Consent from the Inside Out: Overcoming Hurdles for Informed Consent

(Draft: Do not quote – links to this article permitted)

Most parties to the issue of research ethics agree that the use of human subjects in biomedical research is necessary (and sometimes sufficient) to develop beneficial therapies for human diseases and pathologies. And in testing heretofore untested drugs, devices, or procedures without knowing exactly what they will do risks treating human subjects merely as a means – it risks acting unjustly towards them. The two precepts adverted to here are (i) the utilitarian value of medical research – we need to do research on human subjects in order to know how to treat illnesses of various sorts – and (ii) the requisite respect for persons involved in research. Medical research on human subjects plausibly yields valuable knowledge concerning how to better human health and treat illnesses. On the other hand, the subjects are human subjects and thus, intuitively, care must be taken so as to ensure that such subjects are not unjustly harmed or treated merely as a means.¹

To keep these precepts from clashing in any particular case, there are established measures to ensure that the dignity of a potential subject (hereafter subject is understood as human subject) is respected. Among these measures are (a) the benefits of the research outweigh the risks to the subject, or the risks are reasonable in relation to the anticipated benefits; (b) the selection of subjects is equitable; and (c) if the research requires it, consent from the subject should be obtained based on adequate disclosure of information (i.e., informed consent). This list is certainly not exhaustive but in most every summary of the ethical criteria, a favorable risk-benefit ratio is mentioned as well as a requirement to obtain informed consent. The problem I wish to address, however, is how one can actually protect subjects. A review of the current literature on research ethics indicates that the locus of difficulty in protecting subjects concerns getting informed consent, i.e., satisfying condition (c).

This essay focuses on three questions concerning informed consent. First, it is quite clear that obtaining consent from a subject on the basis of adequate information respects the dignity of that subject.² But it is certainly less clear why such an action respects that person. Getting clear on

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¹ Harming someone is not exhaustive of treating her unjustly. For example, research on a patient who had dissented, is now unconscious, but such research does not issue in any adverse events looks like an obvious candidate of treating her unjustly, but no harm was done.

² There are exceptions to this in cases where the research is quite risky, but the subjects consent anyway. To the extent that one can consent to being wronged, consent is not sufficient to justify research activity. That activity has to be permissible itself.
why informed consent respects the person will help to keep the informed consent process from becoming perfunctory. In addition, being clear on why consent matters may help in authoring research protocols that get IRB approval with more facility, and may help in conducting the informed consent process more productively. Second, after showing why informed consent is important, the next pertinent question is whether there are problems with obtaining it. The third question addressed in this essay is what solutions are there to the problems of obtaining informed consent.

I. The Ethical Basis for the Respect of Persons

Being clear on why obtaining consent from a subject respects that person’s dignity requires first knowing what it really means to respect the dignity of the person at all. What does it mean to respect someone and further, what is it about a person that grounds a person’s worth?

Typically, ethicists point to Immanuel Kant as being the main figure in the history of ethics to advert our attention to the dignity of persons and the respect due to them. Kant’s states, “Act in such a way that you always treat humanity, whether in your own person or in the person of any other, never simply as a means, but always at the same time as an end” (Kant, 1964, 67). Several important points are worth noting about this dictum. First, the object of action is humanity in general. By humanity, Kant is saying that every human person is the object of respect and infinite worth. Kant is not saying here that we are to respect an abstraction—humanity in general. Rather, he is advocating a strong egalitarian view of human worth. This point is particularly important in regard to research on subjects without capacity such as infants, and the demented or mentally disabled. Second, that ‘part’ of a person that is morally relevant to our actions is that which is present in all of us considered as a person. That is, we are not to consider others (morally) simply on the basis of whom they are – their talents, social position or rank – or what they possess, i.e., desires, inclinations etc. We are to consider persons in terms of what they are – their status as human beings. As one commentator on Kant observes, “We have an absolute and irreplaceable worth, for our value is not dependent on our usefulness or desirability” (Sullivan, 1989, 197). The idea is that the respect due to us is a function not of what we can do or how we can be used by others, but rather is a function of what we are, i.e., persons with the ability to reason and choose ends. It is no mistake that Kant does not use the term “honor” when delineating his law of respect. Respect, on

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3 I find this convention typical but wholly inaccurate. Kant did not discover the idea of human dignity any more than Leibniz discovered the notion of substantial form. For obvious reasons, such an issue is far outside the goals of this article.
the other hand, is tied to the person considered *qua* person. What this looks like practically is that respect (the root meaning of the term being ‘too look upon’, ‘to look back upon’, ‘to consider’) requires one to look at the person stripped of all her desires, inclinations and imported usefulness to the onlooker.

The second point worth noting is that Kant says that we can never treat another person *merely* as a means. Here Kant recognizes the practical necessity of considering persons in terms of their talents and usefulness. In the business world, persons are considered in terms of their skills and marketability. This is not immoral on Kant’s view, so long as business transactions do not consider such persons *merely* as being useful or marketable.

Lastly, the respect for humanity applies both to oneself as well as to others. This is important because often in ethical discussion on healthcare issues, we start by asking whether the physician’s action (or potential action) in question would respect the dignity of the patient. But little attention, it seems, is paid to whether the physician is behaving in a way that is respectful to her own self. This absence is probably most clear in discussions on conscience rights, though the converse of this absence can be seen in discussion on research ethics. The focus both in the scholarly literature and for IRB’s is whether the informed consent process conveys the requisite information *to the subject*. Few discuss the actions of the researcher in doing the research (Elliott, 1995). The importance of this observation becomes apparent when we consider whether it is possible to consent to being mistreated. Since I think it is possible (Tadros, 2011), research ethics must devote more attention to the actions of the researcher.

We can now provide a ground for why subjects should be respected even in the face of opposing utilitarian value. Kant thinks the properties constitutive of a person are self-determination,

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4 A clear endorsement of this claim by Kant occurs in the following passage from the *Metaphysics of Morals*,

*Humanity itself is dignity; for a man cannot be used merely as a means by any man…but must always be used at the same time as an end. It is just in this that his dignity…consists, by which he raises himself above all other beings in the world that are not men and yet can be used, and so over all things. But just as he cannot give himself away for any price…so neither can he act contrary to the equally necessary self-esteem of others, as men, that is, he is under obligation to acknowledge, in a practical way, the dignity of humanity in every other man (462-463, emphasis mine except on “things”).*

5 Another way to understand Kant’s project is to find what it is that is intrinsically (vs. extrinsically) good about human beings. The distinction can be understood to say that the value accruing to something solely *because* someone desires it has extrinsic value, whereas the value that accrues to something *because* of what the thing is, has intrinsic value. For example, an empty beer can has value only to a beer can collector who desires it. A person S, however, certainly possesses value that is not reducible to whether someone desires S. If persons only possess extrinsic value, then if no one desired S (including S herself) for some purpose, S would not have any value. I assume for this paper that such a result is counter-intuitive.
autonomy, and the ability to freely choose goals and the means to those goals. The idea of a human person on this conception seems very impersonal. It looks like Kant strips all subjective preferences away from human beings and what we are left with is reason and the specific powers of freedom and self-determination, which are a function of reason. I urge that we should resist this understanding for the following reason. If we make respect for the person qua possessor of certain capacities as fundamental, the subjective preferences drop out as being morally tantamount. But on such an understanding, having a rigorous informed consent procedure, which adverts to the subjective preferences of the subject, does not make sense. The subjective wishes of the subject must show up somewhere in one’s explanation for the moral importance of consent.

Instead, I recommend that we not artificially bifurcate the ideas of having a capacity and exercising it in discrete decisions. The same thing that has the capacity to decide is the same thing that decides. This ontological identity resists the bifurcation just mentioned. It is true that a specific decision or preference has the moral importance it does so far as it issues from an exercise of one’s deliberative abilities. Irrational decisions then, are on the view I am endorsing, not a function of one’s own deliberative powers. This is probably why children who do not assent to research approved under CFR Part 46.405 may have their dissent overridden — since the “research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research” (CFR 46.408a).

To give some concrete examples of ethical codes that endorse Kant’s view on this score, the Declaration of Helsinki states, “It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.” And more pertinently, “In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society” (Furrow, et. al., 2001, 1465). Notice the comparison of value in this latter quotation is between the interests of society and the human subject itself.

Given this theoretical background, how does informed consent preserve the respect due to a person? Following Manson and O’Neill (2007), I hold that informed consent should be understood first, as a communicative action between agents. Informed consent of a subject is not merely based on the disclosure of information from which the rational deliberator reflects and makes a choice. For Manson and O’Neill the emphasis for what they call the conduit/container model is on disclosing information to those who need to decide whether to consent or dissent. The conduit/container model has the effect of focusing on types or bits of information to disclose.

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6 To be slightly more accurate, the properties here are powers, and not the actual exercise of these powers. So, the mentally disabled and infants count as persons on Kant’s view.
Rather, on the agency model, which I endorse, informed consent is a transaction between agents and therefore is subject to the norms of justice. The move here is subtle, but important: in the conduit/container model, the ethical debate concerns what type of information and how much of that information to disclose. For the agency model, the ethical debate concerns how to act justly towards this person. Deciding what information to communicate will certainly be a part of that ethical question, but not reducible to it. Important too is having in view the dignity of the agents. By focusing on the question of just action between agents, consent can be thought of as a waiver of what would otherwise be immoral. (Hence, on Manson and O’Neill’s view, dissent can be overridden in cases in which consent does not waive what would otherwise be immoral. I consider this result an argument in their favor.)

Consider some cases to illustrate how Manson and O’Neill’s view is confluent with our intuitions. A medical procedure such as invasive surgery performed on an unconsenting patient is battery; with consent, it is likely beneficial treatment. Conversely, forcing a patient who is in the grips of a manic episode to have IV antibiotics for his bacterial meningitis is permissible, since administering the antibiotics to a patient with an otherwise fatal infection is morally permissible. Manson and O’Neill’s account of consent capture our moral intuitions on a range of cases.

Consent to x is morally charged only because there are background moral obligations against simply doing x to the subject. Morally charged consent functions as a waiver of what would otherwise be immoral. Informed consent, then, should be seen as a communicative act which successfully waives moral obligations. The moral justification for consent is not respect for autonomy, since that someone chooses x does not morally justify doing x. Rather, the moral justification concerns whether the communicative act succeeds in waiving the target moral obligations. And to know whether these obligations have been discharged requires knowing what epistemic and moral norms the communicative act must meet vis-à-vis waiving the target obligations. A 40-page consent form may not satisfy the epistemic or moral norms sufficient to waive the researcher’s right to experiment on the subject. In some cases, a 40-page consent document may be incompatible with meeting these norms. In any case, acts other than a consent document may be required. Acting consistent with these epistemic and moral norms is what successful informed consent accomplishes.

II. ‘Informed’ Consent and Problems in Getting It

Suppose we are researchers and are recruiting human subjects for experimentation. We are obviously concerned about “getting” consent from the individual, but this consent is a function of
multiple factors. First of all, we would certainly want the subject to understand the information we give her. Second, we would want the subject to base her decision on information relevant to such a decision and not on information completely irrelevant. That is, we would want the potential subject to make a rational decision. Third, we would desire that the agent herself makes the decision, that it is hers, it is something she possesses. This third condition may be understood to apply to the act of consent, rather than conditions for giving consent. Understanding the information and reasoning about it are different from executing a decision. The decision to enter a study must be one’s own. The possession condition rules out cases of coercion, but does not necessarily rule out cases of inducement, such as high financial compensation for participation. If I hold a gun to someone’s head promising to pull the trigger unless she consents to the study, I am coercing someone to consent and this decision would not be her own. If I offer someone a lot of money to participate, she may very well make a decision that is her own, weighing the risks against the money promised. Of course, we may judge heavy inducements to be immoral, but not on the grounds that the decision would not be the subject’s own decision. I wish to focus on the understanding condition, since that is the condition that seems most vulnerable in the research setting. I aim to delineate what obstacles there are in getting subjects to understand research protocols and to delineate measures by which we may facilitate such understanding.

Satisfaction of the understanding condition comes in two parts. First, the subject must recognize the propositional content of the relevant information, i.e., concepts such as placebo, randomization etc. But also the potential subject must make the right inferences from this information. To illustrate the difference between these two conditions and the necessity to satisfy both, take the following example from Berg et. al.

One subject, for example, volunteered the information that assignment to active medication or placebo would be on a random basis. When she was asked directly how her own medication would be selected, she said she had no idea. She then added, “I hope it isn’t by chance,” and suggested that each subject would probably receive the medication needed. Given the conflict between her earlier use of the word random and her current explanation, the issue was pursued. She was asked what her understanding of random was. Her definition was entirely appropriate: “By lottery, by chance, one patient who comes in gets one thing and the next patient gets the next thing.” She then began to wonder out loud if this procedure was being used in the current study (Berg, et. al. 2001, 288).

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7 What is wrong about undue inducements is not that they take away choice, they clearly are compatible with the agent making her own choice. The moral problem seems to be that it is exploitative, it is disrespecting the person in some way. See McNeill (1997).
Here is an example in which conceptual understanding is not enough. One must put the pieces together in order to grasp fully the nature of the experiment and thus adequately consent to the research.

It is important to note that satisfying the understanding condition requires recognizing the relevant information. What counts as relevant? The rough answer is that relevant information is whatever a reasonable person would count as relevant. But it is not always clear just what a reasonable person would find relevant. Here I think intuition is a good guide so long as we take into account the magnitude of individual differences. A risk averse person, for instance, may find a 1% chance of forming a malignant tumor as being enough to demur participation, whereas a non-risk averse person may find such a risk negligible. Both persons base their decisions on reasonable grounds and yet the decisions are disparate. The reason is that many of our decisions are a function not strictly of cold reason, but of our ethical character, our value system, personality, and emotional state. And none of these other factors clearly detract from the rational character of our decision making. If we take into account the breadth of what counts as relevant information, a researcher who is authoring an informed consent form should provide information many different kinds of persons would deem relevant. Let me illustrate this with an actual example.

Consider a research protocol aimed to test the efficacy of a drug (drug A). This research dovetailed an earlier experiment involving drug B which aimed to perform the same function as drug A although in a different way. Drug B had the deleterious side effect, however, of increasing the likelihood of forming a malignant tumor by 1.4%. The author of the research protocol requested that this latter information be left out of the present informed consent form insofar as the treatment arm for drug B was different (though very similar) from the treatment arm for drug A. Should the information have been included? It is clear that such information should be included. To see this, label the information that there was a 1.4% increase in one’s chances of forming a malignant tumor upon taking drug B as information T (for ‘tumor’). And let’s label all other information contained in the protocol as information I. Now, it is conceivable that there is a reasonable person for which the following two conditionals of freedom are true,

(A): If subject S understands information I, then S would consent to the research.

And

(B): If subject S understands information I and T, then S would not consent to the research.

It is clear that there is at least one person S, such that both (A) and (B) are true and S is reasonable with respect to the target decision (i.e., consenting to research). Given the ethical basis upon which

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8 See Verplanken and Holland (2002); Lerner and Kelter (2001); Tiedens and Linton (2001).
consent to research is based, information $T$ should be included on the consent form. To do otherwise would attenuate $S$’s ability of self-determination.\textsuperscript{9}

One may respond on behalf of this particular researcher that $T$ should not be included because either (1) such information should not be relevant or (2) the information may be relevant but would dissuade persons from enrolling which would compromise the scientific validity of the study.\textsuperscript{10} In response to (1), if there is at least one reasonable person $S$ for which both (A) and (B) are true, $T$ is relevant to a reasonable person. It seems clear that there is at least one reasonable person for which (A) and (B) are true. With respect to (2), taking (2) seriously would justify withholding relevant information from subjects in order to use them in experiments. But for the reasons delineated at the end of the previous section, this would use a subject merely as a means.

There are more practical problems which plague satisfaction of the understanding condition. There is a common misconception in many subjects across different kinds of research to the effect that subjects believe their involvement in research will benefit \textit{them}. This misconception falls under the rubric called the therapeutic misconception. Empirical evidence for this misconception comes originally from Appelbaum et al. (1987). Interesting extensions of this research were done by Schaeffer et al. (1996) who discovered several important subject-centered obstacles to informed consent. First,

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\textsuperscript{9} One may question whether this is really an immoral act. The argument may run, if the research is going to bring about great benefits, and only a slight attenuation in a research subject’s potency for self-determination, then there is nothing immoral. In response, the point is not whether the subject’s rational will is attenuated, but whether such attenuation would result in the subject choosing otherwise. And clearly, A doing X to B, to the extent that B would have chosen otherwise had it not been the case that A does X to B is not sufficiently respectful of B’s personhood. To see this more clearly, there are two ways in which one may do violence to another’s will. They are,

\textbf{Strong violence:} Person A does violence to person B \textit{iff} A thwarts B’s personhood potencies.

The idea is that one can manipulate or coerce someone into performing an action. To do strong violence, A acts upon B’s will in such a way that goes \textit{against} B’s will. B would have done otherwise had A not acted upon B.

\textbf{Weak violence:} Person A does weak violence to person B \textit{iff} A knowingly does not promote B’s potencies to choose.

The idea of promotion here is that if A knows that some piece of information or action will enhance B’s ability to choose rationally, but withholds the information (or the relevant action) anyway, then A does weak violence to B. And we may stipulate that B would have chosen otherwise, had A promoted B’s will. What makes both of these cases a case of violence is that in each B would have chosen a different option had the circumstances been such that A neither thwarts nor fails to promote B’s will. For weak violence, B would have chosen otherwise, had A revealed more information. For strong violence, B would have chosen otherwise had A not coerced B. I assume in this outline that B’s choice in each counterfactual situation is a rational one. I say this to avoid the response that if A thwarts B’s choice and B’s choice is irrational, then A is not doing violence to B’s personhood, on Kant’s view. This is so because B would be acting on her subjective desires and not reason. Now stipulating this proviso is not assuming too much, for one can argue that all human action is rational insofar as choice requires the operation of reason.

\textsuperscript{10} I thank Sandy Johnson for suggesting these reasons to me.
In the present study, we observed marked differences in the way ill...participants and healthy volunteers retained information and made their decisions to participate in research.... While healthy volunteers retained the greatest amount of risk information, severely ill Phase I and Phase II [oncological patients] subjects retained the most [information] about study procedures (Schaeffer, 1996, 266 – emphasis mine).

One explanation for this disparity is that patients who are ill are looking for something (anything!) that can help their condition. And this motivation may direct the attention of the potential subject to select only specific information from the consent form. There are numerous studies which suggest that motivation directs the focus of our attention to those features of our environment that are emotionally salient.11

A second related finding from the Schaeffer study is that “...severely ill participants in a Phase I protocol entered the study primarily for treatment purposes, despite contrary consent document information, and that the consent document was rated as less useful by participants with more advanced disease” (Schaeffer et al. 1996, 266). One can see here that subjects do not understand the information and this is a function of the way in which groups of people (patients with a disease) process information. In these studies, ill patients evinced therapeutic misconceptions but healthy volunteers evince this misconception as well, as indicated in the passage above about the woman who did not make the right inferences concerning the term “randomization.” In the next section I delineate practical measures by which such hurdles can be traversed, but for now it is important to explain further hurdles for obtaining informed consent.

Probably the most important area of cognitive research that impacts issues of understanding comes from literature on risk assessment. The most relevant of these experiments concern the findings that people become either risk-averse or risk-seeking depending solely on the way in which the information is presented. I shall refer to this phenomenon as risk sensitivity. To see what is involved in risk sensitivity Kahneman and Tversky (1984) offer the following two thought experiments. Suppose one were given the choice between (a) 85% chance of winning $1000 and 15% chance at winning nothing and (b) winning $800 for sure. Most people would take option (b), even though the expected value of (a) is greater (.85 x 1000 + .15 x 0 = 850, as opposed to 800 in option b). Now suppose we modify this scenario and describe the outcomes as losses. Suppose one were to choose between (a) an 85% chance of losing $1000 with a 15% chance of losing nothing, and (b) a certain loss of $800. Most people would choose option (a) even though the expected value

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of (a) entails a greater loss – a loss of $850 as opposed to an expected loss of only $800 for option (b).

Eraker and Sox (1981) duplicated these results in the health care context. To be brief, they conclude, “…patients are averse to taking risks when they are certain of therapeutic benefits from the drugs but are likely to accept risks to avoid otherwise inevitable adverse drug effects” (Eraker and Sox, 1981, 37). The fallout of their findings is that “When the effects of the drugs are dissimilar but equivalent, emphasis on comparing their favorable effects might lead the patient to a different decision than if their adverse effects were compared” (Eraker and Sox, 1981, 37). In both of these experiments, risk sensitivity is a function of whether the relevant outcomes are phrased in terms of a loss, or a gain. The implication for these studies extends also to the therapeutic context in which treatments are described in terms of ‘survival’ rates or ‘mortality’ rates. Depending on the description, the subject may choose otherwise.

Risk sensitivity is also a function of the very terms that are used to describe various probabilities. Sutherland et. al. (1991) had subjects assign a numerical probability value to probability terms (e.g., always, common, unusual, rare etc.). Two different methods were used to record the numerical assignment, one of which was linear analogue scaling and the other was magnitude estimation.12 Regardless of method, however, subjects were widely disparate in their numerical interpretations of probability terms. For some terms, the standard deviation was as high as 36 (Sutherland et al. 1991, 728).13

I have taken some time delineating obstacles in satisfying the understanding condition. I turn in the next section to practical measures aimed to promote sufficient understanding of research protocols.

III. Conceptual Clarification, Consent and The Process of Disclosure

In this section I discuss some solutions to the practical problems concerning understanding just delineated. Most of the recommended solutions involve actions on the part of the researchers themselves. It is, of course, not clear why the researchers bear such a duty, so I begin this section

12 Magnitude estimation simply required the subject to assign a numerical value to the term. Linear scaling required the subject to pick out a point on a scale (running from 0-100) which they thought reflected the numerical value of the term.
13 See also, Mazur and Merz (1994).
14 For more on the therapeutic misconception see Appelbaum et al. (1987); Appelbaum et al. (1982); Meisel and Roth (1983).
outlining reasons why they do bearing in mind the my endorsement of Manson and O’Neill’s agency-model of informed consent.

Researchers bear a duty to achieve better understanding because the empirical research recapitulated thus far indicates that the way in which information is disclosed can affect the processing of that information (the evidence canvassed here applies equally well to the therapeutic context as well). Now, the mode by which information is disclosed can either (i) enhance, (ii) remain neutral to or (iii) is pernicious to veridical processing of the relevant research (or therapeutic) information. The next step in the argument is that the researchers (and staff) are in control of the mode by which the information is disclosed. Now, clearly we want information to be disclosed in a way that enhances veridical processing. It follows that researchers are responsible for disclosing information in a way that enhances such processing. The basic idea here is simple: being in control of X entails one is responsible for X. Let’s turn then to some practical recommendations aimed to promote information disclosure in the right way.

As adumbrated above, there are two parts to understanding, conceptual recognition and inference. I related the story of an actual subject who did not fully understand that she might receive a placebo even though she understood the concepts of randomization, and placebo. Berg et al. (2001) make the following obvious recommendation for this particular problem. They state, “After being told that they [potential subjects] are being asked to participate in a research project, potential subjects can be informed that the procedures in the project differ from those of the clinical care they would ordinarily receive” (Berg et. al. 2001, 293). The researchers can then move on to explain that treatment is not the goal of the research setting and thus things will be done differently than in a clinical care setting.

Regarding the concept of randomization Jessica Berg et al. recommend explaining the idea in the following way, “You will receive one of the three treatments we discussed, but the one you receive will be selected by chance, not because we believe that one or the other will be better for you.” And with respect to placebos, they recommend saying,

Some subjects will be selected by chance to receive sugar pills that are not believed to help the condition you have; this is done so we can find out whether the medications other patients get are really effective, or if many people with your condition would get better even with no active medication at all (Berg et. al. 2001, 293, emphasis mine).

Reflection on these recommendations can generate a general recipe. The researchers are to communicate face-to-face with potential subjects regarding the barriers outlined above (i.e., risk sensitivity, therapeutic misconception). Adding to this recipe further, Appelbaum et. al. (1987) suggest that in the early stages of subject procurement, the researcher herself should be the one who
conducts the requisite screening procedures. I do not hold this view as other health professionals are just as capable of communicating the relevant information and in some cases are more sensitive to potential subjects’ misgivings. Therefore, I would add to these recommendations that other professionals could perform the initial procurement screening and other aspects of the consent process.

There are several reasons for this, one of which is that other professionals (e.g., psychologists, professors etc.) may be more adept at determining whether the subject understands the relevant information. Furthermore, other professionals may have more time, and certainly no conflicts of interests, which may affect the disclosure of information.15

Regarding face-to-face interviews with the subjects, this strikes me and many researchers as being difficult to implement especially for research that involves many research directors over a short period of time, or the study is a longitudinal study that takes place over several years and at different sites. But it is in just these cases that communication with the subjects is most important in that the more distant the subjects get from their researcher, the greater chance a subject’s understanding might not be sufficient to waive the relevant moral obligations to her. To act justly towards a research subject at least requires knowing the person. Furthermore, the importance of informed consent is co-extensive with the level of risk and/or the lack of knowledge about the test article. Both features are present in phase 1 trials. But phase 1 trials have very few subjects, making separate and involved conversations manageable.

To promote understanding of risk, Schaeffer et al. recommend that risk information should be presented repeatedly, “…and at less stressful times as than the signing of the consent document…”(Schaeffer, et al. 1996, 267). And furthermore, they recommend,

[d]eveloping worksheets that can be completed by the researcher and participants and used as discussion guides. More emphasis needs to be placed on oral dialogue and on fact-to-face interaction, especially in light of our finding that the more time a researcher spent with the subject, the better the subject’s retention level (Schaeffer et. al. 1996, 267-268).

I would only add to this that the interaction look like an educator to a student. The researcher is to take on the task of asking questions which allow the subject herself to recapitulate what she understands. For instance, the researcher should ask “What do you expect to gain from this study?” or “What do you think the goals of this research are?” Furthermore, the informed consent form itself should be interrogatory insofar as straightforward text tends not to capture reader’s attention.16

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15 I owe these additions to Sandy Johnson.
16 I owe this latter suggestion to Jerome Spitzer.
With respect to the Sutherland study, which discovered that subjects have widely disparate interpretations of probability terms, one suggestion is that actual numerical values should be given for the risks and benefits. Now, Sutherland et al. suggest such a tactic, but even this is insufficient. Kimihiko Yamagishi discovered that even if one presents numerical probabilities, subjects poorly assess them. He discovered that, “Participants rated cancer as riskier when it was described as ‘kills 1,286 out of 10,000 people’ than as ‘kills 24.14 out of 100 people’, and similar results were observed regarding the remaining 10 causes of death” (Yamagishi, 1997, 495). Mathematically, of course, the second description clearly indicates a higher risk. Yamagishi recommends communicating risk information both in numerical terms and comparing such risks with common reference points such as ‘being struck by lightning’, or ‘getting into a fatal car accident’ etc.

In conclusion, this essay addresses (i) the ethical reasons for why informed consent respects the dignity of the person, (ii) some practical problems associated with getting informed consent and finally, (iii) some practical measures that aim to ensure appropriately informed consent. This project is merely one fork of a many-pronged problem. Future work can look at the attitudes of researchers themselves which may pose obstacles to obtain sufficiently informed consent. Also important is to look at the very structure of the consent process. For example, as adumbrated above, researchers often delegate the task of recruitment to those who did not author the research protocol. This may be good in that if non-authors cannot understand it, then plausibly a potential subject may not.

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17 Similar results are duplicated in McFarland and Miller (1994), and Denes-Raj and Epstein (1994).
18 Several researchers already use this tactic but it is unclear whether this is an established practice and to what extent it improves understanding.
19 I would like to thank Sandy Johnson and Jerome Spitzer for helpful comments on earlier drafts of this essay.