

# The Nature of Informed Consent



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# Key Principle



- ‘Required is the voluntary, well-informed, understanding consent of the human subject in a full legal capacity’ (Nuremburg Code)
- ‘Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.’ (Helsinki Declaration)
- ‘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 is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.’ *Schloendorff v. Society of New York Hospital*, 105 N.E. 92 (N.Y. 1914)

## Two other areas



- *Sexual consent*: sexual behavior is permissible if and only if it is freely consented to by all participants
- *Liberal legitimacy*: the exercise of political power is legitimate only if it is freely consented to by those subject to it:
- ' Men being,....by nature all free, equal, and independent, no one can be put out of this estate and subjected to the political power of another without his own consent, which is done by agreeing with other men.' (John Locke)

# The Moral Magic of Consent



- Consent is a morally transformative power exercised by will or performance whose effect is to give permission to another that they may do what would otherwise be wrong.
- Heidi Hurd: ‘the moral magic of consent’



# How does consent work?



- *Attitudinal or will* - consent might be a mere exercise of will (Heidi Hurd)
- *Performative* - it might be a particular performance (or behavior) (Joan McGregor)
- *Hybrid* combination of will and performance (more particularly a performance that is an expression of will (Alan Wertheimer)

# Conditions of consent



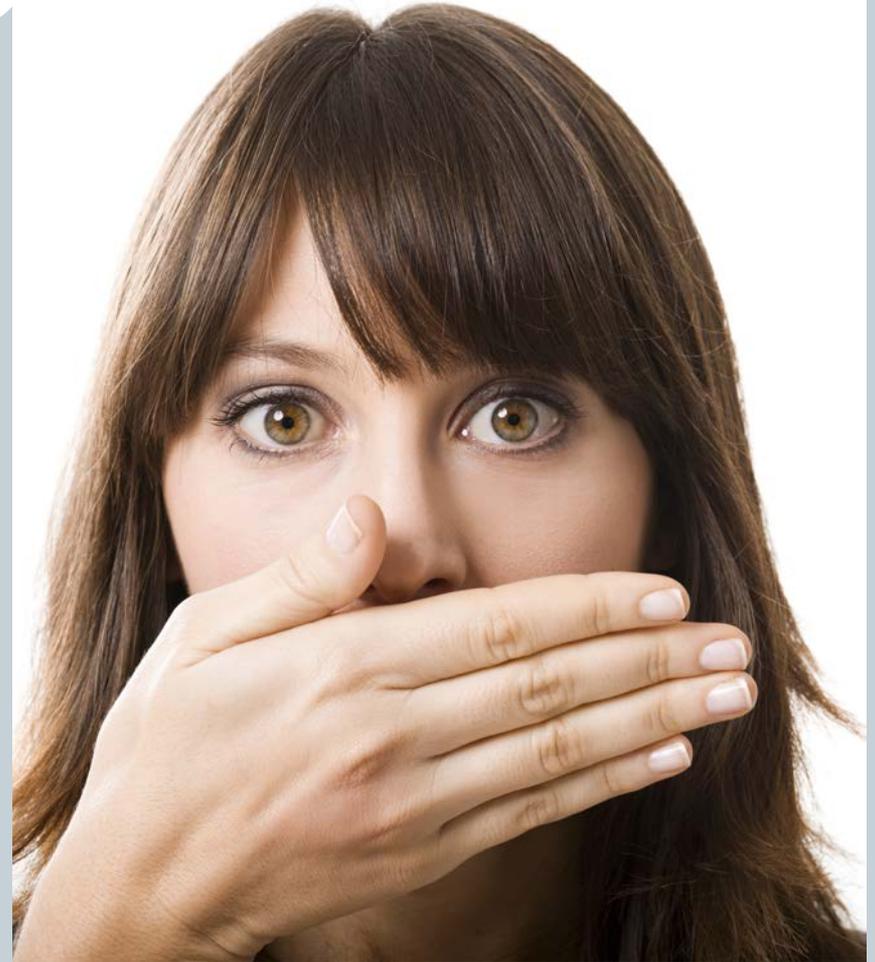
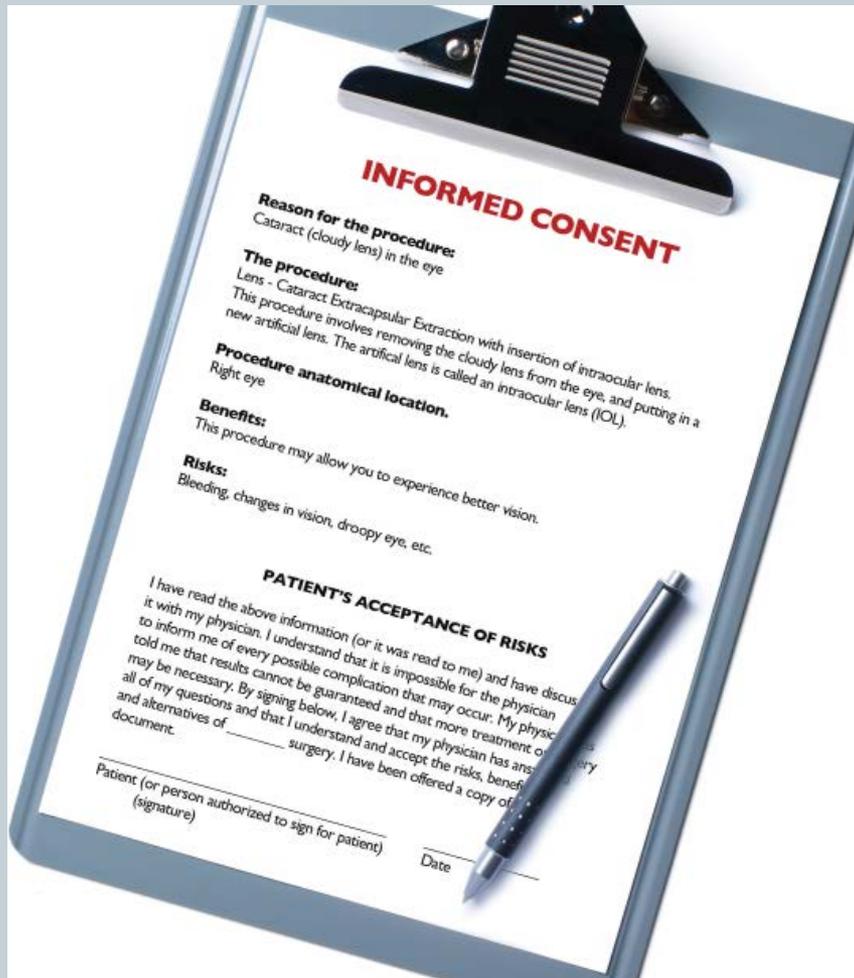
- Conditions of consent are essentially threefold:
- (i) possession of the capacity to exercise normative power that is both general (are you someone who can give and withhold consent) and particular (do you have the ability to consent to this particular action)  
Absence of two defeating conditions –
- (ii) ignorance;
- (iii) coercion.
- Thus *able, informed and voluntary*.

# Knowledge and Understanding



- General capacity is a moral power that is based on an understanding of what it is to give consent.
- Particular capacity will be a command or understanding of what it is that is being consented to. This is relative to the particular matter. The more serious the matter the greater is the requisite capacity. Note that seriousness is in two dimensions – complexity and significance.
- To illustrate: a medical decision is complex if there are many choices, or the risks are complex, or if any one option has many features, or involves difficult to grasp science
- A medical decision is significant to the extent that it makes a difference to the quality or extent of one's life.
- So whether or not to have a heart transplant is simple in terms of the options (have it or not) and easy to grasp what is involved, and the attendant risks; it is highly significant in that not having a transplant may straightforwardly shorten one's life.

# Explicit and tacit consent



# Quasi-consent/Estoppel



# Proxy consent



- *Proxy consent* is the process by which people with the legal right to consent to medical treatment for themselves delegate that right to another person.
- Distinguish between cases in which the right is explicitly (legally) delegated and ones in which that right conventionally comes with a particular relationship to the other
- Do parents have right to give proxy consent for their children's treatment and participation in research, and, if so, why?

# Ulysses contracts



- Ulysses contracts are a method by which one person binds himself by agreeing to be bound by others
- These are ethically problematic inasmuch as it seems to involve giving unwarranted weight to a temporally prior consent over a later refusal.
- Consent to  $\Phi$  at  $t_1$  is preferred to refusal of  $\Phi$  at  $t_2$ .

# Solutions to problem



- Later refusal is by person not competent to give or withhold consent.
- Different persons at different times: Derek Parfit's Russian nobleman example
- At  $t_1$  person does not just consent to  $\Phi$ , but to  $\Phi$  in circumstances  $C$  (i.e. those where the person is unreasonably disposed to refuse). So in those circumstances the refusal does not count. However then the problem is to properly distinguish between refusal in  $C$  and a well motivated refusal.

# Hypothetical consent



- *Hypothetical* consent is that which would be given by someone when in the given circumstances a person is unable to consent (e.g. unconscious)
- Evidentiary problem: how do we know or be reasonably sure we know what a person would consent to? Advance directives may work here such as DNRs
- Justificatory problem is that exposed by Ronald Dworkin: a hypothetical contract is not a paler form of an actual contract and cannot bind.
- Moreover what does the justificatory work is not the contract or consent if hypothetical but the reasons why there would have been agreement.
- So maybe if we appeal to what someone would have consented to we are honoring not their consent, albeit hypothetical, but their wishes (what they would have wanted).
- But what if what they would have wanted is not in their best interests? What weight should we give to those wishes?