealth: "No one can force me to be happy in his way (according to how he conceives the welfare of other human beings), rather each may pursue happiness in the way that he sees fit, as long as he does not infringe on the freedom of others to pursue a similar end, which can coexist with the freedom of everyone in accordance with a possible general law (that is, with the same right of another)."[60] Here we can see clearly that FH has a social dimension. It is not simply about individual rights; rather, it is about how we as rational beings should treat one another in a community.

In short, Kant's FH offers a reason why we have moral rights but at the same time also bear or are constrained by correlative obligations to one another: given that rational nature itself demands that human beings ought to be treated in certain ways but not in others, it grants me *moral rights* while imposing correlative *obligations* upon others, but it also reminds me that I owe the same moral obligations to others

[58] Ibid.: 45; see Kant, 4:428.
[59] Irwin 2009: 48.
[60] Kant, "On the Common Saying: This May Be True in Theory, but It does not Hold in Practice," selected in *Toward Perpetual Peace and Other Writings on Politics, Peace, and History*, edited by Pauline Kleingeld and translated by David L. Colclasure 2006: 45 (= Kant, 8:290).

since they also possess the same moral rights that I possess. This expresses the social dimension of FH: we should treat one another equally and fairly in a community of ends in themselves.

2.3 The ultimate value lies in humanity instead of personality

FH explicitly asserts that it is humanity (in the pragmatic sense) as "self-sufficient end" that demands respect. Kant further takes humanity to be the ground of moral law: "But suppose there were something *whose existence in itself* had an absolute worth, something that, as *end in itself*, could be a ground of determinate laws; then in it and only in it alone would lie the ground of a possible categorical imperative, i.e., of a practical law."[61] However, it might seem striking that the ultimate moral value as end in itself lies in humanity instead of personality. If, as indicated in the last section, (the predisposition to) personality is a capacity directly linked to morality, or more precisely, a rational capacity for legislating the moral law and then obeying it, then it seems that the source of ultimate moral value should lie in personality. Is there any good reason to support Kant's claim that the absolute worth indeed lies in humanity? Irwin and Wood offer similar reasons on behalf of Kant: If I am to value my rational nature, I should value it in all its functions and not merely in its moral function.[62] If personality alone, and not humanity, was to count as an end in itself, then it would have to be *only in virtue of* having the predisposition to personality that we count as ends in themselves. What deserves respect would then have to be people *qua* having the predisposition to personality, and what deserves protection and promotion would have to be the *moral* ends (or *morally obligatory* ends) that people pursue *qua* having the predisposition to personality. This seems to contradict Kant's idea that what

[61] Wood 2002: 45; see Kant, 4:428.
[62] See Wood 1999: 120, and Irwin 2009: 48. This interpretation can still be challenged, however, since Kant's writing on this issue is not crystal-clear. Though it is a very interesting issue in Kant study, it lies outside of the scope of my thesis.

deserves protection and promotion is not only moral ends, but also whatever morally *permissible* ends people pursue qua having the predisposition to humanity (or rational nature).[63] For one thing, Kant explicitly indicates that what our duty of beneficence toward others obligates us to bring about is *not* exclusively their morally obligatory ends but their *morally permissible ends* as "the natural end that all human beings have," namely, "their own happiness."[64]

2.4 Formula of Humanity and its immediate implications

Our moral status as "end in itself" demands not only, negatively speaking, that people should avoid infringing upon others' moral rights based on rational agency, but also, positively speaking, that they should at least sometimes help each other with their pursuit of morally permissible ends. *From the negative side*, an immediate implication is that everyone has moral rights to survival and bodily integrity. Thus, people should avoid injuring, poisoning and killing others. Moreover, given that it is rational nature that possesses "absolute worth," respect for it demands that people ought to refrain from subjecting others to coercion, deception, manipulation, and so on, which infringe on their exercise of rational agency. On the other hand, given the fact that no one is self-sufficient in achieving all rational ends one sets for oneself, an immediate implication *from the positive side* of our moral status as "end in itself" is that we have a duty to assist others in their pursuit of morally permissible ends. Wood puts this point clearly: "The reason it would be impossible to will that others not help me is that their refusal would show contempt for my humanity, which I must regard as an end in itself. Insofar as their existence contains the same rational ground for respect, it

[63] Simply put, what does not violate moral duty is morally permissible, whereas the morally obligatory refers to what is required or demanded by moral duty.
[64] Wood 2002: 48; see Kant, 4:430.

is equally impossible for me rationally to will that I should not extend the same help to them."[65]

As suggested in 2.2, FH has a social dimension: it is not only about my moral rights and how others ought to treat me; it is at the same time about my obligations to others, who possess the same moral rights as I do because, as rational beings, we all possess rational nature. As Irwin indicates, this in turn suggests that we, in virtue of our common rational nature, constitute "a kingdom [or realm] of ends": "since the [moral] principles that everyone has reason to accept treat everyone as an end [in itself], the rational agents who accept these principles constitute a kingdom of ends."[66] Kant himself indicates this line of thought when he says: "For rational beings all stand under the *law* that every one of them ought to treat itself and all others *never merely as means*, but always *at the same time as end in itself*. From this, however, arises a systematic combination of rational beings through communal objective laws, i.e., a realm that, because these laws have as their aim the reference of these beings to one another as ends and means, can be called a 'realm of ends' (obviously only an ideal)."[67] According to Kant, such an ideal when combined with the Formula of Autonomy leads to the Formula of the Realm of Ends: "Act in accordance with maxims of a universally legislative member for a merely possible realm of ends."[68]

Now one might question whether the moral status granted by one's rational nature as end in itself applies *exclusively* to mature and competent adults, for it appears that only *they* have the chance to better exercise the rational capacity indicated in the pragmatic sense. If this is the case, as many have taken it to be, then it seems to suggest that children and those non-competent people who temporarily or

[65] Wood 1999: 150.
[66] Ibid.: 112.
[67] Wood 2002: 51; see Kant, 4:433.
[68] Ibid.: 56; see Kant, 4:439.

permanently lose competence due to injury or illness would not possess the moral status indicated above and thereby would be excluded from "the realm of ends." Arguably, as Wood tries to show, FH applies not only to "persons *in the strict sense*," namely, "rational beings who are capable of instrumental, of prudential, and above all of moral reason, and who are morally responsible for what they do."[69] Given that the absolute worth of end in itself finds its grounds in humanity as a *predisposition* to use rational capacities in the way explained earlier in 2.2 and 2.3, it seems reasonable to claim that children and people who once possessed rational capacities but now temporarily or permanently lose it due to injury or illness—Wood calls children and these unfortunate people "*persons in the extended sense*"—are also protected by FH.[70] Although, given their not-yet-mature or impaired rational capacities, persons in the extended sense lack the full-fledged rational capacities to guide their lives for themselves and thus "cannot have the same right to direct their lives that persons in the strict sense have," they are still protected by FH. That is, they "have just the same right not to be killed as persons in the strict sense, and we have the same obligations to consider their interests and treat them as ends in themselves that we have toward persons in the strict sense."[71] If this interpretation is acceptable, FH offers a moral reason in support of Manson and O'Neill's argument for (what they call) "parallel considerations" for non-competent people in cases of surrogate decision-making. When a patient is not competent to choose or refuse treatment, others such as family members or physicians would need to make decisions for his or her sake. But according to what criteria can one make such surrogate decision? Manson and O'Neill

[69] Wood 2008: 95.
[70] Wood did not actually mention those who permanently lose their rational capacities, however. But given that they, like those who temporarily lose their rational capacities, were once possessed of rational capacities, I think it is reasonable to include them in "persons in the extended sense." But how far would this category of "persons in the extended sense" go? Although it is an important and intriguing issue, I must leave it aside here.
[71] Wood 2008: 97.

suggest that one can make surrogate decisions by making sure that "underlying obligations to those with cognitive or other impairments are not waived, unless for reasons that would also be adequate in the case of the fully competent."[72] In other words, surrogate decision-making is to proceed by relying on considerations "parallel" to the ones that competent people are to rely on in making their own medical decisions; hence, the term "parallel considerations."

Given that we all have a duty of beneficence, a duty derivable form FH as has been explained at the outset of this section,[73] the Formula of the Realm of Ends further suggests that, provided that there is proper protection of the moral rights we have qua ends in themselves, to participate in medical research aiming at common good is one of many possible ways for us to fulfill our (imperfect) duty of beneficence. Nevertheless, it may be noted that, as far as medical research conducted by a profit-seeking pharmaceutical company is concerned, participation in such research may have its moral binding force greatly reduced, sometimes even to a vanishing point. This is because, as long as profit-seeking is a pharmaceutical company's goal (or at least one of its goals), medical research conducted by it may or may not coincide with common good. To give an extreme example, vital drugs developed by the company might be sold at unreasonably high prices unaffordable by the poor, so as to exacerbate social inequality contrary to Kant's claim about the realm of ends in themselves. In such a case, we have no obligation at all to participate in the company's medical research on those drugs.

Given the above analysis of FH and how certain humanity-based, fundamental moral rights and obligations can be derived from it, FH can, hopefully, provide

[72] Manson and O'Neill 2007: 193.

[73] For Kant, the duty of beneficence is what he calls an "imperfect" as opposed to "perfect" (or "wide" as opposed to "narrow") duty, a kind of duty which leaves "free room" for us to decide when, to whom, and to what extent to fulfill it, even though we still in any case have a duty to develop the virtue or character-trait of beneficence in us; see Kant, 4:421, 424.

persuasive moral reasons for us to accept, thereby grasping the rationale behind, the fundamental rights and obligations appealed to by Manson and O'Neill's model. If this is so, FH can be seen as providing a possible moral basis that underpins those fundamental rights and obligations against the background of which informed consent procedure makes sense according to their model. Not surprisingly, the fundamental rights cited in their illustration of the model, such as rights against injury, poisoning, killing, coercion, deception, manipulation, and so on are, as indicated above, what we can immediately derive from FH. Nevertheless, FH gives rise to more than such negative rights/obligations. As indicated at the outset of this section, it also gives rise to the positive duty of beneficence (or mutual aid). Given that FH also has a social dimension, namely, that we qua beings with rational nature constitute "a realm of ends [in themselves]," this suggests that, assuming there to be proper protection of the rights that we have qua ends in themselves, participation in medical research aiming at common good is a possible way to fulfill our (imperfect) duty of beneficence. Last but not least, if the above interpretation sounds acceptable, FH also gives a moral ground for Manson and O'Neill's "parallel considerations" in the case of non-competent people, as we have seen earlier in this section. In the next chapter, I will elaborate more on this new way of looking at Manson and O'Neill's model so as to show how such a model may help us to resolve some difficult issues in biomedical research in ways more satisfactory, I believe, than those suggested by the hitherto commonly received model of the informed consent procedure.

Chapter Three

Some Practical Implications

3.1 Unsolved challenges

In both clinical and research settings, informed consent has long been regarded as both necessary and sufficient for protecting the personal autonomy of patients and research participants. Since the promulgation of Nuremburg Code of 1947, generally regarded as putting forward the first authoritative requirements of participants' consent to experiments, its emphasis on "the voluntary consent of the human subject" has become a paramount concern in biomedical ethics.[74] The latest version of the Declaration of Helsinki, a very important international regulation on medical research involving human subjects, expresses this concern in a more *specific* way:[75]

> 24. In medical research involving competent human subjects, 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, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the special information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.[76]

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[74] See http://ohsr.od.nih.gov/guidelines/nuremberg.html for the Nuremburg Code.

[75] The Code only requires that participants need to comprehend "the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." By contrast, the latest, 2008 Helsinki Declaration requires more specifically that "sources of funding, any possible conflicts of interest, institutional affiliations of the researcher" be also included in the informed consent form.

[76] See http://www.wma.net/en/30publications/10policies/b3/index.html for the 2008 revision of the *World Medical Association Declaration of Helsinki—Ethical Principles for Medical Research*

Manson and O'Neill question whether such regulation can effectively protect participants' "right to self-determination."[77] For it seems to be an unreasonable burden on them to grasp all the complex scientific and institutional information offered in the informed consent form. As I have indicated in 1.1, conditions of illness may cause one to feel over-worried, fearful and depressed and may therefore hinder one's proper understanding of the information provided. Without proper understanding, one's "informed consent" will not meet the Helsinki standards. Nevertheless, this problem may well be avoided in the case of the establishment of a human genetic biobank for prospective epidemiological studies, insofar as such a project seeks only to recruit healthy people who do not suffer physically or emotionally from illness.

Unfortunately, the establishment of such biobanks also raises challenges to the Helsinki Declaration. At first sight, informed consent seems to be definitely required if we are to protect the personal autonomy of participants. But this consideration overlooks an important characteristic of biobanking projects, namely, the infeasibility of (specific) informed consent when it comes to recruiting participants. As the Helsinki Declaration understands it, informed consent is *specific* to a given research project with a specific purpose and procedure, and with specific potential risks and benefits that go with the project. But in the case of a human genetic biobank that is to serve *prospective* studies, the matter is totally different: when collecting samples for such a database, it is as yet unknown for what research projects these samples will be used in the future. Therefore, people deliberating on whether or not to participate in a biobank of this kind cannot be provided with adequate and specific information about

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Involving Human Subjects.

[77] In Article 11, the Declaration explicitly points out that, in addition to other duties, it is physicians' duty to protect potential subjects' right to self-determination. See Manson and O'Neill 2007: 8-9, for their criticism.

exactly how their samples will be used in the future, nor for this reason can they give (specific) informed consent.

A different issue confronts secondary research uses of biological samples and information originally obtained and stored through proper informed consent procedure. Epidemiological investigations and population studies, for example, usually rely on further analysis of these samples and data. If, according to the above-cited Article 24 of the 2008 Helsinki Declaration, every medical research involving human subjects must obtain informed consent from participants, this entails that every secondary research use of data must also obtain further informed consent (or re-consent, in short) to it from the original donors so long as it has not been specified in the initial informed consent form. As a matter of fact, this requirement of re-consent is adopted in many countries. In the UK and Taiwan, for example, the current regulations of secondary research uses of left-over biological samples are basically the same: re-consent is required if the samples are not "delinked," that is to say, if donors of the samples are still identifiable.[78] Although this requirement of re-consent accords with the spirit of respect for participants' personal autonomy, it creates tremendous practical difficulties. First, the requirement imposes significant financial and administrative burdens on researchers. When the research is largely dependent on government funding, this creates problems such as unfair allocation of government budget, which otherwise could be used in a fairer and more effective way. Second, research seeking to find a cure for current epidemic diseases, such as SARS

[78] For relevant regulations, see UK *Data Protection Act* 1998, http://www.opsi.gov.uk/acts/acts1998/ukpga_19980029_en_1; UK *Human Tissues Act* 2004, http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1; and *Regulations on Human subject Experiments*, the Department of Health, Taiwan, http://dohlaw.doh.gov.tw/Chi/FLAW/FLAWDAT0202.asp. European Union seems to have similar regulation; e.g., *Convention on Human Rights and Biomedicine*, http://conventions.coe.int/treaty/en/Reports/Html/164.htm.

or H1N1, need to accomplish the task in a relatively short time, and it would be impracticable to obtain re-consent as this would be time-consuming.

One might argue that the above worries are over-stated. For, in Article 25 of the 2008 Helsinki Declaration, it is clearly indicated that exceptions to the requirement of re-consent are allowed:

> 25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

Although informed consent is "normally" required, exceptions are permissible under conditions "where consent would be impossible or impractical." But a question immediately arises: What are the conditions "where consent would be impossible or impractical"? Under a more sympathetic reading, the 2008 Helsinki Declaration may be taken to suggest that the establishment of human genetic biobanks on the one hand and secondary research uses of biological samples (originally obtained through proper informed consent procedure) on the other are precisely occasions for exception from the requirement of re-consent. But the Declaration's statement that "physicians must normally seek consent for the collection, analysis, storage and/or reuse" seems to require that whenever physicians or researchers propose to collect, analyze, *store*, and *reuse* data, they should still obtain (further) informed consent unless it is "impossible or impractical." This makes it sound as if physicians and researchers (or, rather, members of a research ethics committee who are responsible for approving or disapproving an exception) are falling back on a "second-best" option, something less than a (specific and explicit) re-consent, when it comes to using the data stored in a biobank or to secondary research uses of left-over samples. The point I am trying to make here is that given that the *default* requirement is specific and explicit informed

consent in the case of any medical research using human biological samples and the information derived from them, any exception to the requirement must have moral grounds that carry sufficient justifying weight. Unfortunately, the 2008 Helsinki Declaration provides no clue as to what such grounds might be, let alone precisely what conditions there might be "where consent would be impossible or impractical." Thus it seems that unless such grounds are specified, the Declaration might risk allowing exceptions to the requirement of re-consent in arbitrary ways.

Suppose that, after the review by a research ethics committee, re-consent is still required in good faith for the protection of participants' personal autonomy although it is reasonable to assume that the research utilizing data stored in a biobank or the secondary uses of left-over samples will not violate their rights. In this case, even though the participants are approached again for the sake of protecting their personal autonomy, they might regard the procedure for re-consent as tedious, unnecessary or even obtrusive. Moreover, this procedure might even lead them to feel suspicious of the trustworthiness of both the research ethics committee and researchers. They might wonder: "If the proposed research would not violate my rights, then why would they ask for re-consent? Doesn't the act of 'consent' itself imply that I have to bear any possible undesirable consequences for me? Can I really trust them when they assure me that there will be no violation of my rights?" Worse still, such (unnecessary) suspicion, as well as the inconveniences that the re-consent procedure will cause to the participants, might in the long run encourage a free-rider attitude: knowing that I as a member of society would benefit from medical progress which usually depends on research involving human subjects, I might decide not to participate myself: why not let those who are more altruistic participate? If everyone adopts this free-rider attitude, medical progress would be severely limited, if not impossible.

The foregoing considerations may serve to show limitations or inadequacies inherent in the hitherto standard model of informed consent which places much emphasis on personal autonomy. Not only will such a model regard exceptions to the informed consent requirement in the case of future usage of samples as a second-best option or even a necessary compromise, but it might also lead to the free-rider problem if re-consent is nevertheless required in some cases. In particular, since the model places much emphasis on personal autonomy (which, as we have seen, Beauchamp and Childress hold to provide the "primary justification" of informed consent practice), it must leave it entirely to people's own decision as to whether or not to participate in research projects which do not exclude the possibility of approaching them for re-consent in the future. Thus, the model lacks any resources *within itself* to address the free-rider problem.

By contrast, the new model advocated by Mansion and O'Neill may have such internal resources available to it: free-rider attitude toward participation in medical research contradicts our (imperfect) duty of beneficence, which, as we have seen in Chapter 2, can be derived from Kant's Formula of Humanity. Even if participation in medical research is only one of the possible ways in which people may fulfill the duty of beneficence, the free-rider attitude may indicate morally reproachable indifference toward others' well-being, and worse still, it may also indicate a morally reproachable tendency to take unfair, exploitative advantage of others, a tendency which directly contradicts the moral requirement imposed by the Formula of Humanity that we should respect others as ends in themselves and never merely as means to our own advantage.

To sum up, as may be seen from the 2008 Helsinki Declaration and many other current regulations, informed consent is by now still generally regarded as both necessary and sufficient for protecting the personal autonomy of patients and research

participants. Nevertheless, as I have argued in this section, the result of over-emphasis on *specific* informed consent cannot satisfactorily address challenges raised by the establishment of human genetic biobanks and by secondary research uses of biological samples. Is there any way to address these challenges more satisfactorily?

3.2 A new prospect

As we have seen in 1.3, Manson and O'Neill propose a new way to conceive informed consent as a waiver and a *context-dependent* speech act. They stress that the informed consent procedure is to take place and make sense against a *background* of rights and obligations: "Informed consent has a role *only* where activity is already subject to ethical, legal or other requirements."[79] To view informed consent as a waiver means that it is required *when and only when* there are fundamental rights to be temporarily waived for specific medical purposes. Where there are no fundamental rights to be waived in order for a medical treatment or research to proceed, there is no need for informed consent. Furthermore, as suggested in Chapter 2, their model could be interpreted as embedded in Kant's Formula of Humanity, which further enriches their model. With its social dimension, the Formula of Humanity implies, first and foremost, that everyone ought to be treated fairly and equally as an "end in itself" (given that everyone possesses humanity as a predisposition in human nature and is therefore to be endowed with the same moral status). Furthermore, given that we as ends in themselves constitute a "realm of ends," we ought also to (actively) promote common good, which as such is conducive to everyone's well-being, and this in turn suggests that participation in medical research is at least one of the many possible ways for us to fulfill the duty of beneficence.

[79] Manson and O'Neill 2007: 72.

Even if it is one possible way to fulfill the duty of beneficence, participation in medical research might have its (already not so stringent) moral binding force reduced if there was no proper and trustworthy measure for ensuring that medical research conduct will not violate the fundamental rights that participants have in virtue of being ends in themselves. Given that it is practically impossible for citizens to monitor research conduct themselves, the key lies, as it is usually thought to lie, in the existence of a trustworthy regulatory body in charge of ensuring the accountability of researchers and physicians. An example of such a regulatory body is the "research ethics committee" that the 2008 Helsinki Declaration refers to: the mission of such a committee is to decide whether the design and procedure of a medical research is morally permissible, to "monitor ongoing studies," and to decide whether exception to informed consent requirements can be allowed, especially when recruitment for participants in a biobank at its initial stage, or secondary research uses of left-over samples are in question.[80] Granted that a research ethics committee is such an important regulatory body, who should partake in it? Although there is no stipulation on its exact composition, the 2008 Helsinki Declaration demands its impartiality: "This committee must be independent of the researcher, the sponsor and any other undue influence."[81] Of course impartiality is of vital importance, but it is not enough. What if only medical, legal, and ethical experts partake in the committee? Shouldn't it also include "lay people" whom we can reasonably expect to speak for the interests of participants during the deliberation of the committee?[82]

[80] Helsinki Declaration 2008, Articles 15 and 25.
[81] Ibid.: Article 15.
[82] Although Manson and O'Neill discuss some possible problems concerning representativeness, they nevertheless do not put much emphasis on participation of ordinary citizens. I want to highlight participation of ordinary citizens and suggest that deliberative democracy could play an important role here. But I leave it open as to how to incorporate such an ideal into bioethics in the most promising way(s). See also Manson and O'Neill 2007: 169-177.

Admittedly, research ethics committees typically involve lay people as members, but here I want to stress that when they review projects for the establishment of a biobank, or for the secondary uses of left-over samples, they should involve, more specifically, those lay people *who can represent the participants whose interests may be at stake*. In such cases, representativeness of a research ethics committee is as important as its impartiality. This is because, as implied by Kant's Formula of Humanity, the basic interests of everyone qua end in itself ought to be accorded equal respect. Given that the informed consent procedure is intended to safeguard the basic rights and interests of participants, a research ethics committee should find trustworthy ways to ensure that informed consent does achieve this aim. In whatever ways this is done, it seems to me indispensable that, in cases of biobanking and secondary usage, participants as a group should get representation in the deliberation of a research ethics committee. I would suggest that such representation may vary with different kinds of medical research, which may have different stakeholders. For example, representation for a large or even national biobank may be different from representation for secondary research uses of biological samples. In my view, a research ethics committee's deliberation for the former should include lay representatives selected from the general public, since such a grand project deeply affects the whole society and is in need of public trust and support. On the other hand, deliberation for projects of the latter kind should include lay representatives selected from those among the original donors who are willing to partake in the deliberation and speak for the original donors as a group of stakeholders.

Moreover, in order to ensure that the function of a research ethics committee will not be compromised by power struggles and to ensure that it does pay due respect to all stakeholders as "ends in themselves," as required by Kant's Formula of Humanity, it is very important that the deliberative outcome of review by a research ethics

committee concerning the kinds of cases in question should be based on reasons that are, to put it in a Kantian way, "universally endorsable." In other words, the research ethics committee should have a fair deliberative procedure for ensuring as much as possible that its outcome would be *reasonably* acceptable by all members of the society. This ideal of universal endorsability excludes at least one morally problematic outcome, namely, that members of a research ethics committee base their decision on the ground that it is to the benefit of a particular group, or conducive to general welfare, *but* at the cost of the fundamental rights of participants. This is an outcome that runs counter to moral requirements derived from Kant's Formula of Humanity, and whose exclusion can only be ensured by a procedure that incorporates something like universal endorsability into it.

Finally, if a research ethics committee is to prove itself to be trustworthy, transparency is also important. Without good communication with research participants in particular, or with the public in general, such a committee cannot gain people's trust even if it fairly represents everyone's interests and deliberates in universally endorsable ways. Transparency is usually seen as essential for good communication. But, as Manson and O'Neill point out, transparency is not achieved by simply disseminating information on the internet or making it public in other ways.[83] What matters is *the act of communication*, and in order for such an act to be successfully performed, what is to be communicated should be comprehensible by the intended audience and relevant to them, and opportunities should be provided for anyone who is interested to raise questions and get response from the committee. Since transparency and good communication are necessary for public trust, and public trust is in turn necessary if a regulatory body like the research ethics committee is to attain recognition of its moral legitimacy from members of society as free and equal

[83] Manson and O'Neill 2007: 178-179.

citizens, the requirement of transparency and good communication may also be thought to be grounded in Kant's Formula of Humanity.

Manson and O'Neill's model highlights the background of fundamental rights and obligations against which the informed consent procedure operates and makes sense. By grounding their model in Kant's Formula of Humanity, we may be able to uncover convincing rationale in support of some familiar institutional designs for regulating the informed consent procedure. The most prominent of such designs is the so-called "research ethics committee," which, for reasons I have tried to bring out in this section, ought to represent the basic interests and rights of research participants adequately and fairly, to base its decisions on universally endorsable reasons, or reasons that would be reasonably acceptable to all members of the society, and finally to be transparent in the sense that the committee maintains good communication with research participants in particular and with the public in general. Now, in what follows I will use this new prospect to suggest some ways to meet the challenges raised by secondary research uses of biological samples (originally obtained and stored through proper informed consent procedure), and by biobanking projects, especially those conducted for the purpose of prospective epidemiological studies in the future.

3.3 The case of secondary research uses

One might think, as Manson and O'Neill do, that there is no need of re-consent in the case of secondary research uses of left-over biological samples provided that these were already legitimately obtained and stored in the past. In their view, if there would be no further "invasive" actions conducted by researchers on participants, such as blood taking or saliva collecting, then further uses of left-over samples do not violate

participants' right to bodily integrity, a right which the participants have, therefore, no need at all to waive for further research on their samples.[84]

However, it has long been acknowledged that, even if no invasive action will take place, secondary research *might* turn out to be "*intrusive*" and thereby violate one's right to so-called "informational privacy." Such a worry can be, as Manson and O'Neill argue, well addressed by ensuring that the samples and information in question have been "adequately secured by reversible anonymisation."[85] Proper regulation of this reversible anonymisation can be put in place through the supervision of a research ethics committee. Hence, if accountable and trustworthy mechanisms for regulation have been established so that there would be little risk of fundamental rights being violated as a result of secondary research, then, according to Manson and O'Neill, it is reasonable to think, within their model of informed consent, that there is no need at all to acquire re-consent from the original donors.

Here we can see that the new model advocated by Manson and O'Neill provides a better solution to the challenges raised by secondary uses of samples than does the dominant model, according to which informed consent requirements stand *as the rule*, and it is only under exceptional conditions "where consent would be impossible or impractical" that we are allowed to fall back on the second-best option, as suggested by the 2008 Helsinki Declaration, of letting the research ethics committee have a final say on the permissibility of the secondary uses of left-over samples. Furthermore, where participants' rights are already properly protected by an accountable regulatory framework subject to the continuing supervision of a trustworthy research ethics committee, dispensing with further and (according to the new model) redundant informed consent would avoid giving rise to the kind of suspicion and free-rider

[84] Manson and O'Neill distinguish "invasive" actions from "intrusive" ones; see ibid.: 22.
[85] Ibid.: 157.

attitude that I mentioned in 3.1. In short, if we take the new model of informed consent seriously and recognize the importance of instituting accountable regulatory mechanisms in the background, then what is regarded by the 2008 Helsinki Declaration as a second-best option will actually turn out to be the most reasonable option we can think of.

3.4 The case of human genetic biobanks

The kind of human genetic biobanks I have in mind here includes UK Biobank and Taiwan Biobank, although the latter is still in the "pilot project" stage.[86] The most significant character of such biobanks is that it aims at recruiting a very large number of voluntary healthy people whose biological samples, life-style information, (continuing) medical records, and genealogical data will be collected and stored for prospective epidemiological studies in the future. UK Biobank, for example, intends to recruit 500,000 people aged from 40 to 69.[87] Many believe that such large-scale collection and storage of biological samples and information can facilitate understanding of complex interplay between genetic predisposition and environmental exposure in the etiology of chronic and often life-threatening diseases such as diabetes and cancers. Research on such diseases is highly valued in the area of epidemiology, pharmacogenomics and population genetics. It is believed that, with better understanding of such diseases, we can find more effective cure and/or treatment, thereby making people healthier and live longer. Thus, biobanks of this kind and magnitude can be considered an important means to significant improvement of health care and to the promotion of common good. But given that it is a large-scaled project and involves utilization of legally protected personal data, its operation must

[86] See Tai and Chiou 2008: 105-109, for the design and current status of the Taiwan Biobank.
[87] According to its official webside (http://www.ukbiobank.ac.uk/), the UK Biobank managed to recruit 488,754 people until June 15, 2010.

rely heavily on government support and funding, and public trust. Furthermore, unlike other medical research which usually recruits patients whose motivation for participation might be a hope for cure, recruitment for a biobank appeals more to people's good will and altruistic motivation, since it is healthy people that are targeted. Thus a biobank of this kind can be viewed as a joint endeavor of the entire society, and it requires long-term support of the general public as well as participants in it.

As mentioned in 3.1, given that there is no way to know in advance what specific research projects will apply for usage of samples and information stored in a biobank, it is impossible at the time of recruitment to go through the standard procedure for (specific) informed consent. What can be acquired at this initial stage is at most the so-called "general" or "broad" consent. If we think of informed consent, as Beauchamp and Childress do, as both necessary and sufficient for protecting the personal autonomy of research participants in medical research, then either the establishment of a biobank will have to be regarded as morally unjustified, or it will have to resort to the second-best option, allowed by the 2008 Helsinki Declaration, of taking an exception to the rule when re-consent is impossible or impractical, and then letting a research ethics committee have a final say on the permissibility of research projects that intend to utilize samples and information stored in the biobank.

Now, according to Manson and O'Neill's model, informed consent is required *when and only when* there are fundamental rights that need to be temporarily waived by their holders for specific medical purposes. As suggested in the case of secondary uses of biological samples, if there is a trustworthy research ethics committee to ensure that there will be little risk of participants' rights being violated, there is no need to acquire re-consent. Can we employ similar reasoning in case of the establishment of a biobank? Would *general* consent be morally justified if conditions similar to those in the case of secondary uses of biological samples obtain? Would

general consent be already enough, once and for all? Or is further informed consent to specific, individual research projects still needed when it comes to making samples and information stored in the biobank available for research use?

Regarding the last question, I would suggest that, after the general consent acquired at the initial stage, further informed consent may or may not be necessary in the future when it comes to making the stored samples and information available for research use, depending on whether or not, in spite of appropriate regulatory mechanisms being already instituted, there may still be high risk of violation of some basic interests or rights, especially those of the participants who belong to vulnerable social groups. For example, not only must the privacy right of individual participants be protected in the case of a biobank, but stigmatization of vulnerable social groups (to which some of the participants belong) by results of research utilizing the biobank must also be especially guarded against.[88] Although personal identifiers will be removed from data stored in a biobank, subsequent research using the data often needs group identifiers such as race, gender, occupation, and so on. By itself, the use of these group identifiers is not morally wrong, but what we should be especially cautious about is whether research results are presented in a way that leads (unintentionally) to stigmatization of already vulnerable groups about their overall dispositions to particular diseases. Stigmatization will very likely lead to unfair discrimination against individual members of the group stigmatized. So, in order to guard against stigmatization of vulnerable groups, there should be proper review of

[88] See Liu and Tai 2009: 35. In the context of Taiwan Biobank, worries about stigmatization of aboriginal groups are of particular importance, since they have long suffered from distributive injustice and unfair discrimination. Given this already unfriendly atmosphere for aboriginal groups, it is crucial that we should avoid deepening injustice. Tai and Chiou thus argue for "community consent" by aboriginal population in Taiwan as to whether or not they would, as a group, allow their individual members to choose to participate in Taiwan Biobank; see Tai and Chiou 2008. Although this idea of "community consent" involves intriguing issues over group rights and their relation to individual rights, and over deliberative democracy and its practical designs, I must leave these issues for another occasion.

research projects intending to make use of the biobank, and when the risk of it is foreseeably high, it may be necessary to return to participants belonging to the group at risk, and to seek their informed consent to the specific research project that exposes their group to such risk.

Although protection of the fundamental rights of participants, and avoidance of stigmatization are necessary in the case of biobanks of the kind that concerns us here, they are not sufficient for a *complete* moral justification of general consent. As Williams and Schroeder point out, even if a research ethics committee aims to protect participants' rights and guard against stigmatization of vulnerable groups, its task is nevertheless "essentially *negative*: it can only stop unethical or unwanted research from being undertaken, but cannot pro-actively steer the usage of a DNA bank."[89] A positive and all-important reason for the establishment of a biobank is, as mentioned above, to improve health care as an essential common good. Since the ideal is to promote common good, and since this is also used as an appeal to potential participants at the time of recruitment, the ideal cannot remain an empty slogan: an equitable distribution of benefits generated in the future from research utilizing the biobank is morally required. Therefore, a mechanism to ensure equitable distribution of benefits generated is another necessary condition for the moral justification of general consent. In fact, the "International Declaration on Human Genetic Data" promulgated in 2003 by the United Nations Educational, Scientific and Cultural Organization (UNESCO) has explicitly stressed that "benefits *resulting from* the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be *shared* with the society as a whole and the international community."[90] Benefit sharing, however, needs not be monetary. It can take many

[89] Williams and Schroeder 2004: 98

[90] See http://portal.unesco.org/en/ev.php-URL_ID=17720&URL_DO=DO_TOPIC&URL_SECTION=

other forms such as "the provision of new diagnostics, facilities for new treatments or drugs stemming from the research; support for health services; and capacity-building facilities for research purposes."[91] Moreover, as suggested by Liu and Tai, what counts as benefit sharing or "what constitutes 'benefit' and 'sharing' would depend on the needs, values, priorities, and cultural expectations [of a given society]"; hence, in what ways benefits in health care are to be fairly distributed as common good is, in a democratic society, an issue to be settled through "properly designed democratic procedures of public deliberation."[92]

In short, even though in the case of a biobank of the kind that concerns us, general consent by individual participants is unavoidable at the stage of recruitment, whether or not the use of general consent is morally justified may have to depend on whether or not effective measures are taken to ensure protection of participants' rights, avoidance of stigmatization of vulnerable social groups, and equitable distribution of benefits generated by research utilizing the biobank in the future. It is primarily the responsibility of a research ethics committee to see to it that these conditions are indeed satisfied, but the committee must also rely on the informed consent procedure and some procedure of public deliberation (or consultation) to determine, respectively, whether (and in what way) participants belonging to a vulnerable group are willing to bear the risk of stigmatization in connection with a particular research that proposes to use their samples for epidemiological purposes, and how benefits generated through the use of the biobank will be equitably shared by all members of the society. I would claim that unless the above-mentioned conditions are satisfied, general consent

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201.html, especially Article 19. Although the Declaration rightly also indicates the need for benefit sharing with "international community," how to achieve this noble goal and make it compatible with the existing patent system leads us to issues of global justice. Even though it is also a crucial issue, I will not pursue it here.

[91] Rynning 2009: 289.

[92] Liu and Tai 2009: 36-37. See also Tai 2005.

appealed to at the recruitment stage of biobanking cannot be morally justified. Moreover, only when these conditions are satisfied can the government make the morally compelling claim that people ought to support the biobank or even to participate in the biobank as a possible way to fulfill their duty of beneficence mentioned in Chapter 2.

To sum up, I have suggested in this chapter that, given proper institutional design mentioned in 3.2, there is no need to acquire re-consent in secondary research uses of biological samples so long as they were originally obtained and stored through proper informed consent procedure. Also, in the case of the establishment of a large or even national human genetic database such as the UK Biobank and the Taiwan Biobank, general consent may be appropriately used for recruitment, but its moral justification lies in adequate institutional designs to ensure that the fundamental rights of participants are well protected, that the results of research using data stored in the biobank will not pose serious risk of stigmatization for vulnerable social groups, and that the mechanism for equitable distribution of benefits generated through the use of the biobank has been instituted on publicly acceptable grounds brought out by way of deliberative-democratic procedure. In this way, and within the new model advocated by Manson and O'Neill, general consent is no second-best option when specific informed consent proves to be impossible or impractical, but the best available option for the protection of people's fundamental rights.

Conclusion

I have tried to argue, along the line proposed by Manson and O'Neill, for a "paradigm shift," so to speak, in conceiving the informed consent procedure in medical practices. If informed consent is viewed as a waiver, and as a context-dependent speech act which becomes meaningful only in a given context, it follows that informed consent is required when and only when fundamental rights are to be temporarily waived by a patient or participant in order for a medical treatment or research to proceed on her. This shift of focus from informed consent itself to the context in which it is to be given highlights the background of rights and obligations against which the informed consent procedure operates and makes sense.

Such a normative background can, as suggested in Chapter 2, find its moral foundation in Kant's Formula of Humanity, which further enriches Manson and O'Neill's model and through which we may be able to uncover convincing rationale in support of some familiar institutional designs for regulating the informed consent procedure. The most prominent of such designs is the so-called "research ethics committee," which, for reasons I have tried to bring out in 3.2, ought to represent the basic interests and rights of research participants adequately and fairly, to base its decisions on universally endorsable reasons (reasons that would be reasonably acceptable to all members of society), and finally, as is required for the universal endorsability of reasons, to be transparent in the sense that the committee maintains good communication with research participants in particular and with the public in general.

With this new prospect, I have further suggested some ways to meet the challenges raised by secondary research uses of biological samples and information

originally obtained and stored through proper informed consent procedure, and by the establishment of large biobanks, especially those designed for prospective epidemiological studies in the future. As to the former challenge, I have argued, in keeping with the new model proposed by Manson and O'Neill, that if accountable and trustworthy regulatory mechanisms have been set up so that there would be little risk of fundamental rights being violated as a result of secondary research, then it is reasonable to consider acquisition of re-consent from the original donors as unnecessary. On the other hand, in the case of the establishment of a large or even national biobank, such as the UK Biobank and the Taiwan Biobank, I have tried to argue that the so-called "general consent" may be appropriately used for recruitment, but its *complete* moral justification must appeal to the existence of adequate institutional designs which can reliably ensure that the fundamental rights of participants are well protected, that the results of research utilizing the biobank in the future will not pose serious risk of stigmatization for vulnerable social groups, and that the mechanism for equitable distribution of benefits generated through the use of the biobank has been instituted on publicly acceptable grounds brought out by way of deliberative-democratic procedure.

Hopefully, such "paradigm shift" to the background institutional designs will shed different light on the aim and importance of the informed consent procedure and open up new possibilities to better address challenges and difficulties not limited to those I have discussed. Admittedly, much of what I have done remains at the theoretical level, since I have mainly tried to explore the rationale behind such "paradigm shift" and its moral justification. More details about institutional designs such as the deliberative-democratic procedure referred to above in connection with benefit-sharing need to be filled in. But I must leave this for future investigation.

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