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Myth or Magic?

Towards a Revised Theory of Informed Consent in Medical Research

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Abstract

Although the principle of informed consent is well established and its importance widely acknowledged, it has met with criticism for decades. Doubts have been raised for a number of different reasons. In particular, empirical data show that people regularly fail to reproduce the information provided to them. Many critics agree, therefore, that the received concept of informed consent is no more than a myth. Strategies to overcome this problem often rest on a flawed concept of informed consent. In this paper it is suggested that informed consent is a communicative act between two persons. The challenge is to elucidate the norms and constraints for successfully performing such a communicative act. The view developed here has major consequences with regard to the standards for information disclosure as well as for the general scope of informed consent.

Keywords

Informed Consent; Biomedical Research; Research Ethics; Speech Act Theory

1. Introduction

Hardly any other principle of medical ethics and research ethics is as widely recognized as the principle of informed consent.[1] Today, it is commonly acknowledged that informed consent is normally a sufficient and in most cases also a necessary precondition for including human participants in medical

[1] In this paper I will focus on medical research. A good deal of the argument does also apply to informed consent in medical practice, although there are some important differences between the two areas.

research. Strong paternalism, which was prevalent in medicine until at least the mid-twentieth century, is outdated. In spite of this, informed consent—or at least the received concept of informed consent—has come under criticism. With regard to some groups, such as minors or cognitively impaired persons, informed consent is not readily applicable. Moreover, empirical evidence suggests that even in competent adults informed consent raises serious questions. This is, of course, not a new insight. However, the discussion on informed consent has recently intensified (Manson and O'Neill, 2007; Corrigan, Liddell and McMillan, 2009; Miller and Wertheimer, 2010).[2] A characterizing feature of this new discussion is that not only mere modifications or adaptations of informed consent in practice are at stake. Rather, the received concept as such has come under close scrutiny.

2. The Myth of Informed Consent

Although the principle of informed consent is well established and its importance widely acknowledged, it has met with criticism for decades (Kaufmann, 1983, 1657–1664). Doubts have been raised for a number of different reasons. Many critics agree, however, that the received concept of informed consent is no more than a myth.

Fellner and Marshall were apparently the first to criticize "the myth of informed consent," though not with respect to research settings, but in relation to kidney donation (Fellner and Marshall, 1968, 2703–2707; 1970, 1245–1251). They remark "that all the donors and potential donors interviewed by us reported a decision-making process that was immediate and 'irrational' and could not meet the requirements adopted by the American Medical Association to be accepted as an 'informed consent'" (Fellner and Marshall, 1970, 1250). However, they do not conclude that the decisions taken by the donors and potential donors were objectionable on moral grounds. Rather, they argue that "[t]he criteria required for an 'informed consent' type decision simply do not apply to the potential donor in this situation" (Fellner and Marshall, 1970, 1251). At the same time, Fellner and Marshall observe that

[2] For a legal perspective see Westen, 2004.

"[f]rom a brief review of the literature it appears that in an experimental situation decision making is indeed mostly a very sane and rational process" (Fellner and Marshall, 1970, 1250).

Later studies show, however, that this evaluation was too optimistic, at least under the assumption that the validity of the consent is strongly correlated to the comprehension of the information provided beforehand. Notably, Paul Appelbaum and colleagues have explored the comprehension of potential research subjects and coined the term "therapeutic misconception" for the mistaken belief that all aspects of a research project have been designed for the direct benefit of participants. They show that this fundamental error is quite prevalent among research subjects (Appelbaum, Roth, and Lidz, 1982, 319–329; Appelbaum et al. 1987, 20–24).

Poor retention rates of information provided during consent processes were also reported prior to Appelbaum's research and associated with the "myth of informed consent." Lebb, Bowers, and Lynch interviewed 100 patients before surgery using a standard format to collect data about their retention rates of information given to them preoperatively. They found an average retention rate of only 35 percent (Lebb, Bowers, and Lynch, 1976, 280–282).

Herz, Looman, and Lewis conducted a study with 106 patients who were subject to routine neurosurgical procedures and found a performance rate of 43.5 percent immediately after the provision of information; that dropped to 38.4 percent after six weeks (Herz, Looman, and Lewis, 1992, 453–458). The authors conclude: "Considerations must be given to the concept that fulfillment of the doctrine of informed consent under the intent of the law may very well be mythical" (Herz, Looman, and Lewis, 1992, 458).

The notion of "myth" has also been used to attack the concept of informed consent from a different side. William Silverman's main concern is not the problem of comprehension, but rather that "competing moral imperatives of respect for autonomy, concern for beneficence with emphasis on the value of health, and a vigil for justice" (Silverman, 1989, 6) cannot be satisfied by the current practice of informed consent. Silverman thus makes a case for balancing competing ethical principles. The "myth"

he has in mind relates to an imbalance between competing ethical principles, rather than a misjudgment of comprehension.

Alan Meisel and Mark Kuczewski, finally, argue that there are also "myths" about informed consent which may, in turn, promote the impression that informed consent itself is no more than a myth (Meisel and Kuczewski, 1996, 2521–2526). They list a total of seven myths about informed consent, namely that a signed consent form is informed consent, that informed consent is a Miranda warning, that informed consent requires that physicians operate a kind of medical cafeteria in which they set out all therapeutic options and let patients choose according to their own appetites, that patients must be told everything about treatment, that patients need full disclosure about treatment only if they consent, that patients cannot give informed consent because they cannot understand complex medical information, and that patients must be given information whether they want it or not (Meisel and Kuczewski, 1996). They think that, if understood correctly, i.e. as a process of shared decision-making, "some of the seeming absurdities and excesses" (Meisel and Kuczewski, 1996, 2526) disappear. Still, empirical data show that people regularly fail to reproduce the information provided to them. The manifest conclusion is that consent is very often invalid. However, if it is right that, from an ethical point of view, informed consent is essential to legitimate experimental interventions then we face a serious problem.

3. Strategies for Dealing with the Problems of Informed Consent

There are different strategies for dealing with the problems described above. With a special focus on informed consent and randomized clinical trials (RCTs), Angus Dawson distinguishes three such strategies, namely (1) denial, (2) upholding autonomy, and (3) revision (Dawson, 2004, 41–52; 48–49). Strategy (1) simply consists in ignoring the fact that research subjects regularly fail to comprehend important details about studies they are taking part in. According to Dawson, an argument in favor of this strategy would be that "*trying* to obtain informed consent might be enough to justify the research" (Dawson, 2004, 48). Additional support might come from the fact that research subjects are apparently quite satisfied with the informed consent process. However, Dawson dismisses this approach as

unconvincing. He argues that "respect for autonomy requires something greater than merely going through the motions of gaining informed consent knowing that it is likely to be meaningless in a significant number of cases" (Dawson, 2004, 48). Strategy (2) reacts to the empirical evidence in that it strictly limits the circle of potential research subjects to those who really understand all the details about a study, including complex issues concerning methodology. Dawson thinks that this constraint is too high a price, since it would dramatically reduce the number of available research participants or else demand very simple research methodologies. Finally, strategy (3) aims at revising the received concept of informed consent. What Dawson has in mind is "that we should [...] move to an approach that puts greater weight on other considerations such as beneficence or welfare issues" (Dawson, 2004, 49). This ultimately means abandoning the idea of self-determination and reintroducing strong paternalistic thinking.

There is another strategy that Dawson does not discuss, namely improving the means of information disclosure with the aim of making informed consent genuinely informed (Lentz et al., 2016). The underlying assumption of this strategy is that it is merely the current way in which information is disclosed that causes poor performance rates on the part of research participants. The strategy is, of course, reasonable to some extent. A recent metastudy shows that improving participant understanding is possible (Nishimura et al., 2013). Nevertheless, it has certain apparent limitations. Even sophisticated methods of information disclosure will not ensure that people come to understand the complex details of research projects. This holds true, in particular, when it comes to cognitively impaired people or minors. However, the reason why this strategy is problematic lies not so much in its practical limitations and adverse implication—namely that research with certain groups would hardly be possible—but rather in the fact that it is based on problematic notions of autonomy, consent, and information. It assumes that consent is a solitary act performed by an individual agent and that the quality, if not validity, of consent is directly correlated with the degree of the agent's understanding. It follows the simple but erroneous logic that deeper understanding leads to better consent and in turn to more autonomy. However, consent is not a solitary act—it takes two to consent.

4. A New Start: Consent as Speech Act

Neil Manson and Onora O'Neill have already suggested an alternative approach to informed consent that places the idea of communication at its center. Their main criticism of the received understanding of consent is that it wrongly emphasizes individual decision-making and information disclosure (Manson and O'Neill, 2007). In particular, this understanding of informed consent is based on a view of communication solely as a transfer of content—following Michael Reddy, Manson and O'Neill call this "the conduit metaphor"—rather than a form of agency (Manson and O'Neill, 2007, 35–38). Additionally, the recipient of information is seen as a "container" into which information can be put. Once sufficient information is being transferred, the recipient can use it in his or her individual deliberation processes. This view of communication obscures the fact that informed consent is a communicative act between two persons. The requirements for successfully performing such a communicative act are complex and cannot, in particular, be appreciated if the persons involved are taken as isolated parties, one of them disclosing information, the other making a decision. This fragmented picture supports exactly the erroneous logic inherent in the notion that "the more information, the better the consent." Manson and O'Neill contrast the dominant view with "an agency model of communication [that] locates informed consent in *communicative transactions between agents*" (Manson and O'Neill, 2007, 69).

The real challenge, then, is to elucidate the norms and constraints for successfully performing such a communicative act. In their study, Manson and O'Neill only briefly mention the classical works on speech acts by John Austin and John Searle (Manson and O'Neill, 2007, 58–59). This is unfortunate since the latter in particular has provided powerful analytical tools for examining such norms and constraints (Searle, 1969; Searle and Vanderveken, 1985).

Before investigating the nature of consent as speech act, it is helpful to introduce a formalized notation. John Kleinig has correctly observed that "to consent" is a three-place transaction that can be formalized as

E: *A* consents to *B* to φ

where *A* designates the person giving consent, *B* the person asking for consent, φ the action in question (i.e. the action that *B* wants to perform and for which consent from *A* is needed), and *E* the particular instance of consent (Kleinig, 2010, 3–24).

A first step in elucidating the norms and constraints for successfully performing this kind of speech act is to determine its particular type. According to John Searle and Daniel Vanderveken the notion of illocutionary points is the basic notion of illocutionary logic (Searle and Vanderveken, 1985, 37). They identify five different illocutionary points, namely the assertive, the commissive, the directive, the declarative, and the expressive point, each of which gives rise to a basic type of speech act respectively (assertions, commissions, directives, declarations, and expressives). It is no trivial matter to locate the speech act of consenting within this classificatory schema.

Searle and Vanderveken themselves understand "to consent" as a "commissive verb" (Searle and Vanderveken, 1985, 195). On closer inspection, however, it becomes clear that they have a slightly different meaning in mind:

> To consent to do something is to accept a directive to do it with the additional preparatory condition that one has reasons for not doing it and therefore one would probably not do it if one had not been requested. (Searle and Vanderveken, 1985, 195)

What they describe is the use of "to consent" in a sentence like "I consent to give a talk on Monday (though I was planning to go hiking)." As such, "to consent" is close to the paradigmatic commissive verb, namely "to promise" (Searle and Vanderveken, 1985, 192). While it is true that "to consent" can be used in this way, this is not the meaning it has in the concept of informed consent. If *A* consents to *B* to φ, *A* does not, at least for the main part, promise to do something. It is rather *B*'s wish to φ that is at issue. *A* only implicitly promises by consenting (to *B* to φ) "to do" something, namely not to interfere with *B*'s intended φ-ing. Since *A* does not (or not primarily) promise to do anything by

consenting, the consent transaction cannot be conceptualized as a kind of contract.[3] Searle and Vanderveken list verbs such as "to contract," "to covenant," and "to bet" as special cases of commissives (Searle and Vanderveken, 1985, 197–198) and define a contract as "a mutual pair of commitments made by two contracting parties" (Searle and Vanderveken, 1985, 197). A characteristic feature of a contract is that one party alone normally cannot annul it. Mutual agreement is necessary. In contrast, given consent can be withdrawn at any time by the consenting party *A* alone. In sum, it is doubtful whether in this special usage consent figures as a commissive verb at all. For it is the characteristic feature—the illocutionary point—of commissions "to commit the speaker to doing something" (Searle and Vanderveken, 1985, 37). If this is not the case, what else could "to consent" be?

Since "to consent" is apparently not an assertion, it seems natural to answer: "a directive." This type of speech act is, according to Searle and Vanderveken, characterized by "trying to get other people to do things" (Searle and Vanderveken, 1985, 37). Typical verbs expressing directives are "to direct," "to request," "to ask," "to urge," and "to command" (Searle and Vanderveken, 1985, 198–201). Yet, by consenting to *B* to φ, *A* does not want to get *B* to do φ. Rather, *B* wants to φ and *A* is accepting this (although there are prima facie reasons against it).[4] However, the list of directive verbs Searle and Vanderveken present also includes "to permit" (Searle and Vanderveken, 1985, 202). This comes closer to the meaning of consent in question. If *A* consents to *B* to φ, *A* somehow permits *B* to φ.

Nevertheless, there is one important feature of "to consent" that has not been covered yet. If *A* consents to *B* to φ, this does not only concern *B* (like in the case of "to permit"). Rather, it objectively changes the moral relation between *A* and *B* with the effect that this new or modified relation can be relevant for any third party *C*. This, in turn, is a typical feature of a declaration: it changes the world by

[3] One could, of course, argue that *A* promises to do what the research protocol requires subjects to do. In fact, almost every research protocol involves some form of activity from subjects. However, these activities conceptually depend upon φ. In contrast, in a contract situation *B's* wish to φ and *A's* wish to ψ are somewhat independent of each other.

[4] Often there are also prima facie reasons in favor of it. The essential point here is that if there were no prima facie reasons against *B*'s φ-ing, no consent would be needed from *A*. See below for details.

saying so (given that *A*, and sometimes also *B*, is in an appropriate position) (Searle and Vanderveken, 1985, 37). "To resign" is a good example (Searle and Vanderveken, 1985, 206). Superficially, it changes the relation between, say, an employer and an employee. But, furthermore, the change of relation also has an impact on some third parties, e.g. on colleagues. For them, too, the relationship between *X* (as employee) and *Y* (as employer) that existed before has come to an end. By uttering "I resign," *X* changes not only the relationship to *Y*, but in some sense changes the (social) world. The same holds true for consenting: If *A* consents to *B* to φ, *A* changes not only the moral relationship between *A* and *B*. Of course, *B* is now allowed to do things that he or she was not allowed to do before. But additionally, the new relation can also be relevant to third parties. *C*, for example, has no obligation (and also no right) to halt *B*'s φ-ing; this would infringe on a right of *A*'s precisely because *A* has consented to *B* to φ. This suggests that we should think of "to consent" in the special meaning it has in the concept of informed consent as a declarative speech act.

5. The Magic of Consent

According to Searle declarations typically serve to constitute institutional facts: "In declarations the state of affairs represented by the propositional content of the speech act is brought into existence by the successful performance of that very speech act" (Searle, 1995, 34; Searle and Vanderveken, 1985, 205–211). "Status functions" play a key role in "the move from the collective imposition of function to the creation of institutional facts" (Searle, 1995, 41). The constitutive rule is "X counts as Y in C" (Searle, 1995, 43–51). The standard example used by Searle is money: This piece of paper counts as money in the United States, i.e. it is the target of the imposition of function (Searle, 1995, 37–43). Without this imposition these pieces of paper could not perform the function in question. A special case is given when there is no physical entity to serve as a target for the imposition of function. The constitutive rule also allows for this. In particular, function can be imposed on a speech act. In this case, performing the speech act in appropriate circumstances constitutes the imposition of that function, i.e. will constitute the new institutional fact (Searle, 1995, 54). Searle's example is "I appoint you chairman." Uttering this

sentence in appropriate circumstances will make it the case that you are chairman, i.e. it will create a new institutional fact, namely that you are chairman. It is fair to speak of "an element of magic" in this context (Searle, 1995, 45). This "element of magic" gives rise to different powers, inter alia "deontic powers," i.e. to the creation of rights and obligations (Searle, 1995, 100–101).

Heidi Hurd and Larry Alexander have used the notion of "magic" explicitly in the context of informed consent (Hurd, 1996, 121–146; Alexander, 1996, 165–174). Hurd states: "We regularly wield powers that, upon close scrutiny, appear remarkably magical. By sheer exercise of will, we bring into existence things that have never existed before" (Hurd, 1996, 121). She attempts "to explore one of these remarkable powers of personhood—the power to consent" (Hurd, 1996, 121). But there is an important distinction to be identified, notably at the very outset of Hurd's examination: for her "to consent" is "an exercise of will," not a speech act.

Hurd and Alexander consistently define the function of consent as that of a "moral transformative" (Hurd, 1996, 123–124; Alexander 1996, 165).[5] A further step in elucidating informed consent is to analyze the constraints and conditions of success for the speech act "to consent", i. e. to answer the question "Under what circumstances is this specific declarative speech act transformative?" For each element (A, B, φ, E) some general requirements can be identified that give rise to further constraints (Kleinig, 2010, 5–11):[6]

(1) A must be an agent who can waive some of his or her rights;

(2) B must be an agent (or a group of agents) who is in the position to perform an action φ that concerns A in some relevant sense and that B wants to perform;

(3) φ is an action that concerns A in such a way that, without consent, φ would infringe on a right A can claim to have;

(4) E is communicated between A and B in an appropriate form.

[5] In fact, Hurd identifies two distinct forms of consent: consent as a moral transformative and as a stained permission.

[6] These constraints are, of course, connected to the "components of illocutionary force" explicated by Searle and Vanderveken. I refrain from commenting on the details.

Constraint (1) limits the circle of those who can, in principle, give consent. Animals, for example, do not belong to this circle, since they are not agents who can dispose of rights. This is, of course, not equivalent to the claim that they do not possess rights at all. The point is rather that they cannot dispose of them. But who can? The formal account suggests that this question cannot be answered in general. As indicated, a particular instance of consent E is always related to a concrete action φ. Therefore, it is inaccurate to say that someone is or is not capable of giving consent without further qualification of the concrete conditions. Nevertheless, many regulations and laws speak of "persons able or unable to consent" as if this is a characterization that can be given independently of the concrete conditions. Someone is or is not capable of consenting to some particular φ. Hence, the capacity to consent is different from contractual capacities for which the law normally sets a fixed age.

While in the literature there is controversy over how comprehensive A's understanding of φ must be for consent to be valid, many regulations assume that full understanding is essential. Regulations like the *Declaration of Helsinki* contain an extensive list of aspects that have to be disclosed to a potential research participant. The list includes "the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study" (World Medical Association, 2015). It is suggested that the capacity to consent depends on an understanding of all these aspects. In addition, standardized tests are available for examining the capacity to consent. One such test is Paul Appelbaum and Thomas Grisso's *MacArthur Competence Assessment Tool* (MacArthur Research Network on Mental Health and the Law, 2004). The *MacCAT-CR* provides a structured format for capacity assessment adapted to the specifics of biomedical research. It measures four components of decision-making competence, namely understanding, appreciation, reasoning, and the ability to express a choice. All four components are, undoubtedly, important. However, putting an emphasis on these components, and in particular on understanding, obscures the true nature of consent as a communicative act between agents. "To consent" appears instead to be a solitary act of decision-making (Faden and Beauchamp, 1986).

Hurd argues in favor of what she calls "the identity thesis": "For a victim's consent to insulate a defendant from liability, the victim must intend what the defendant must intend in order for the defendant to be prima facie liable" (Hurd, 1996, 127). This view supports the high demands on understanding since, according to Hurd, for *A* to consent to *B* to φ *A* must intend to φ. But if *A* must intend to φ in order to consent to φ, *A* certainly must understand φ. Again, this view seems to obscure the true nature of consent. Alexander correctly observes that *A* need not intend to φ—in fact, it is unclear whether it is even possible that *A* can intend to φ if φ is an action of *B*'s—but rather *A* must intend to forgo moral objection to φ (Alexander, 1996, 166). What *A* really must understand is that he or she is (temporarily) waiving a right and, by doing so, (temporarily) obligating him- or herself not to object to φ. This does imply a shared understanding (by *A* and *B*) of the *impact of* φ *on A*, but not necessarily a shared understanding of φ itself. The capacities that are needed for understanding this prerequisite can be considerably lower than the capacities for understanding φ (at least if φ is a complex action).[7] Ultimately, there are constraints regarding *A*'s capacities of understanding. But these constraints concern the fact that by consenting to *B* to φ, *A* waives (temporarily) a right, namely the right to morally object to *B*'s doing φ.

Constraint (2) limits the circle of those who can be recipients of consent. Again, animals do not belong to this circle. The same holds true for persons who do not stand in a suitable relation to the originator of consent (*A*). At least in principle, the recipient of consent (*B*) must be able and willing to perform an action φ. Otherwise, *A*'s consenting to φ would be pointless. It is easily conceivable that *A* is willing to give his or her consent that researcher *B* is doing φ and, at the same time, refuses that researcher *C* is doing exactly the same φ. In practice, this may lead to problems. Since research projects are usually carried out by teams the person getting consent from a research subject is often not the one

[7] A case in point for the distinction between "understanding φ" and "*understanding the impact of* φ *on A*" is a complex medical experiment using MRT. As far as is known MRT is not harmful for humans. A research subject may, therefore, well understand the "*impact of* φ *on A*"—namely: it is not harmful for me—without understanding the experiment itself.

performing an intervention. In turn, a research subject may legitimately claim that he or she did not consent that *this person* does φ. It might, therefore, be appropriate that in the course of the information process an entire research team is introduced to the research subjects. Additionally, this constraint has consequences for the possibility of so-called "open consent," which is discussed in the context of biobanks (Hallinan and Friedewald, 2015, 1–36). To be sure, there is nothing to be said against a relatively open description of φ. However, consent is always given to someone specific, i. e. to an agent or group of agents. In this sense the concept of "open consent" is restricted. In particular, tissue or data collected by a researcher or a research team within a project must not be shared with others without explicit consent by the research subjects.

Constraint (3) concerns the action φ that is in question. φ must be such that it touches upon a right that *A* is acknowledged to have. For example, *A* need not consent to get a present from *B*, because getting a present does not infringe on any accepted right of *A*. At the same time, the relevant right of *A* must be such that *A* can waive it. This raises fundamental questions with regard to the potential scope of consent. Are there any rights that *A* has, but that *A* cannot waive? (Schaber, 2011, 54–56). An answer to this question depends on the significance one assigns to the right to self-determination. According to a strong liberalistic view the right to self-determination is of utmost importance and not to be limited by any external factor. As a consequence, an agent is free to do whatever he or she likes as long as he or she does not infringe on someone else's right to self-determination. Those, however, who oppose such a strong liberalistic view argue that there are limits to the right to self-determination. In fact, many national jurisdictions include some limitations that are relevant in this context. For example, in some jurisdictions it is impossible to give valid consent to severe forms of bodily injury. A potential victim cannot dispose, or at least not entirely, of the right to protection from harm. In other words, there might be actions φ that touch upon a right of *A*, but that *A*, nevertheless, cannot consent to because *A* cannot waive the right in question. At any rate, the concept of consent raises the question of its scope and this scope is directly connected with *A*'s rights.

Constraint (4) concerns the nature—or, as Kleinig calls it, "the ontology" (Kleinig, 2010, 9–11)—of the particular instance of consent *E*. Broadly speaking, there are two simple but insufficient views. According to the first view, e.g. that advocated by Hurd, *E* is taken to be a mental state of *A*. She claims: "The magic that transforms the morality of another's conduct, in other words, is done entirely by a person's mental state and not by her observable behavior" (Hurd, 1996, 137). Hurd rightly argues that overt behavior alone cannot do the trick. But again, she misses the essential point that consent is a speech act between agents. Therefore, *A*'s mental state alone merely qualifies as unexpressed approval, but is not sufficient for valid consent. Of course, the opposite is also true: the utterance "I consent" alone is not sufficient either. If that were the case, there would be no possibility of differentiating between a successful speech act and an instance of coercion. This indicates that freedom and sincerity are essential preconditions for successfully performing consent. At the same time, it highlights the possibility of abuses. Searle has pointed out that "the possibility of such forms of abuse is characteristic of institutional facts" (Searle, 1995, 48). If valid consent depends to some degree on freedom and sincerity, invalid consent may occur. This is not an argument against this form of conceptualization, but rather an indicator that speech acts can fail for different reasons.

The question as to which concrete form the expression of consent should have in order to avoid abuses is difficult to answer and seems to depend heavily on the context. While, for example, in an intimate relationship formal requirements seem out of place, in medical research strict formal requirements are appropriate. The essential point is that the two parties involved must agree upon those requirements. If, for example, two people agree that nodding one's head is a clear expression of consent, this gesture can be sufficient. In many cases, such a common understanding is not warranted. In such cases, formal requirements, e.g. a written document, are necessary. However, such formal requirements must not hinder people from giving consent. In biomedical research, for example, there has been discussion of how to proceed with illiterate persons (Dein and Bhui, 2005, 354–356). The fact that someone is illiterate is no reason to deny him or her the exercise of his or her rights. Rather, appropriate means have to be found to make such exercise possible. Generally speaking, if there is no

prior shared understanding it is a precondition of the speech act of consent to agree on the formal requirements that have to be met for valid consent. These requirements are not built generically into the speech act. Reaching agreement about them is a precondition for successfully carrying out such a speech act. The most natural way of reaching such an agreement is by talking to each other. In fact, there is no short cut to valid consent.

6. Implications for Biomedical Research

Despite their important revision, to a certain degree Manson and O'Neill remain connected to the received notion of informed consent. In particular, they stick to the idea of "non-competence" (Manson and O'Neill, 2007, 192–194). In doing so, they only go halfway in applying their revised concept of informed consent as "transactions between agents." With regard to the standards for communication, they are correct in stating that "adequate accuracy is more important than illusory completeness" (Manson and O'Neill, 2007, 90). However, it is equally correct to stress that only "adequate capacities" are needed. Yet, at this point, Manson and O'Neill make use of a moderate form of paternalism:

> [In medical research] the task is not to find a new way of obtaining consent that is easier for those whose ability to consent is impaired. Rather the task is to ensure 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. (Manson and O'Neill, 2007, 193)

This familiar argument refers to "hypothetical reasons." But this is, at least in the context of research, not enough. The question is not whether it is reasonable to think that someone would have consented if only he could have done so. Hypothetical consent is no consent at all. On the other hand, valid consent need not necessarily depend on the capacity to fully understand all the consequences of an action.

This corresponds to the established practice of consent in other areas of human life. A nonmedical example can help to illustrate this point. Let's assume someone wants to enter premises. Normally he would need the consent of the owner. Otherwise he might be guilty of trespassing. Trespass is an offence under most jurisdictions. However, in most cases the requirements for valid consent in such a scenario are pretty low, while the standards for information are particularly minimal.

Take the example of a neighbor asking, "May I get my football from your garden?" Detailed information about the background of the request and an exhaustive explanation about the intended course of action would seem out of place. Imagine if the neighbor were to start to explain: "I was playing football with my son. He accidentally kicked the football into your garden. Now I would like to get it back. I will take the following route through your garden. It will take approximately two minutes. I do not expect any serious problems. Perhaps the bush close to the fence will lose some leaves when I get the ball." Such an explanation would obviously be odd. In other cases, the situation might be different. Now imagine that the neighbor says "I want to make a pond in my garden and in order to carry out the work I would like to get access via your garden." Under these circumstances, more detailed information seems appropriate. Take the case where the neighbor conceals that he intends to use a minidigger that will probably ruin the lawn. Then it seems fair to speak of deception. Any consent given would most likely be considered invalid in retrospect. This example illustrates that—just as Manson and O'Neill claim—the standards for information cannot be determined in the abstract, but only with reference to concrete actions.

A modification of the example above can help to illustrate the further claim that the capacities necessary for giving consent are also case sensitive. Let's assume that the garden owner is suffering from mild Alzheimer's disease. He might still be able to consent to entering the garden in order to get the football. Whether the same is true with regard to making the pond seems questionable. A full evaluation of the case would not only include considering the action in question and the capacities of the consenting person (*A*), but also the person asking for consent (*B*) and his relation to *A*. In this respect Manson and O'Neill are right in pointing to the notion of trust (Manson and O'Neill, 2007, 158–177). Trust does play an important role inasmuch as it is an important factor in complex communicative settings. But trust cannot and must not be considered a substitute for consent.

7. Objections

A serious objection to this revised understanding of consent as speech act is that it lowers the level of protection of research subjects. If persons are asked for consent to participate in an experiment they may, so the objection goes, agree contrary to their real will just because they do not understand the situation correctly. While the danger of putting research subjects at risk is always a serious ethical issue, this objection is mistaken. First of all, informed consent is a means to ensure self-determination and not protection from harm. Of course, often people refrain from actions that are harmful or risky. As a consequence, self-determination can indirectly foster protection from harm. However, in many cases people think that a certain amount of risk is acceptable and in a few cases they even affirmatively agree to being harmed for some greater aim. Informed consent is a means of allowing people to live the lives they want. Secondly, in the context of biomedical research Institutional Review Boards (IRBs) or Research Ethics Committees (RECs) have, among other things, a duty to review the risk–benefit analysis that must be provided in the course of a research proposal. If particularly vulnerable persons will be involved the acceptable level of risk is lower than in other projects. This has already proved to be an effective means of protecting against harm to vulnerable populations in the past.

A second objection to the understanding of consent as speech act is that it renders impossible to prove in retrospect that valid consent was obtained. Apparently, a research subject can always claim at a later date that in his or her view the speech act was not successful. While according to the received understanding of informed consent a researcher can point to the fact that all essential information was provided and that the research subject confirmed the receipt of this information—usually by signing a document—, under the "speech act" view the researcher seems to have no chance to vindicate his or her conduct. This objection is valid to some extend. In cases of conflict it can be really difficult to decide from outside whether a speech act was, at the time it was performed, successful or not ("But you promised me! … No, I didn't!"). However, validity and confirmability are two separate issues. To take one for the other is problematic. Rather than focusing on a fixed list of items, the information process as a whole should be documented. This should provide sufficient evidence for settling cases of conflict, so

that researchers do not have to be afraid of unwarranted allegations. A consequence of this is, however, that the documentation of consent processes might become more complex and time-consuming than it is now.

8. Outlook

The view developed here has major consequences with regard to standards for information disclosure as well as for the general scope of informed consent. This becomes particularly clear if one looks at the requirements laid down in the *Declaration of Helsinki*. It is obvious that considerable cognitive capacities are needed for grasping all the information specified there. What is less clear is that this is necessary for giving valid consent. If conceived as a speech act between two agents consent has rather different standards of success. In the particular case of biomedical research, it is essential that research participants are aware that they are consenting to participate in a research project and that this implies that their personal benefit, if there is any, is not the main concern. Furthermore, they must understand that they are temporarily allowing someone to perform an examination on them. If this examination includes measures involving considerable risks, the person asked for consent must, of course, be able to understand these risks, though in many cases the risks are rather low. At any rate, understanding the specific scientific aims or the methods employed is not essential for giving valid consent. However, if a participant wants to know about these aspects he or she of course has a right to be informed in detail. The essential point is that the validity of consent does not *primarily* depend on the amount of information provided, but rather on the fact that both parties involved successfully perform a specific speech act. The conditions of success for this speech act are—as for many other speech acts—complex. The list of constraints above is an attempt to make these conditions of success explicit. Most notably, the fact that *A* understands that he or she is (temporarily) waiving a right and, in doing so, (temporarily) obligating him- or herself not to object to *B*'s doing φ is essential. This implies a shared understanding of the *impact of* φ *on A*, but not necessarily a shared understanding of φ itself. Under this approach, the concept of informed consent is seen as an activity that two persons must engage in jointly. Any attempt to

determine the exact scope of disclosure and understanding irrespective of a given context misses exactly this point. Put positively, the main focus must lie on supportive conditions for successful communication. In particular, researchers should understand the consent process as a communicative process. Manson and O'Neill have observed "that the everyday views that practitioners, patients, and research subjects take of informed consent, and of the reasons why it matters, are closer to the picture [that the authors offer and that is, at least partly, in accordance with the view developed here]" (Manson and O'Neill, 2009, 198). At the same time, they notice that implementing such an approach "would require a massive change of direction in biomedical practice" (Manson and O'Neill, 2009, 198). Above all, it calls for dismissing ever more demanding requirements for informed consent, illustrated by the growing lists of aspects that have to be disclosed to potential research participants. Instead, ways and means need to be found to foster the communication between researchers and research subjects.

Informed consent is not a myth. Rather, as a declarative speech act that can constitute institutional facts, an element of "magic" is inherent to consent. Just by uttering appropriate words under appropriate circumstances a speaker can change the normative world. Hurd is right in highlighting the importance of this possibility for persons:

> To have the ability to create and dispel rights and duties is what it means to be an autonomous agent. To respect persons as autonomous is to recognize them as the givers and takers of rights and duties. It is to conceive of them as very powerful moral magicians. (Hurd, 1996, 124)

No one should be deprived of being such a moral magician—not even with the intent to protect him or her. Informed consent can appear to be a myth. In fact, many research participants do not fulfil the high demands regarding understanding. However, understanding the complex details of research projects is not essential for valid consent. The crucial point is rather that consenting means waiving a right. Many people can comprehend this basic feature and, consequently, give valid consent. Of course, lowering the requirements for consent may invite abuse. Strong safeguards must be in place to avoid such abuses. A flawed concept of informed consent is certainly not the right way to go.

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