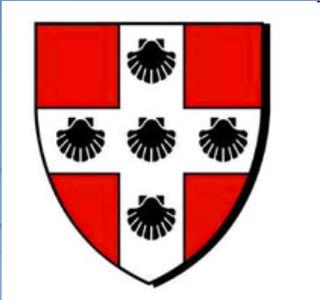
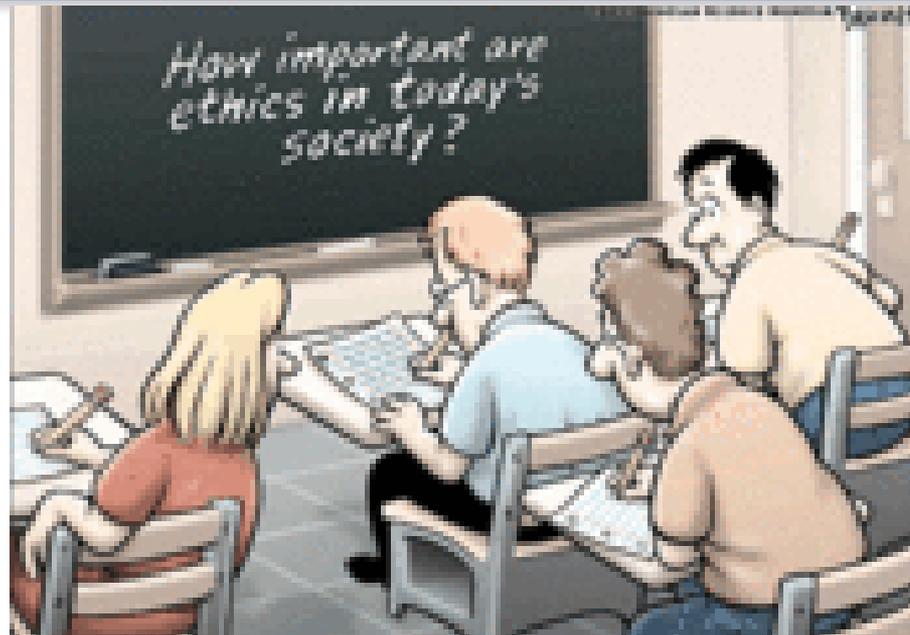


# Human Subjects Protection and the IRB



WESLEYAN  
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- **What is research?**
  - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge or prediction
- **What is a human subject?**
  - An individual about whom an investigator conducting research obtains: 1) data or 2) identifiable private information through intervention or interaction with the individual
- **What is human subjects protection?**
  - Respecting the rights and welfare of people who volunteer to help researchers by participating in their studies
  - Responsibility of the **Institutional Review Board (IRB)** to make sure all research meets this requirement

# IRB Research Decision Tree



<http://www.wesleyan.edu/acaf/support/IRB%20Chart.pdf>

- 1947 – Nuremberg Code for ethical conduct of research involving human subjects was developed
  - Nuremberg Trials for Nazi war criminals. Of the 23 physicians/scientists tried, 16 were found guilty and 7 were sentenced to death.
- 1964 - Helsinki Declaration released by the World Medical Association further developed ethical guidelines for research involving human subjects.
  - Strong focus on importance of informed consent

- 1974 – National Research Act which established a National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - Result of 1932-1972 U.S. Public Health Service study in Tuskegee, Alabama
- 1975 - Title 45 of Federal Regulations entitled *Protection of Human Subjects* was announced (45 CFR 46 – “The Common Rule”)
- 1979 – Belmont Report was presented by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  - Established 3 basic ethical principles – ***beneficence, justice,*** and ***respect for person***

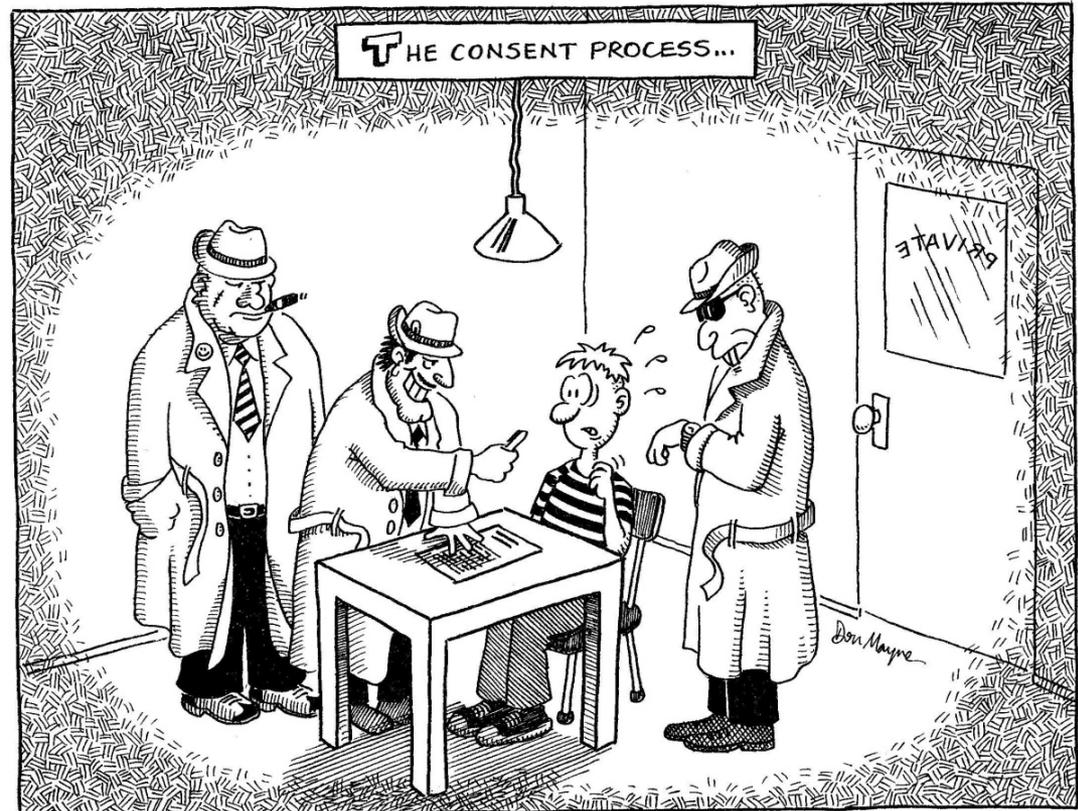
- Promoting the well being of an individual
  - Obligation to do no harm and to maximize possible benefits and minimize possible harms to the research participant
  - **Minimal risk** - probability and magnitude of harm or discomfort are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
  - One of the biggest risks is a breach of privacy
    - Need to minimize risk of confidentiality being violated

- Fairness – are the benefits to participants worth the risks of participating in the research?
- Is it justifiable for participants to take on the risks of participating if they do not directly benefit from participating?
- The benefits and burdens of research should be justly distributed. Injustice can occur when:
  - Research participants are selected simply because they are easily available or vulnerable or easy to manipulate, rather than chosen for reasons directly related to the research problem being studied.
  - Some participants are deliberately excluded

- Autonomy – the right of individuals to make their own decisions
  - Participants need to be properly informed
  - Individuals who are not able to make and carry out decisions for themselves (for example children, pregnant women, mentally or physically ill people, prisoners) must be protected from coercion by others and from activities that harm them
  - Requires that participants enter into a research program voluntarily and with good information about the research goals
    - Informed consent

# Informed Consent Process

- Not just a signature on a form
- Researchers must educate potential participants to ensure that they can reach a truly informed decision about whether or not to participate in the research
- Informed consent must be given freely, without coercion, and must be based on a clear understanding of what participation involves
- Needs to be presented in a way that is easily understood
- Vulnerable populations may require consent from a guardian. For example, children under the age of 18 typically require parental consent. In this case, children are asked to provide their assent, which is an active affirmation of a desire to participate. Differs from consent, which is recognized as being granted from an individual with the legal authority to do so.



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# 8 Basic Elements of Informed Consent

- 1) A statement that the study involves research, explanation of the purposes and the expected duration of participation, and a description of the procedures to be followed.
- (2) Any reasonable foreseeable risks or discomforts.
- (3) Any benefits to the participant or to others
- (4) Appropriate alternative procedures or courses of treatment, if any
- (5) How confidentiality of identifiable information will be maintained.
- (6) If more than minimal risk, whether there are any treatments or compensation if injury occurs and, if so, what they consist of, or where further information may be obtained.
- (7) Who to contact if participants have questions about the research and their rights, and whom to contact in the event of a research-related injury to the participant.
- (8) That participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the participant may discontinue participation at any time without penalty or loss of benefits.

# The Institutional Review Board

- Purpose is to safeguard the rights and welfare of human subjects
- Has the authority to approve, require modifications, or disapprove research

- All proposed research by faculty, staff, and students must be reviewed by the IRB or the departmental Ethics Committee



- **Exempt**

- Research that does not meet one or both of the elements of research (intervention/interaction with human subjects and generalizable knowledge or prediction)
  - **Some interviews and oral histories** that do not involve the collection of individuals' private information or for which the goal is *not* generalization or prediction
  - **Program improvement activities** where goal is to collect data that is intended *solely* for improvement of a local program
  - **Classroom activities** where data are collected *solely* for the purpose of educational demonstration
  - **Secondary data analysis** of publically available or de-identified data
- ***IRB or Ethics Committee determines whether research is exempt!***

- **Expedited**

- Research that involves *minimal risk* may be considered for expedited review
  - Anonymous – no identifying information is collected
  - Does not propose to collect sensitive information (for example information on illegal activities or medical information)
  - Does not involve vulnerable populations (children, pregnant women, prisoners)

- **Full**

- More than minimal risk
- Vulnerable populations

- Established for Psychology, Sociology, and Anthropology
- Student research that is minimal to no risk and does not involve vulnerable populations can be reviewed by the department's Ethics Committee.
- Information/Instructions for submission of protocols:
  - **Psychology:** <http://www.wesleyan.edu/psyc/resources/index.html>
  - **Sociology:** <http://www.wesleyan.edu/soc/>. Click on Guide to Obtain Ethics Approval for Research
  - **Anthropology:** proposals accepted in Spring. Instructions coming soon to the departmental web site. E-mail from Dept. Chair to Juniors in Spring with info

# How do I submit a protocol for review?

Wesleyan IRB:

- Go to the Wesleyan IRB web site:

<http://www.wesleyan.edu/acaf/support/reviewboard.html>

- Scroll down to **SUBMISSION MATERIALS** and click on the **Description of Research Form**
- Complete the form and e-mail the form and other study materials (consent forms, questionnaires, etc) to **irb@wesleyan.edu**
- Any changes in the research protocol have to be approved by the IRB/Ethics Committee before being implemented.
  - Complete and submit a **Change of Protocol Form**
- IRB approval is valid for 1 year. If study continues beyond the 1 year approval period, then a **Project Continuation Form** must be submitted

# What should I put in the IRB form?

- Follow instructions carefully
- In addition to general information about the study you will need to provide:
  - A description of the goals of the research and the methods
  - A description of the participants you want to recruit and how you intend to recruit them, eligibility criteria, incentives or compensation, potential for perception of coercion
  - Type of informed consent that will be used
  - How the data will be handled and confidentiality maintained
  - Risks and benefits to the participant
  - Debriefing protocol
- The IRB will review the protocol to ensure that federal guidelines (based on the basic ethical principles of the Belmont Report) are adhered to:
  - 1) Beneficence (assessment of risks and benefits)
  - 2) Justice (selection of participants)
  - 3) Respect for person (informed consent)

# What is Human Subjects Certification?

- Getting trained on human subjects protection principles
- Requires taking online training modules with a test
- Required for key personnel on federally funded research studies
- Passing the test will provide you with a certificate of completion that shows that you have received human subjects training
  - Quick and easy – so quick and easy that it doesn't hurt to get certified
- Where to go to get the training:
  - Links to online training are provided on the Wesleyan IRB web site
    - Human Subject Assurance Training from Dept. of Health and Human Services
    - Protecting Human Research Participants Training from National Institutes of Health
      - More comprehensive