Informed Consent

Theory

The concept of informed consent is guided by these analytical components, termed elements of consent.

Disclosure: the subject receives a thorough disclosure of information about an intervention.

Comprehension: the subject fully comprehends the intervention.
Voluntariness: The subject acts “voluntarily” in consenting.

Competent: The subject is fully competent to give consent.

Consent: The subject consents, either orally or with written consent.
Two Concepts of Consent: Sense 1 and Sense 2

Informed consent as Sense 1 is “Autonomous Authorization”; the full authorization of consent as an autonomous individual. This is without duress or the need to yield to another. It is with complete and adequate information with full intentionality, in the absence of controlling influences (:278).
Sense 2 – Informed Consent as Effective Consent

- In this second sense of informed consent, it does not refer to autonomous authorization but to a legally and institutionally effective authorization.

- It is obtained through procedures that satisfy the rules and requirements of a specific institution involved in health care or research.
Less than substantially autonomous consent can be considered “valid” as an institution may establish a threshold below the level of substantial autonomy.

There may be compelling moral or policy recommendations for requiring only “effective consents”.

Photo by U.S. Army - Africa
The Concept of Autonomy for Sense 1 Informed Consent

► **Ideal State of Autonomous Person**

► The autonomous person is consistent, in command, independent, resistant to control by authorities, and the source of his/her basic values and beliefs; one’s whole life expresses self-directedness.

Photo by Nationaal Archief
Theory on Autonomous Actions

- The subject acts with autonomy only if she/he acts with
  - intentionality
  - with understanding
  - without controlling influences
The Condition of Intentionality

► Every person needs to have a fully conscious will and intention in his/her action of a judgment.

► “I never conceived of this, I never willed this,” could be a reaction of a research subject.

► Intentional acts require plans, the integration of cognitions into a blueprint for action.
Intentionality

The relationship between intentional action and action plans is that these actions must correspond to the subject’s conception, his/her plan of the act in question.

The subject has willed his/her consent in accordance with a plan. We use a model of willing, not one of wanting (Chapter 7).
Intentional consents can involve acts of tolerance; undesirable consequences or risks of harm that attend particular procedures. These are common in informed consent.

Intentionality can be measured by criteria of consciousness, reflectiveness, and correspondence to a action plan.
The Condition of Understanding

- Patients and research subjects exhibit wide variability in their understanding of information about diagnoses, procedures, risks, prognoses, and research methods/outcomes.
- Theories on understanding have focused on ideas, belief, perception, mental concepts, processes of knowing, the structures of memory and knowledge involved in word recognition, sentential understanding, and discourse interpretation.
In informed consent settings, patients and subjects need to come to understand that they must consent to or refuse a particular proposal by understanding what is communicated in an informational exchange with a professional.
Understanding One’s Action

► What does it mean to understand that one is performing a certain act? The person has total understanding if he/she correctly apprehends all the propositions or statements that describe

► (1) the nature of the action and

► (2) the foreseeable consequences and possible outcomes that might follow as a result of performing or not performing the action.
Impediments to Full and True Understanding

- That definition might not be demanding enough if the agents involved do not have adequate information about unforeseen or unknowable consequences.

- Evidentiary standards – a justified belief standard is created rather than a full and true belief standard.

- False beliefs can inhibit adequate understanding. Evidential standards can be developed for evaluating the acceptability of a belief standard.
Evidentiary standards are usually guided by theories. Sometimes theories can put forward competing standards.
The Condition of Noncontrol

- Noncontrol (free from controlling influences) has equal standing with intentionality and understanding.

- The condition of noncontrol is used with the concept of “voluntariness” which is often equated with autonomy in the literature on informed consent.

- Voluntariness emphasizes the free power to choose without the intervention of any element of force.
Voluntariness

In other treatments, voluntariness is loosely related to ideas about agency, authorship, nonsubjection to authority, privacy, personal command, authenticity and choice – all commonly associated with autonomy.

Faden and Beauchamp avoid the word “voluntariness” and use noncontrol instead.
Conditions of Noncontrol

► With completely or fully noncontrolled acts, the subject has not been the target of an influence attempt, or if they have, it did not deprive the subject of in any way of willing what he/she wishes to do or to believe.

► By contrast, completely controlled acts are entirely dominated by the will of another.
Three Main Forms of Influence

- Persuasion, coercion, and manipulation are three categories of influence on consent decisions.
- Persuasion is restricted to appeals for reason; to fully accept the beliefs, attitudes, values, intentions, or actions advocated by the persuader.
- Nonclandestine form of interpersonal influence. The persuader openly puts forward the reasons for accepting or adopting what is advocated.
From Persuasion to Manipulation

- Persuasion can be difficult to distinguish from forms of manipulation. A presentation of persuasion may contain elements like tone, manner and order, word choice, time and setting and the appearance, style and character of the presentation agent.

- These can be potentially manipulative.
People generally choose and act in the face of competing wants, needs, familial interests, legal obligations, persuasive arguments and the like. These factors are influential vs. substantially controlling.
Manipulation is a catch-all category for any intentional and successful influence of a person by noncoercively altering the actual choices available to the person or by nonpersuasively altering the person’s perception of choices.
Manipulative Influences

Manipulative influences fall into three different categories:

- manipulation of options – offering rewards, threatening punishments, increasing or decreasing options.
- manipulation of information – modifying perceptions.
- Psychological manipulation – causing changes in mental processes.
Problems of Exploitation

- Taking unfair advantage of vulnerable subjects.
- Exploitation moves into problems of justice, the distribution of benefits and burdens.
The nature of coercion is that

(1) The need to influence is based on a severe threat.

(2) There must be a credible threat.

(3) The threat must be irresistible.

A mere perception of coercion held by the subject is not enough and the subject’s conduct as a result of the perception are not sufficient for coercion to exist.
The essence of coercion is control of a person’s behavior by negative sanction of presenting a threat.

Threats are essential to coercion.

Many want to claim that very attractive offers, financial gifts, are coercive. Only the statement that a threat exist, constitutes coercion.
Coercion only occurs if the person finds the threat to be irresistible. Some threats will coerce all persons, other threats will coerce only a few persons.

A judgment of coercion must await a case-by-case analysis, depending upon the subjective responses of those at whom attempted coercion is directed.
Coercive Situations

► People can make other people feel threatened unintentionally. Illness or economic necessity present threats of serious harms that a person feels compelled at all costs to avoid.

► These circumstances create coercive situations.

► The person cannot act freely, is tightly constrained, without any alternatives. A choice is forced which could be eliminated by the coercer.
Voluntariness Reading/Questions

If a researcher came in to a poor community and offered DVDs for interviews for psychological testing to mostly single-mothers, does that violate full noncontrol (voluntariness)?

Do you believe it is appropriate or generally ethical to do this?
Voluntariness- Ques. 2

► If a drug addict needed some other drug to reduce his addiction pain, is it full non-control for him to enroll in a clinical trial to get that substitute drug?

► How ethical is this for you, do you have other approaches to this?
Voluntariness- Ques. 3

I am observing that all the students in my psychology class have agreed to participate in the professor’s psych survey. I don’t know if it will hurt my grade if I don’t do it. So I decide to participate.

Is this voluntary control?
Question 4 - Voluntariness

In your new CBPR study, most of the study participants are used to being paid for interviews. They claim that they always are asked for interviews and deserve to be paid.

What will you do?
A prisoner sees that other inmates get a weekend furlough if they participate in a clinical trial at the prison. He decides to participate in the trial in order to get the same benefit.

What do you think about this?