The Ethics of Research with Human Participants

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20 June, 2019

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Outline for the Hour

- Territory
- Moral Case for Biomedical Research with Human Beings
- Three Perspectives on the Ethics of Human Research
  - consent
  - risk
  - justice
- Informed Consent

Territory of the Talk:

- Biomedical research with human beings
  - "healthy subjects"
  - clinical research with patients
- Increasing integration and overlap - the lines are blurring
  - biomedical research and clinical care
  - biomedical research and public health
- What's in a name
  - research with human beings
  - research with human participants
  - human subjects research
  - human experimentation

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The Moral Case for Biomedical Research with Human Beings

- Advancing human well-being
- Health as a core element of human well being
- Research with human beings necessary step towards advances in:
  - prevention, treatment and cure
  - relief of suffering, enhancing quality of life
- Someday this may change

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Three Ways to Think About Ethics of Human Research

- Research morally defensible, often praiseworthy, but also morally complex and sometimes morally perilous
- Three different ways to think about what makes research ethically complicated, three different frames or lenses
- Each lens brings into sharp relief one piece of the puzzle that is research ethics
  - consent
  - risk
  - justice

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The Consent Frame

- The moral problem: using people as means to the ends of others
- Placing only a few at risk while all stand to benefit
- What could possibly make such an arrangement morally acceptable? If the few voluntarily and knowingly agree to accept the risks
- To fail to obtain a meaningful consent is to fail to respect
  - the equal moral standing of the human participant
  - the person's dignity
  - the persons right to make choices over what happens to her own body and its information

The Risk Frame

- The moral problem: imposing unacceptable risks on human beings
- Sometimes risks so negligible and social benefits so high, consent may not even be needed

- Sometimes prospect of direct clinical benefit so great, ethics of clinical research approximates ethics of clinical practice: consent is important but clinical judgment also looms large
- **But sometimes the risks are so grave that is unconscionable to even consider asking human beings to assume them**
- Under this view, there are moral limits to what risks people can consent to
- To fail to attend first to the acceptability of the risks is to risk violating moral injunction to not harm others

The Justice Frame

- **The Moral Problem-** Failing to fairly distribute the risks and the benefits of biomedical research
- **Fairness and Risk**
- **Fairness and Benefit**
  - **Fairness to Individuals:** Fair Access to Trials with the Prospect of Direct Benefit
    - **Inclusion in research studies**
  - **Fairness to Classes of Individuals:** Fair Access to Advances in Biomedical Research
    - **Inclusion in the research agenda**

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The Justice Frame: Fairness and Risk

- **Fairness and Risk**
  - animated by concerns similar to the consent frame
  - risks on few, benefit for all: **critical who these few are**
  - it is unjust to impose risk on the socially disadvantaged, marginalized or powerless, particularly if the benefits disproportionately fall on more advantaged groups

The Justice Frame: Fairness and Benefit

- **Fairness to Individuals: Fair Access to Trials with the Prospect of Direct Benefit**
  - sometimes in the best interest of persons to participate in research (cancer, vaccine trials)
  - unjust vs acceptable justifications for exclusion
  - fair access to research is not equivalent to automatic or presumptive access
  - the stronger the potential net benefit of participation, the higher the burden of justification for exclusion
  - **inclusion in research studies**

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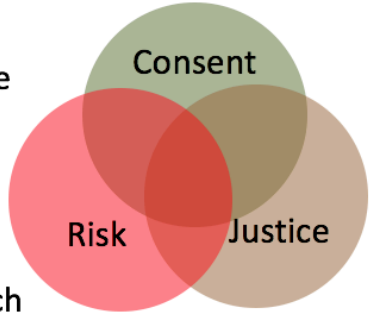
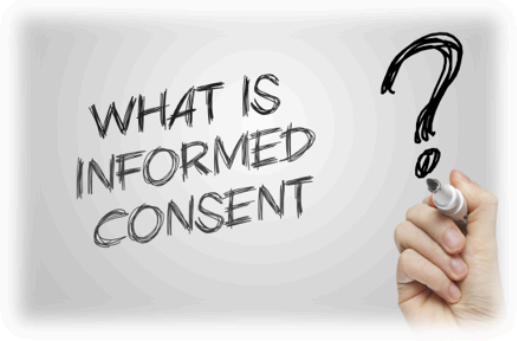
The Justice Frame: Fairness and Benefit

- **Fairness to Classes of Individuals: Fair Access to Advances in Biomedical Research**
  - societal investment in biomedical research
  - all social groups should benefit equitably from this investment
  - gaps in evidence base
  - children, women, pregnant women, elderly
  - rare "orphan" diseases
  - **inclusion in the research agenda**

Intersection of Consent, Risk and Justice

- Three frames for research ethics are not mutually exclusive
- Charged with thinking about all three, and the moral commitments they represent
- Three different lenses through which the moral issues can be viewed. Some issues in research ethics require using one lens more than the other
- Challenge of research ethics: which lens or lenses best fits the problem **without** losing sight of the relevance of the other two





- **Sense $_1$: Informed Consent as Autonomous Authorization**

- **Sense$_2$: Informed Consent as Effective Consent**

Sense $_1$: Informed Consent as Autonomous Authorization

- **An autonomous action by a research participant that *authorizes* a professional to involve the participant in research**
- Authorization as moral permission giving
  - the researcher has no moral authority to use another person in research
  - someone else with moral standing has to provide that authorization
  - in the classic informed consent context, that person, the person with moral standing, is the research participant

Sense $_1$: Informed Consent as Autonomous Authorization

- **An informed consent in sense$_1$ is given if a participant with**
  - (1) substantial understanding and
  - (2) in substantial absence of control by others
  - (3) intentionally
  - (4) authorizes a professional to enroll the participant in research

Sense$_2$: Informed Consent as Effective Consent

- **A legally or institutionally effective authorization from a research participant**

  - sense$_2$ consents are effective because they satisfy the procedures, rules and requirements of a particular institutional setting

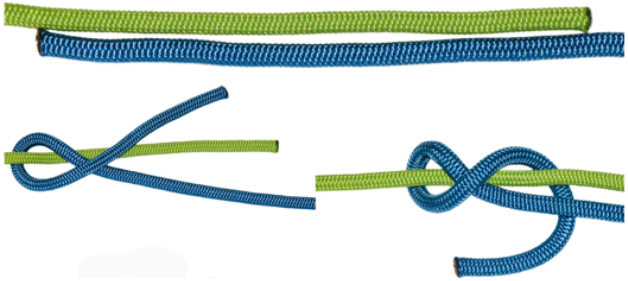
  - focus on the behavior of the consent-seeker, less on the consent giver

  - what is disclosed, not what is understood

  - what can be easily monitored and audited

Relationship of Sense$_1$ and Sense$_2$

- Sense$_1$ as the normative standard for Sense$_2$



- Sense$_2$ rules and practices are better if they result in more sense$_1$ consents (and refusals)

Challenges to Informed Consent

- **IC Sense1 is conceptually or ethically flawed**
  - relational objections
  - cultural objections
  - power dynamics
- **IC sense1 and IC sense2 poor fit for some contexts**
  - classes of people who can't consent
  - emergency contexts
  - genetics
  - big data

Challenges to Informed Consent

- **IC sense1 impossible to secure in the real world**

- **IC sense2 is completely unmoored from sense$_1$**

  Legal document fails to serve the moral values that informed consent was intended to respect

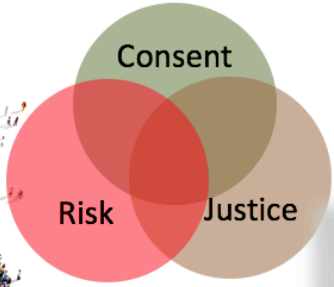
  - the equal moral standing of the human participant
  - the person's dignity
  - the persons right to make choices over what happens to her own body and its information

Future for Informed Consent

- Indispensable moral role for informed consent

- Relationship between risk and consent
  - higher the stakes, the greater the risks
  - the more dramatic the alternatives

- Rules and practices are better if they result in more sense1 consents (and refusals) **when sense$_1$ consents are morally most important**



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