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# Consent and autonomy in contemporary Bioethics

Consent plays a key role in contemporary bioethics. It forms an integral part of the current consensus in the field that those who are subjects of medical treatment or research should engage in any such practices on the basis of their freely given informed consent[1].

As a moral (and a legal) notion, it carries normative force. Consent transactions are such that they make it permissible for A to act with respect to B in a way that would be impermissible absent valid consent. Consent in health care and biomedical research has been framed almost exclusively as "informed consent", which highlights the supreme importance attached to the disclosure of information to patients or research subjects. Its justificatory underpinnings have been taken mostly to lie in the principle of respect for patient (or research subject) autonomy and the right to self-determination.

One of its major historical origins goes back to the Nuremberg Code (1947)[2]. In article 1, the notion of voluntary consent is introduced as a necessary prerequisite of any kind of research involving human subjects:

[1] There are different domains of consent, such as consent in sexual relations, in commercial transactions, in the law, or in political relations as the basis of political obligation. Consent in medical contexts has for decades been discussed in isolation from similar discussions in political philosophy, contract theory or sexual ethics. This has been changing in recent literature. Cf. Franklin Miller and Alan Wertheimer (eds.), *The Ethics of Consent: Theory and Practice,* Oxford, Oxford University Press, 2010.

[2] http://www.cirp.org/library/ethics/nuremberg/. For a reconstruction of the historical context and, particularly, developments prior to the Nuremberg Medical Trial, see Paul Weindling, "The Origins of Informed Consent: The International Scientific Commission on Medical War Crimes, and the Nuremberg Code", *Bulletin of the History of Medicine*, 2001, 75/1: 37-71. Also, see George J. Annas and Michael A. Grodin (eds.), *The Nazi Doctors and the Nuremberg Code,* New York, Oxford University Press, 1992.

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as *to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion*; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

The next important transition, which marks a transformation in the conceptualization of consent requirements, is the World Medical Association Declaration of Helsinki (1964), a rolling document with successive reformulations, which extends the centrality of informed consent in the context of research globally and offers a far more elaborate account of consent procedures. In its 2013 formulation, it stresses:

> Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary [... ] no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees"( article 25).

Detailed processes are specified immediately afterwards:

> […] each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. 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 specific information needs of individual potential subjects as well as to the methods used to deliver the information (article 26)[3].

Emphasis is given on procedure, whereas nothing is said about individual autonomy.

The Council of Europe's Convention on "Human Rights and Biomedicine" (Oviedo, 1997)[4], in article 5**,** states that "an intervention in the health field may only be carried

[3] http://www.wma.net/en/30publications/10policies/b3/. The World Medical Association Declaration of Lisbon on the Rights of the Patient stresses that patients everywhere have a right to self-determination and to information, cf. http://www.wma.net/en/30publications/10policies/l4/index.html (revised 2005).

[4] http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm. In the Explanatory Report which accompanies the Convention it is stated that the above article "makes clear patients' autonomy in their relationship with health care professionals and restrains paternalist approaches which ignore the wish of

out after the person concerned has given free and informed consent to it". The person must be given "appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time". In Article 26, the consent requirements are extended to all contexts of research, and it is stressed that the necessary consent should be given expressly and specifically and it should be documented.

Some interesting comparisons and contrasts may be drawn. The Nuremberg Code addresses only contexts of medical experimentation involving humans. It lays emphasis on the ability to consent, thus children, demented individuals, prisoners or otherwise detained persons are to be excluded from taking part. A key clause for valid consent is "the absence of any element of *force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion*". The Helsinki Declaration, on the other hand, makes explicit specification of procedures for obtaining consent and extends the requirements to health care contexts. Further, in the Oviedo Convention the scope of informed consent requirements extends to the acquisition, possession, storage and dissemination of medical and genetic data (databases, biobanks). Different types of information are acknowledged and particularly detailed emphasis is again given to procedures. The demand for "multidisciplinary review of consent's ethical acceptability" is formulated, whereas its association with individual autonomy is established.

Overall, in international documents there has been a gradual shift toward specification of detailed processes of consent and a close link to rights-based discourse coupled with appeal to the principle of individual autonomy.

*Conceptual requirements of consent*

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the patient" (§ 34). It then underlines the importance of the information being presented clearly so as to place the patient in a position "through the use of terms he or she can understand, to weigh up the necessity or usefulness of the aims and methods of the intervention against the risks and the discomfort or pain it will cause" (§ 36).

The idea of "informed consent" is well entrenched in medical care and medical research and forms an outstanding feature of bioethical reasoning. It is taken to signify a paradigm shift from a discredited model of medical paternalism in medical ethics. Despite its pervasiveness, however, the notion is complex and not always clearly understood.

"Informed consent" is literally a pleonasm, granted that if the agent is not sufficiently informed, then we cannot talk of his/her giving any consent at all. For consent to be capable of exerting normative guidance, it has to be based on the appropriate kind of cognition and the appropriate kind of choice. It has to be informed and free. Consent that is not informed (e.g., it is based on ignorance or deception) or not free (e.g., it is the result of coercion or duress) cannot morally legitimize action. If a distinction between genuine consent and a spurious substitute of it is to be sustainable, then specifying the conditions for "free" and "informed" consent practices is of crucial methodological importance.

The above core conditions (that it be given freely and on an informed basis) need to be interpreted and the subject of consent needs to be properly specified. For there to be valid consent, somebody has to have the relevant capacity or competence to consent. This means, in turn, that competent persons will be able to understand and apply the information that is relevant to the decision and will be capable of forming their own judgement and make their own decisions, free from the influence of others.

Put slightly differently, consent is valid in relationships between "consenting adults", and this implies between agents who are "in the maturity of their faculties", as John Stuart Mill would put it[5]. Consenting agents should be appropriately informed, should have the capacity to understand the information furnished and should also be in a position to make a voluntary choice either to accept or to refuse the intended intervention. Determinate cognitive and volitional capacities need to be specified.

However, such determination is a thorny issue. Regarding volitional capacities, firstly, we need a defensible conception of free and voluntary action; secondly, we need

[5] John Stuart Mill, "On Liberty", in *Utilitarianism, On Liberty and Other Essays,* Mary Warnock (ed.), London, Fontana, 1962, p. 189.

a clear conception of its application in diverse contexts that will enable us to interpret specific acts as being free and voluntary or otherwise. At a minimal level, this requirement implies that genuine consent cannot be the product of undue influence, manipulation, explicit or implicit forms of coercion. However, beyond this bare minimum, the concept of voluntariness is indeterminate and its conceptualization controversial. As the philosopher Bernard Williams has aptly suggested, in ethics we should not put too much weight on the fragile structure of the voluntary[6].

Equally challenging conceptual puzzles relate to the requirement that consent should be "fully informed". Genuine consent as to what happens to oneself in medical contexts implies the informed exercise of a choice. However, how much information should be made available before one's consent is sufficiently informed? Who should regulate the flow of information, the doctors or the expectations of the patients, and why? How wide should its scope be, and how complete, in order to be adequate? By which criteria can this be settled? How do medical practitioners exhaust their obligation to inform the patients? How can the criteria of assessing patient's competency to understand the relevant information be identified? Such puzzles tend to produce conceptual instability in the notion of consenting. In an attempt to meet difficulties, much emphasis has been given to formalizing and standarizing procedures, expressly given through written documentation, although it is understood that genuine consent requires far more than a mere signature on a form[7].

*The scope of consent. Its relevance, necessity and sufficiency*

[6] Bernard Williams*, Ethics and the Limits of Philosophy* , London, Fontana Press, 1985; Bernard Williams, "Voluntary Acts and Responsible Agents", *Oxford Journal of Legal Studies*, 1990, 10/1: 1-10.

[7] For a discussion of complexities in the consent process, see Arthur Caplan, «If It's Broken, Shouldn't It Be Fixed? Informed Consent and Initial Clinical Trials of Gene Therapy», *Human Gene Therapy,* 19/1, 2008: 5-6. Also, for empirical studies assessing subject comprehension of written informed forms and showing limitations which undermine a voluntary choice, see L. A. Siminoff, "Toward improving the informed consent process in research with humans", IRB Suppl., Sep-Oct. 2003, 25/5:S1-S3.

Consent concerns the patient's agreement to an intended act or proposed decision of a specialist, doctor or researcher. It legitimizes morally (and legally) a doctor's or researcher's intervention which would otherwise be illegitimate. However, consent is not necessary in all medical contexts where decisions about interventions have to be made. It cannot be required in medical emergencies, where action taken without consent is morally required precisely because it is an emergency. It cannot be required of patients who are clearly not competent to consent (or refuse consent), e.g. patients who are comatose, retarded, mentally deranged, or indeed infants or young children[8]. Often in medical practice, many people seeking medical care are not in the "maturity of their faculties", either temporarily or permanently. These are discussed as the "hard" cases. When consent is not possible because one or more of its conditions are absent, there is consensus that we have to rely on criteria derived from considerations involving some degree of paternalism, either in the form of best interests or substituted judgement. There are further limitations, however. In some cases, people may not be intellectually competent but under duress or such forms of constraint that they are vulnerable and unable to exercise free and un-coerced choice (e.g. soldiers or prisoners), something which makes it morally problematic to recruit "volunteers" from such groups as subjects of experiments or clinical trials.

A large area where informed consent procedures cannot be validly invoked is that of public health, where policies address groups or the whole of the population. If a person contracts HIV, then his /her right to sexual freedom may be trumped by an interest in public health. As the British Nuffield Council on Bioethics has put it, quarantine is recommended as an effective part of the control of infectious disease, for

[8] Onora O'Neill, in a number of publications, has systematically analysed the structure of consent practices in treatment and research and highlighted forcefully its limitations in decision-making. The remarks that follow are much indebted to her arguments. See her "Informed Consent and Genetic Information", *Studies in the History of Philosophy of Biology & Biomedical Sciences,* 2001, 32/4: 689-704, particularly 691-694; "Some limits of Informed Consent", *Journal of Medical Ethics,* 2003/29: 4-7; "Informed Consent and Public Health", *Philosophical Transactions: Biological Sciences,* 2004/359: 1133-1136*; Autonomy and Trust in Bioethics,* Cambridge, Cambridge University Press, 2002, particularly, ch. 2, 7; also, Neil C. Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics,* Cambridge, Cambridge University Press, 2007.

"while it is an individual's choice to accept or not accept treatment, their choice has to have limits when it impinges on another person's right to health"[9].

Public health is an area where consent requirements have limited application. In this domain, some measures provide public goods as opposed to private ones. The latter refer to kinds of goods, such as commercial products, which are distributable to individuals, and thus the intended act can be dependent on the consent of those involved. Public goods, on the other hand, are not individually distributable; nobody will have less of them if others also enjoy them (e.g. safe roads); it is impossible to exclude others from enjoying them if they are provided, whereas their enjoyment by additional people has no extra cost (e.g. safe foods). Put differently, nobody can be excluded from enjoying them on the ground that he has not paid for them, but they can be enjoyed by all without somebody's enjoyment undermining their enjoyment by others. When it comes to public goods, the morally required decision cannot rely on individual choice. It is not morally acceptable to subject or adjust, for instance, the requirements for food safety or the quality of water or clean air to individual choice.

Some public health measures have to be compulsory and not a matter of individual consent. Here questions of justice arise, which concern the legitimation of compulsion. The latter takes us to considerations concerning the democratic procedure, and in this way to arguments in political philosophy.

Another area where individual rights may be waived, and informed consent practices may be set aside, is in health care uses of information involving third parties, disclosed without their consent. The nature of medical information is such that often it is disclosed to medical practitioners (family history, genetic information, etc.) without the consent of all with whom the information is associated. We do not expect relatives to give their consent when a patient is asked to give information about family history and disposition to disease. Indeed, such a requirement would be impractical if not completely unrealizable.

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[9] Nuffield Council for Bioethics, *Public Health: Ethical Issues,* London, Nuffield Council for Bioethics, 2007, p. 72.

In addition, rapid advances in biomedical technologies, particularly in genetic information technologies, make possible the storage of vast amounts of information and data, which may be accessed and used in the future for purposes of research. Advances in genetic information technologies make it feasible to gather and store massive quantities of complex information in ways which exceed individuals' abilities to grasp what is at stake, or to give genuinely informed consent. Gathering medical and genetic data in databases creates additional ethical challenges. Seeking case-by-case consent procedures in any future use may be extremely difficult and unrealistic. Here, other means have to be employed in order to protect the subjects/donors from harm and forms of deception or manipulation, violations of privacy and their personal autonomy. It ought to be stressed, in addition, that the use of previous patients' data is crucial in understanding disease as well as finding cures. Stringent requirements for seeking each and every one's consent in each particular future use in research may lead to unnecessary, impractical and morally pedantic restrictions on scientific research.

What the above considerations show is that the requirement of consent should not be overstressed or exaggerated. It cannot be considered as necessary for all ethically permissible medical practices. As we saw, it cannot be required in cases of incompetency, it cannot be asked from vulnerable or dependent subjects such as prisoners or soldiers, it cannot be invoked in choosing many public health policies, or in all cases of third party disclosure of information in medical diagnosis or research. In addition, its invocation becomes difficult in cases of storage and use of medical data at a large scale.

On the other hand, the existence of consent does not immunize acts from moral criticism. It is not always a sufficient condition for the moral permissibility of an intended act (or for its lawfulness). If it were a sufficient condition, this would entail that, if somebody agreed to be eaten by a cannibal, the cannibal would do nothing morally wrong to the person who so consented. Consensual torturing, consensual slavery, consensual cannibalism, are morally reprehensible despite any permission expressed in their favour. Certain acts are morally illegitimate regardless of whether the

person affected consents to their performance. Particularly, if fundamental moral principles are been violated, irrespective of whether the act in question is performed with the consent of those affected, consent is not normatively binding and has no obligatory force[10].

In addition to the above limitations regarding its scope, there are also deeper, conceptual, difficulties surrounding the notion of consent. As Onora O' Neill has forcefully argued, consenting, like believing, desiring, expecting, hoping, is what philosophers call a "propositional attitude"[11], which means that the consenting person consents to the intended act or practice only under a certain description of it. And there may be numerous such descriptions of a specific act. Consenting is directed at a specific proposition that describes an act of intended intervention or treatment. Any such intervention can be described in many ways. Even in the "easy", ordinary, cases as opposed to the "hard" ones, subjects consent to a specific description of an intended act, and they may not be aware of others, let alone of what is entailed by it, or what certain results produced by it might be. Propositional attitudes are "opaque"[12]. The consent given to one description cannot extend to all relevant descriptions. This conceptual and semantic issue is pertinent and causes ambiguities in discussions in bioethics.

Often a demand is raised to improve the consent procedures by specifying more closely the requirements of information and by making more explicit the conditions of consenting. Consent, it is claimed, should be explicit and direct, rather than implicit and indirect, and specific rather than generic. This is thought to be safeguarded by stipulating formal procedures and written documentation, mostly targeted at avoiding complaints and litigation. Implicit consent, on the other hand, is inferred or implied

[10] Cf. Mill's argument against the legitimacy of the position of the "contented slave", in "On Liberty", ch. 5.
[11] Onora O'Neill, "Informed Consent and Genetic Information", *op. cit.,* 691-694; "Some limits of Informed Consent", *op. cit.,* 5-6; *Autonomy and Trust in Bioethics,* pp. 42-44, 154-155; Neil C. Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics,* pp. 12-16, 42-43, 45.

[12] The phrase belongs to Quine, quoted by Onora O'Neill in her analyses mentioned above. See W. v O. Quine, 'Reference and Modality', in his *From a Logical Point of View ,* New York, , Harper Torchbooks, 1953, pp. 139–59.

from a patient's action (e.g. the action of rolling up one's sleeve and offering one's arm in a case of venipuncture), and no formal documentation is required.

However, explicit consent is not self-standing. It relies on background conditions of understanding which remain implicit. Even the longest description of conditions cannot be complete. Similarly, demands for specificity are a source ambiguity. Specificity concerns the particular descriptions to which consent is given. But how specific should a description be in order to be morally adequate? Here, too, the problem is that the descriptions given are always incomplete, and one can give more and more specifications *ad infinitum*.

Epistemologically speaking, understanding information cannot but be selective. The consent subsequently given relies on a selective understanding of a proposition conveying information about a future act. It depends on a whole host of implicit and indirect norms, and no matter how hard one tries to specify necessary and sufficient conditions, the latter will depend on a whole framework of rules and principles which are implicit and indirect.

The above epistemological point becomes particularly prominent in medical contexts, where decision-making rests on a cognitive asymmetry between doctors (and researchers) and patients (and research subjects). The complexity of medical information but also diagnostic uncertainty may cause additional obstacles. It is a false idealization to think that patients can grasp and understand fully all the information that concerns them. The danger is to create a highly idealized picture of the patient, an extremely inflationary conception of individual consent, and extremely unrealistic requirements for individuals who, precisely because of illness, are vulnerable and of limited capacity of exercising "fully" informed, voluntary choice.

To sum up so far, there are systematic limitations to the justification that informed consent processes can offer. On the one hand, consent cannot be considered as either necessary or sufficient for all morally acceptable medical interventions. On the other hand, in contexts where it is required, it is important not to lay too much stress on exaggerated, idealized, models of "fully" informed, "fully" explicit and specific consent

procedures, as formally documented. It is important to take into account the vulnerabilities and specificities of those required to give their consent.

*Models of consent and their justificatory framework. The principle of autonomy*

A viable perspective on consent in bioethics requires a broader understanding of its ethical environment. A background moral theory is needed upon which its justification can be drawn. Some take as their starting point the notion of patient autonomy. However, the notion of autonomy is vague and many diverse conceptions of it are invoked in contemporary discussions[13].

Contemporary rights-based theorists relate the justification of consent to a principle of individual autonomy, understanding the latter as a capacity exercised by individuals that entails recognition of their right to make their own choices, to exercise control over their own person and privacy and say "yes" or "no" to what may happen to them. It is a prevailing idea in bioethics that individual autonomy is the basic principle for the justification of informed consent.

A paradigmatic exposition is to be found in Tom Beauchamp and James Childress, *Principles of Biomedical Ethics* (1979). Autonomy is taken to include the negative freedom which involves protection from "controlling interference by others and from limitations such as inadequate understanding, that prevent meaningful choice", and the positive freedom to "act freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and sets its policies"[14].

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[13] As Gerald Dworkin characteristically remarks, autonomy has been equated with "liberty (positive or negative…dignity, integrity, individuality…independence, responsibility and self-knowledge..self-assertion..critical reflection…freedom from obligation… absence of external causation…and knowledge of one's interests", in his *The Theory and Practice of Autonomy,* Cambridge University Press, 1988, p. 6.

[14] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* , New York, Oxford University Press, 6th ed. 2008, p. 58; cf. also, Tom L. Beauchamp, "Autonomy and Consent" in Franklin Miller and Alan Wertheimer (eds.), *The Ethics of Consent: Theory and Practice,* pp. 55-78.

Another eminent defender of individual autonomy, the bioethicist John Harris, in a characteristically Millian tone, asserts:

> Autonomy, the value expressed as the ability to choose and have the freedom to choose between competing conceptions of how to live and indeed of why we do so, is connected to individuality in that it is only by the exercise of autonomy that our lives become in any real sense our own[15].

Within the Millian frame of argument, an influential reconstruction of autonomy is that which understands it not as mere preference or independent exercise of individual choice but as involving the reflective exercise of such a choice, manifested in second-order endorsement of certain desires or preferences by an agent. It is associated with desire-driven accounts of motivation and refers to the performance of action that seeks to satisfy desires that are well ordered, to which, in other words, the agent accords second-order endorsement.

Viewed in this light, autonomy is coupled with authenticity. An agent is regarded as autonomous if and only if he/she identifies with the motivations of his/her own acts and is not alienated from them. Harry Frankfurt is an eminent exponent of this view[16]. Autonomous agents are taken to be those who possess an appropriately distanced self-reflection, such that second-order, considered desires are formed about first-order ones.

However, difficulties lurk behind this account. Firstly, second-order choosing does not mean that the chooser will adopt morally acceptable principles. Some second-order choices may conform to moral requirements, some others may not. The fact that a choice is the outcome of second-order choosing does not make it *eo ipso* moral.

Secondly, the identification of autonomy with some kind of internal individual authentication is problematic. To rely on subjective endorsement of preferences or desires just misses the point of the intersubjective nature of moral ascriptions. Conceptions of individual autonomy, whether they see it as the sheer pursuit of

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[15] John Harris, "Consent and end of life decisions", *Journal of Medical Ethics,* 2003/29: 10-11.

[16] Harry Frankfurt ,"Freedom of the Will and the Concept of a Person", *Journal of Philosophy,* 1971/ 68: 5-20.

preference or desire, or as the pursuit of the right sort of preference or desire (i.e., as second-order endorsement of first-order ones), substitute self-expression for moral obligation. In this way, a core component of moral ascription is thwarted. Moral autonomy includes an intersubjective, impersonal component. A person's autonomy is not to be judged merely by his ability privately to endorse his volitions and acts but by his ability *to control* his own acts (and volitions) under *principles* that are valid from the standpoint of all. Autonomy is an impersonally reflexive notion. To make it a matter of individual preference, albeit a second-order preference to have preferences, misses the other-involving character of moral ascription.

This brings us to an alternative way of understanding autonomy in ethics and bioethics, which is to be found in Kant's practical philosophy. In its Kantian origins, autonomy is associated with the principle of respect for persons. It is conceptualized as the "autonomy of the will" (not of individuals), and it is understood as "the idea *of the will of every rational being as a will giving universal law*"[17]. It concerns a structural feature of the obligating force of moral principles. It precisely constitutes the way in which we subject ourselves to moral principles. It states that we are subject to the requirement that all our subjective principles of action conform to a universal law through our own free will; they constitute an act of "self-legislation" ("autonomy").

Kant arrives at this conceptualization by appealing to considerations which concern the structure of human agency, that is the agents' capacity to act, to set and pursue their own ends. Moral reasoning engages with human agency, it addresses agents. His notion of the categorical imperative[18] captures the unconditionally binding, universalizable character of moral ascription. The ground of all practical moral reasoning lies in a prescription (an imperative) which is "law-like" in form and universal in scope, which make it fit to be a universal law. That moral principles are universally binding (universalizable) means that they must be ones that can be consistently endorsed as

[17] Immanuel Kant, *Groundwork of the Metaphysics of Morals* (1785) [from now on GMM], in Immanuel Kant, *Practical Philosophy,* ed. & trans. Mary J. Gregor, Cambridge, Cambridge University Press, 1996, p. 81, 88 (*Kants gesammelte Schriften*, ed. by the Royal Prussian Academy of Sciences, Berlin, Georg Reimer et. al., later Walter de Gruyter, 1900- , vol. 4: 431, 439).

[18] Kant, GMM, in Kant, *Practical Philosophy,* esp. pp.72- 86 (*Kants gesammelte Schriften*, 4: 420 – 437).

principles for all (Formula of the Universal Law)[19]. Principles which could acquire moral legitimacy would have to be ones that others could adopt, ones that other agents under similar conditions could accept as binding.

Autonomy is linked with a special kind of evaluative relation to human subjects' practical capacities as persons. Through their reasoning capacity, human subjects can conceptualize, and act according to, the fundamental requirement of respect of each other's agency, that is, according to a requirement of treating others as "ends-in themselves" and never "merely as means" (Formula of Humanity)[20]. Each human subject, *qua* person, is, in the name of his/her non-eliminable capacity for moral agency, *eo ipso* the holder of a fundamental claim to be recognized as such. The recognition of this fact is the categorical presupposition of all moral relationships between agents.

Persons are self-governing beings capable of acting on principles valid from the standpoint of all. They have a capacity to engage in reciprocal obligations. This means that under no circumstances should a person be treated as a mere means or instrument for the achievement of any other ends. Human beings, *qua* persons, deserve respect, in their individuality. Each and every human agent deserves respect of the conditions of their agency in the name of their practical competence for moral agency, and thus of a concomitant claim to be recognized as beings capable of moral agency ("ends-in-themselves").

The grounding idea of the "formula of autonomy", which succeeds that of humanity, is that each rational being, simply by virtue of being an end-in itself, makes it necessary ("legislates") that it be treated always as an end. The legislation given by each is also universal, applying to himself/herself as well as to every other rational being. Hence, the third version of the categorical imperative commands not acting on any maxim that could not qualify *as giving* universal law. In this way, Kant links autonomy with respect for persons.

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[19] "[…] *act only in accordance with that maxim through which you can at the same time will that it become a universal law*", Kant, GMM, p.73/ 4:421.
[20] Kant, GMM, pp.78-80/ 4: 428-430.

In his writings, autonomy means the "self-legislation" of moral requirements; as he puts it, the will's becoming "a law to itself". Autonomous willing is that which has the form of law, so it is expressed in law-like determinations of the will. Autonomous choosing is "law-like" (rational) choosing. "Auto-" in autonomy (or "self-" in self-legislation) is thus a reflexive and not an individualistic notion. It applies to a certain justification of principles. In morals, reasoned claims must be such that they have the form of law, that is, they must be sharable, capable of being followed by any and all reasoners. The metaphor of self-legislation links autonomy to the capacity of being a universal law. Autonomy furnishes the fabric out of which all our duties, obligations and rights are made. It is manifested in a life structured by principles which could be chosen by all, which could be fit to become "universal laws".

In accepting the force of (Kantian) autonomy, as being bound by principles capable of being principles for all, we accept the moral "fact" of other selves, and in this way the possibility of a moral community (the formula of "the Kingdom of Ends")[21]. As a structural principle of moral reasoning, autonomy requires that we act on principles that are open to others too. Thus those principles that cannot be consistently willed are those which, if acted on by some, cannot be acted on by others. In this way, coercion or deception, degradation or humiliation cannot be made into universally acceptable principles.

The biting idea in this notion of autonomy is that maxims or subjective principles are morally illegitimate if they cannot be shared. It is in this sense that (Kantian) autonomy is not a narrowly individualistic notion. It implies acting on principles making consent or dissent possible *for all*. It thus provides the basis for an account of the underlying principles of universal obligations and rights which can structure relationships between agents.

In this way the polarity between individualist reconstructions of autonomy and communitarian criticisms of it within contemporary ethics and bioethics collapses. Such a polarity misses the mark, if we take seriously the Kantian origins of autonomy.

[21] Kant, GMM, p.83/ 4: 433.

Kantian autonomy avoids the tension between an ethics of individualism and that of an intersubjective, communicative ethics, a tension found in many contemporary understandings of consent that threaten to thwart any attempts to stabilize its requirements. Persons are self-governing agents capable of acting on principles valid from the standpoint of all. Being self-governing agents, they demand respect of the conditions of their agency. They have a capacity to engage in reciprocal obligations[22] .

Fundamental rights of personality follow from the above requirements and constrain each and every act of medical intervention in treatment or bio-medical research involving human subjects. The principle of respect for persons rules out, *ab initio*, every and any form of exploitation, deception, coercion or degradation of a human being. The demand for the consent of a patient or research subject after he/she has been deceived or coerced, manipulated or humiliated violates "humanity in his/her own person", and is therefore morally (and legally) absolutely impermissible.

This model of (Kantian) autonomy offers a different route by which to justify consent, one that bypasses the conceptual and practical tensions mentioned earlier. The practice of consent stresses the importance of a *shared* decision between physicians/investigators and patients/research subjects. This shared decision relies on a communicative act that serves to alter the moral relations in which A and B stand. Consent, as a communicative act, is intended to convey to B a permission or entitlement, which, once communicated, now gives B a right that he previously lacked.

Consenting, in this context, structurally depends upon a normative network of interrelated principles which generate obligations, duties, rights. Within such a wider network, it functions as a protective shield against the intrumentalization of persons, against treating them "as mere means". Its moral significance is thus rooted in the protection it provides against violations of fundamental principles, which would otherwise wrong patients or research subjects. Consent practices demarcate invasive interventions that might cause harm or wrong to the individuals concerned, if consent

[22] Kant, GMM, p. 85/ 4: 435.

were absent. Only those who genuinely consent to a practice that affects them can waive important ethical principles that would otherwise be unethically violated.

Medical interventions are such that they may at times threaten to breach important moral (and legal) principles, from which obligations follow, such as not to intrude on others' bodily integrity, not to constrain their freedom of action, not to infringe on their privacy and their corresponding rights. The need to put aside such rights, in particularly specified and strictly demarcated circumstances, is what gives informed consent its moral strength.

Consent furnishes a powerful procedural justification of intended acts of intervention. It operationalizes fundamental ethical principles linked with respect for persons. It functions like a normative gate that a subject opens to allow another's access, something that would be impermissible, absent the act of its voluntarily opening. If we think of consent as an exercise in individual autonomy merely (or as an instance of self-expression), we overlook the complex web of underlying principles that are waived in consent transactions. There are background requirements, duties and rights, not reducible to considerations of personal choice or to merely saying "yes" or "no" to a kind of treatment, care or research practice.

As a communicative act between A and B, consent places emphasis on the *responsibility* of medical practitioners and researchers to respect those conditions that are necessary for free and equal communication between them and the patients or research subjects. It is important to get away from narrow conceptions which through emphasis on transmitting information shrink the epistemology of consenting to a transmitter- receiver explanatory model[23]. The integrity of informed consent practices is secured through an active communicative interaction between the two parties and not merely by non-directive transmission of information, on the part of doctors or researchers, and isolated individual contemplation, on the part of the patients (or research subjects). Having said that, however, the doctor's or researcher's duty is not compromised by the consent of the patient (or research subject). On the other hand,

[23] See Manson and O' Neill, *Reconsidering Informed Consent in Bioethics*, particularly ch. 4.

just because consent is necessary to neutralize an alleged violation of right, it does not follow that it creates an obligation on the doctor's part to provide the treatment in question. Consent is a response to a threatened breach of a duty, but it is not the source of obligation in that context.

In discussions in bioethics, all too often we are confronted with a double challenge, regarding the normative force of consent. The latter may be challenged from two directions, i.e., from a perspective of under-evaluation, and from one of over-evaluation or hyper-exaggeration. Over-evaluation creates highly idealized conceptions of consent, which stress formality, specificity and explicitness. Under-evaluation comes from communitarian (or "deconstructionist") critics who view it as spurious because of its taking place in contexts that undermine it (such as dominant power structures in society, which deprive agents from the necessary conceptual resources to understand properly their lives so as to exert un-coerced free choices, and so on).

We need to identify the proper place of consent in the ethical landscape. As it has been argued, its moral force is adequately secured within a justificatory framework which grounds it in the fundamental principle of respect for persons (moral autonomy). The latter has Kantian roots and links autonomy to agents' capacity of setting ends and abiding by principles capable of being principles for all. A Kantian approach grounds consent not merely in free but, specifically, in reasoned, other-regarding choice. We have fundamental moral obligations not to coerce, not to deceive, not to degrade or dehumanize other human beings. Such obligations furnish overriding reasons against imposing treatment or any practices on patients or research subjects without their informed consent.

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