Informed Consent and Autonomy

An Annotated Bibliography

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Even in the field of healthcare ethics the literature on informed consent and autonomy is immense, not to mention in philosophy and in the social sciences. Hence this bibliography is by no means complete. It is the result of selective reading. This said, it covers some of the central references in the field, and a time span from 1970 till October 2005.

The bibliography includes texts that deal with many different aspects of informed consent and autonomy, such as legal, social, and philosophical aspects. At the same time it covers both theoretical and practical aspects, and with matters such as authorization, understanding, voluntariness, decision-making capacity, disclosure, consent forms, policies, and recruitment (in research). To a certain extent it includes literature on the applications of informed consent and autonomy in different fields, e.g. biobank research, people with partial dementia, children etc.

Accordingly the references could be grouped in a large number of ways, making it easier to access for the reader with special interests. However, all classifications have their pros and cons, and most of the references discuss many of the aspects and topics at the same time, hence they would fit into many of the categories, making the list either voluminous or subject to heavy criticism due to “unfair classification”. For these reasons the bibliography is listed alphabetically, which of course has its clear disadvantages. As the text will be available in electronic form, it will possible to search for terms of particular interest.

The annotations differ in length and depth both in accordance with the character of the reference, but also with my personal interests and judgements. Hence, readers may find interesting issues not covered by the annotations. However, as mentioned above, to cover all aspects of the literature on informed consent and autonomy is far beyond the scope of this bibliography.

The objective is rather to ease the work of scholars and students who want to enter the field or just have an overview over it. Hopefully the bibliography will make their way more easy and their road less winding than mine has been.
Appelbaum PS, Liz CW, Meisel A. Informed Consent: Legal Theory and Clinical Practice. New York: Oxford University Press, 1987. The book discusses the ethical foundation of the (legal) doctrine of informed consent, mainly the ethical principle of autonomy, and both deontological and consequentialist justifications of informed consent. It investigates the legal theory of informed consent, consent in research, and consent in the clinical setting. After an analysis of the event model and the process model of informed consent, the authors argue in favor for the latter, and give a practical account how informed consent can and should be achieved in practice. Informed consent is “a doctrine and a set of practices that comprise all values and satisfy none in their entirety.”

Callahan D. Autonomy: A Moral Good, Not a Moral Obsession. The Hasting Center Report 1984; 14: 40-42. Callahan argues that autonomy is one among many values, a necessary but not sufficient condition for moral life. He believes that autonomy is tantamount to subjectivism. Although legitimate, autonomy brings a sterile and strained notion into medical ethics. “My autonomy, I have discovered, is an inarticulate bore, good as bodyguard against moral bullies, but useless and vapid as a friendly, wise, and insightful companion.”


Demy NJ. Informed Opinion on Informed Consent. JAMA 1971; 217: 696-97. In the article Demy criticizes informed consent as inimical to the moral duty of the physician to take responsibility for the patient’s care.

Dworkin G (1988). The theory and practice of autonomy. New York: Cambridge University Press. This is a collection of Dworkin’s writings on autonomy, ranging from defining autonomy, paternalism, representation, the value of choice, and informed consent. He differentiates autonomy from liberty, confidentiality, and privacy. Parallel with Harry Frankfurt Dworkin has developed a conception of autonomy as second order reflection on first order desires. Dworkin also investigates paternalism in the light of hard cases, and shows through counterexamples that the common conception of “more choice is better than less” is flawed. Dworkin also investigates various kinds of representation, such as individual interests, substituted judgement and best interest, which he differentiates from autonomy.


Faden R. Beauchamp T. A history and theory of informed consent. New York: Oxford University Press, 1986. Through an analytical approach searching for the necessary conditions for informed consent Faden and Beauchamp argue for a gradual conception of
informed consent. They refer to a theory combining notions of authenticity and freedom. Informed consent is based on an autonomous action of autonomous authorization, and subjective criteria of understanding and non-control (persuasion and manipulation). The book presents the history of informed consent, in moral theory, in law, and in research, and it points out an important change in 1957. Before 1957 informed consent was based on a beneficence model, focusing on physicians’ duties, but after this informed consent was dominated by an autonomy model, emphasizing patients’ rights. Faden and Beauchamp distinguishes between two types of informed consent, where the first is related to actions according to moral theory, and the latter refers to the status of persons in law. They show how intentionality, understanding, non-control and authorization are necessary conditions for informed consent in the first sense.


Gert HJ. Avoiding Surprises: A Model for Informing Patients. The Hastings Center Report, Vol. 32, 2002: 14-22. Gert argues that discussions of informed consent have made us believe that the information that physicians are required to give to patients consists of the information the patients need in order to make rational decisions about their treatment. Most physician give more information than necessarily needed. However, unpleasant surprises that can result from treatment should be prevented (by giving enough information), because not giving it can make patients feel betrayed (even if the information would not have changed their treatment decision).

Grundner TM. Informed Consent. Owings Mills MD: National Health Publishing, 1986. A tutorial to informed consent to research, it discusses the application of informed consent forms in research. After briefly describing the historical and conceptual background for consent the author presents practical measures to apply informed consent. A series of situations and hard cases are described and addressed in order to find solutions.

H. Tristram Engelhardt, Jr, The Foundations of Bioethics. New York: Oxford University Press, 1996. In his much referred work Engelhardt takes into the account a postmodern secular situation, where we no longer have a moral foundation for determining what is right, since we do not agree with each other about what is good. Hence, we must settle for the next best thing: a procedural, secular morality, grounded in the ‘principle of permissions’. Using the powers of our will and what is left of reason, we can agree to cooperate and to live with the contradiction expressed in the words: ‘You have a moral right to do what I and my moral friends regard as evil.’ According to Engelhardt the “principle of permission” is a moral authority legitimized by the autonomous choices of those who collaborate, that is, it is a secular moral authority guided by the common consent of the whole group.

Hyuin I. Waiver of Informed Consent, Cultural Sensitivity, and the Problem of Unjust Families and Traditions. The Hastings Center Report, Vol. 32, 2002: 14-22. Hyuin examines the authenticity conditions for waiving informed consent, and argues that the standard conception of authenticity as the result of a person’s critically reflective approval of her values is insufficient. In stead the social circumstances surrounding the acceptance of these values should be addressed. Hyuin gives five conditions for an ethically acceptable
waiver of informed consent. As the authenticity condition is important, it appears to be important to take seriously the complexity of authenticity.

**Jennings B. Autonomy. Forthcoming in: Oxford Handbook of Bioethics.** Jennings distinguishes between autonomy being a concept in theoretical ethics, in bioethics, and as an ideological concept. The divide between the two former follows the lines between moral philosophy and applied ethics. Autonomy in bioethics is much closer to Mill’s concept of liberty than Kant’s concept of autonomy; in particular it goes along the version of liberty that Isaiah Berlin dubbed “negative liberty”. In ethical theory, autonomy is a complex concept with a series of different definitions according to the context. In the social context, autonomy means being self-sovereignty, right to live your own life in your own way as long as you do others no harm, being true to yourself. Furthermore, within bioethics Jennings identifies three tenets: moral individualism, moral constructivism (features in society are products of human choice and artifice), and moral voluntarism (living according to rules given to oneself). He also distinguishes between an objective and subjective understanding of autonomy, the first referring to reason and liberty, rationalism and naturalism respectively, where autonomy moves from the first to the latter: from being the basis of obligation to being the object of obligation.

**Katz J, Capron AM. Catastrophic Diseases: Who Decides What? New York: Russell Sage Foundation, 1975: 82-90.** The Function of Informed Consent: 1) Promotion of individual autonomy, 2) promote the patient-subject’s status as a human being (protection of patients and subjects), 3) avoidance of fraud and duress, 4) encouragement self-scrutiny by medical professionals, 5) promotion of rational decisions, and 6) involvement in the public. Limitations of consent: There is a substantial impact a) of the inner world (unconscious processes), b) of the outer world (family), c) of the relationship (doctor/researcher-patient), and d) faith. The consent model in perspective: informed consent is not a single act, but a process of contracting, negotiating, and recontracting, that is, a process of bargaining.

**Kultgen J. Autonomy and Intervention: Parentalism in the Caring Life. New York: Oxford University Press, 1995.** The basic relationship between people for Kultgen is one of care, and the caring life is the highest which humans can live. However, care that is ill-considered can easily become an illegitimate intrusion on autonomy. Autonomy is a basic good, not to be abridged without good reason. On the other hand, it is not, Kultgen argues, the only good. It is sometimes necessary to intervene in the lives of others in order to protect them from harm or provide important benefits. Guidelines, must be established so that care is both respectful and balanced. Kultgen examines weaknesses in arguments against paternalism (in terms of intervention without consent) and proposes new guidelines for paternalism. This philosophical treatise explores the place of paternalism in caring for others. It provides guidelines for balancing respect for the recipients' autonomy with the good that can be provided by intervening in their lives. The key point is that the principle of paternalism requires a professional to abstain from paternalism unless there is good evidence that intervention will improve the net welfare of the recipient.

**Ludlam JE. Informed Consent. Chicago: American Hospital Association, 1978.** Overview of the court cases aiming at giving a basic definition and understanding of informed consent in order to facilitate appropriate application in the everyday practice of health care.

**Morrissey JM, Hofmann AD, Thrope JC. Consent and Confidentiality in the Health Care of Children and Adolescents. NY: The Free Press, 1986.** How are we to handle consent for children? This is the key question of the authors address by analysing the law and
its development. Key concepts are privacy and informed consent. The book covers US laws, but refers a series of challenging cases of more general nature. Informed consent is conceived in terms of “basic rights of free people: the inviolability of the human body and the right of a person to exercise complete domination of his or her own person.” (p.13)

Nikku, Nina. Informative Paternalism: Studies in the ethics of promoting and predicting health. Linköping: Linköping’s Studies in Arts and Science, 1997. In her Ph.D-dissertation Nina Nikku argues that there is paternalism inherent in giving information, that is informative actions can be paternalistic because in asking for consent you already have to give the information that the person is consenting to having given to him or her. The dissertation analyses concepts such as paternalism, autonomy and consent in order to find a way to handle this challenge. Different justifications for paternalism are analysed. Autonomy is conceived of as practical self-governance. Paternalism is justifiable under the assumption of future increase in autonomy.

Nordenfelt L. On the complexity of autonomy. In: P-E. Liss and N.Nikku (eds.) Health Promotion and Prevention. Thoretical and Ethical Aspects. Linkping: Department of Health and Society, Swedish Council for Planning and Coordination of Research, 1994: 17-23. Nordenfelt differentiates between having the ability to act and to have the opportunity to act. To Nordenfelt a person is autonomous in the full sense only if this person has both ability and opportunity to decide and act, or refrain from acting.

O’Neill O. Autonomy and trust in bioethics. Cambridge: Cambridge University Press, 2002. O’Neill argues that the conception of individual autonomy in bioethics are philosophically and ethically inadequate, and that it undermines relations of trust. She uses Kant's non-individualistic view of autonomy to provide a stronger basis for an approach to medicine, science and biotechnology. She investigates misplaced trust, as well as undeserved mistrusted. O’Neill argues contrary to conceptions of individual autonomy that procedures of informed consent contribute to trust which is a precondition to autonomy. She illustrates her arguments with issues raised by practices such as the use of genetic information by the police or insurers, research using human tissues, uses of new reproductive technologies, and media practices for reporting on medicine, science and technology.

Quill TE, Brody H. Physician recommendations and patient autonomy: finding a balance between physician power and patient choice. Ann Intern Med 1996;125:763-9. The authors analyze how medical care in the United States has moved from a paternalistic approach to patients and toward an emphasis on patient autonomy. They do this by means of two models; the "independent choice" model of decision making, in which physicians objectively present patients with options and odds but withhold their own experience and recommendations to avoid overly influencing patients, and “enhanced choice model”. The “independent choice model” confuses the concepts of independence and autonomy and assumes that the physician's exercise of power and influence inevitably diminishes the patient's ability to choose freely. It sacrifices competence for control, and it discourages active persuasion when differences of opinion exist between physician and patient. The authors promote the "enhanced autonomy" model, which encourages patients and physicians to actively exchange ideas, explicitly negotiate differences, and share power and influence to serve the patient's best interests. Recommendations are offered that promote an intense collaboration between patient and physician so that patients can autonomously make choices that are informed by both the medical facts and the physician's experience.
Rosoff AJ. Informed Consent: A Guide for Health Providers. Rockville: Aspen Publication, 1981. What was for many years the standard work on informed consent. With basis in law Rosoff gives an outline of the concept of informed consent. The book deals with a wide variety of aspects concerning consent, such as hospital responsibility assuring valid consent, consent from persons other than the patient (minors, incompetents, spouses), consent to special procedures (circumcision; blood, organ, and tissue donation), research involving human subjects, refusal consent, and proof of consent. The topics are followed by a state by state analysis with respect to law (USA). At the end a empirical study on attitudes and practices with respect to informed consent is presented.

Rozovsky FA. Consent to Treatment: A Practical Guide. Boston: Little Brown and Company, 1984. After clarifying the liability of consent, and pointing out that consent is a process, and not a form, Rozovsky explores the application of consent in various areas, such as women and reproductive matters, prisoners and detainees, minors, mentally ill or retarded people, treatment refusal, research, organ donation and autopsy. The book explores many cases and concludes with giving rules for consent.

Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92, 93 (1914). An oft cited Court case where Justice Gardozo stated that: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages.” This statement has made scholars argue that informed consent has a long tradition in law. However, others, such as Faden and Beauchamp (1986), argue that it stems from the Salgo case in 1957.

Schneider CE. The Practice of Autonomy. Patients, Doctors, and Medical Decisions. New York: Oxford University Press, 1998. Carl Schneider investigates the patients’ perspective in medical decision-making, and he finds that patients want more from doctors than autonomy; they want competence and kindness. They do not primarily want to be “empowered”, but are rather ambivalent and ambiguous. The author investigates three arguments for patients’ reason for not making their own decisions: 1) It is difficult to make medical decisions, 2) other enterprises are more pressing for the sick, and 3) the sick may want to be dissuaded from decisions they would otherwise make. Additionally he points out that they do not feel competent (lack of knowledge). He applies two models of autonomy, the optional model and the mandatory model. The latter is normally defended by the prophylaxis argument (the physicians have to be checked), the therapeutic argument (patients in control will become well sooner), the false-consciousness argument (succumbing to childlike fears), and the moral argument (patients know what is best for them, and have an obligation to become well). Schneider’s main thesis has four points: 1) The objective of autonomy can not be achieved in the modern context of depersonalized medical care and patients’ rights. 2) There is an inherent contradiction in the autonomy principle as it has been transformed from a doctrine that entitles the patient to take an active role in treatment decision making, to a mandatory view that treats patients as morally obligated to act autonomously. 3) Reluctance or incompetence by physicians has sometimes resulted in pro forma and useless autonomy rituals. 4) There are alternatives to the autonomy paradigm that may more effectively meet patient needs. He encourages us to move from consumer choice to consumer welfare, kindness being a core term.

Tauber A. Patient Autonomy and the Ethics of Responsibility. Boston: MIT-Press, 2005. The author argues that the idea of patient autonomy is an extrapolation from political and social philosophy and that it fails to ground medicine's moral philosophy. He proposes instead
a reconfiguration of personal autonomy and a renewed commitment to an ethics of care. In this formulation, physician beneficence and responsibility become powerful means for supporting the autonomy and dignity of patients. Beneficence, Tauber argues, should not be confused with the medical paternalism. Rather, beneficence and responsibility are moral principles that not only are compatible with patient autonomy but also strengthen it. Coordinating the rights of patients with the responsibilities of their caregivers will result in a more humane and robust medicine. Tauber examines the historical and philosophical competition between facts (scientific objectivity) and values (patient care) in medicine. He analyzes the shifting conceptions of personhood underlying the doctor-patient relationship, offers a "topology" of autonomy, from Locke and Kant to Hume and Mill, and explores both philosophical and practical strategies for reconfiguring trust and autonomy. Framing the practicalities of the clinical encounter with moral reflections, Tauber calls for an ethical medicine in which facts and values are integrated and humane values are deliberately included in the program of care.

Tauber AI. Historical and philosophical reflections on patient autonomy. Health Care Anal. 2001;9(3):299-319. Tauber argues that American bioethics driven by complex cultural forces united in the effort to protect individuality and self-determined choices. An extrapolation from case law to rights of patients was accomplished under the philosophical auspices of 'autonomy.' Autonomy arouse as the idea of self-governance, and although it received its most ambitious philosophical elaboration in Kant's moral philosophy, it is evident that neither his universal moral imperative nor his rigorous application of self-legislated ethical action can sustain our own notions of moral agency in a pragmatic, pluralistic society. However, Tauber argues that the Kantian position is useful in highlighting that self-governance is not equivalent to 'autonomy,' and this distinction defines the limits of autonomy in the clinical setting. A critique of Engelhardt's idea of 'principle of permission' is used to illustrate autonomy's eclipse as a governing principle for medical ethics.

Veatch RM. Autonomy's Temporary Triumph. The Hasting Center Report 1984; 14: 38-40. The triumph of the principle of autonomy in medical ethics is only a triumph over Hippocratic paternalism in medicine. It is a triumph over the domination of beneficence on the level of individual person. In the same manner, Veatch argues, the domination of beneficence has to be checked on the social level: the strive for efficiency and cost-benefit-maximization has to be by issues of justice. Hence, autonomy can only be one part of an ethics that can handle social ethical questions, that is the part that handles the special cases where community is reduced to being only one person.
Wear S. Informed consent: Patient autonomy and physician beneficence within clinical medicine. Dordrecht: Kluwer Academic Press, 1993. In order to address the shortcomings of the legal conception of informed consent, Wear promotes an event model of informed consent. The first stage of this model is comprehensive disclosure, the second stage is core disclosure, the third stage is assessment, clarification, and patient choice. He discusses different challenges with competence assessments, and points out that such assessments are necessary in few cases. Instead people should be assisted in making decisions themselves. Wear accepts emergency exception and waiver exception, but rules out the therapeutic privilege as justified exception to informed consent.

White BC. Competence to consent. Washington DC: Georgetown University Press, 1994. White shows that without competence the goals of informed consent cannot be guaranteed, that is, respecting autonomy and patient welfare. A person is competent to consent if he has the ability required for decision making in health care settings. White shows that there has been great confusion with respect to necessary and sufficient conditions to competence, and with respect to defining versus measuring competence. She identifies four general criteria for competence: informability, cognitive and affective capability, and the abilities to make and explain a decision (83). With background in the moral principles of autonomy and beneficence White’s analysis leads to a definition of competence: a person is competent to a given degree with respect to a task if s(he) possesses the requisite cognitive and affective capacities for decision-making (i.e. the person can acquire cognitive and affective information about options, cognitively and affectively consider their probabilities of achieving chosen aims, choose on the basis of those considerations, and recount the cognitive and affective decision-making process) (144). Although she provides no test for competence, White argues that the definition provides the necessary preconditions for developing such a test. She also refers to autonomy (and beneficence) to justify her definition of competence. White defines autonomy as a person’s ability to set and act according to his value structures, and argues that a person deserves respect according to what extent he is autonomous (103).
Bibliography


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