INSTITUTIONAL REVIEW BOARD (IRB)

BASICS

"ETHICS

AND

HUMAN SUBJECT PROTECTIONS"

SOUTH COLLEGE

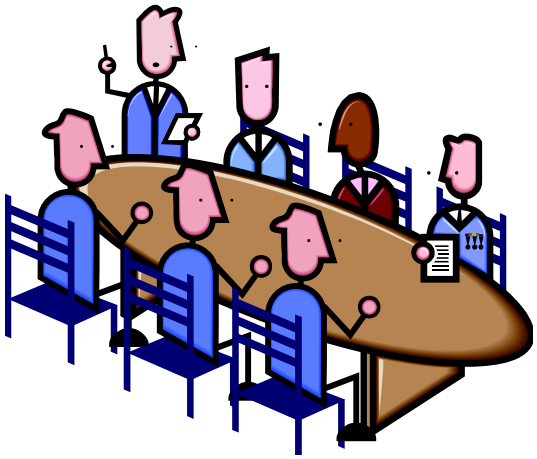
OFFICE OF SPONSORED PROGRAMS

AND

RESEARCH

IRB FUNCTION

The purpose of an IRB is to review research involving human subjects and to ensure the rights and welfare of the subjects are adequately protected.



WHY DO HUMAN RESEARCH SUBJECTS NEED PROTECTION?

Trigger Events	Ethical Milestones
The Nazi Experiments	Nuremberg Code 1947
Tuskegee Syphilis Study	National Commission for the Protection of Human Subjects of Biomedical & Behavioral Research 1974
	* Belmont Report 1978 * Common Rule 1991

THE BELMONT REPORT

- The principles of the Belmont Report govern all research supported by the U.S. Government.
- The ethical principles outlined in the report are the basis for subsequent regulations designed to ensure protection of human subjects in research.

THE BASIC PRINCIPLES OF THE BELMONT REPORT

1. Respect for Persons
2. Beneficence
3. Justice

RESPECT FOR PERSONS

- Treat individuals as **autonomous agents**
- Do not use people as a **means to an end**
- Allow people to **choose for themselves**
- Provide **extra protections to those with diminished autonomy** (i.e., Prisoners, Children, Cognitively Impaired, etc.)

BENEFICENCE

The two general rules formulated from the principle of beneficence are:

- First, **do no harm**
- Second, **maximize possible benefits and minimize risks**

JUSTICE

- Treat people **fairly**

- Fair **sharing of burdens and benefits** of the research

An injustice occurs when:

1. benefits to which a person is entitled are denied without good reason, or

2. when burdens are imposed unduly.

RULES DERIVED

- **Respect**
  - Informed Consent Process
  - Respect for Privacy
- **Beneficence**
  - Good research design
  - Competent investigators/researchers
  - Favorable risk-benefit analysis
- **Justice**
  - Equitable selections of subjects

THE COMMON RULE

The “Common Rule” is the set of regulations that were developed to ensure compliance with the principles of the Belmont Report. The regulations fall under the Department of Health and Human Services (DHHS). These regulations have been adopted by many other federal departments that regulate human research.

There are many other regulations with which South College is required to comply, such as the Food and Drug Administration (FDA), but these are all in addition to the “Common Rule.”

PROTECTIVE MECHANISMS ESTABLISHED BY THE COMMON RULE

- Institutional assurances of compliance
- Review of research by an IRB
- Informed consent of subjects

INSTITUTIONAL ASSURANCE

South College has negotiated with the Office for Human Research Protections (OHRP) that all of the institution's human subjects research activities, regardless of funding, will be guided by the Belmont Report, and will comply with the Common Rule and other regulations as applicable.

This is referred to as a Federalwide Assurance (FWA).

IRB REVIEW OF RESEARCH

All research projects involving human subjects fall into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.

- **Research Not Involving Human Subjects**
- **Exempt Review**
- **Expedited Review**
- **Full Review**

IRB REVIEW OF RESEARCH

- Complete descriptions of each research category and directions for submitting human subjects research protocols to the IRB may be found in the “South College IRB Policies and Procedures Manual for Human Subjects Research.”

- The manual and application forms may be downloaded from the South College Office of Sponsored Programs and Research website.

RESEARCH NOT INVOLVING HUMAN SUBJECTS

- Human subjects research is any systematic investigation that is designed to contribute to generalizable (scholarly) knowledge, and which uses living humans or identifiable information about living humans.

- Some research that involves coded private information or specimens does not fall under the definition of human subjects research and does not require IRB review.

- **Only the IRB can make this determination.**

EXEMPT REVIEW

- Although this category is called “Exempt,” this type of research requires IRB review and approval.
- Exempt research is research with human subjects that falls under one or more of six exempt categories listed in the federal regulations (45 CFR 46.101b)
- After initial approval, an exempt research project does not require continuing review by the IRB.
- **Only the IRB can make this determination.**

EXPEDITED REVIEW

- If the research presents no more than minimal risk to human participants and it falls under one of seven expedited categories (initial submissions) listed in the federal regulations (45 CFR 46.110), the IRB may determine that it qualifies for an expedited review.

FULL REVIEW

- Research projects that involve more than minimal risk to human subjects require full board review at a convened meeting at which a quorum of IRB members is present. For the research to be approved, it must receive the approval of a majority of those members present.

CONTINUING REVIEW

- Continuing Review of all projects initially approved by Expedited Review and Full Review is required at least annually
  - even if no changes have been made in the project,
  - even if the only project activity is participant follow-up, and
  - even if the only project activity is data analysis.

CRITERIA FOR IRB APPROVAL

- **Risks are Minimized** - Consistent with a sound research design and does not unnecessarily expose subjects to risk
- **Risks are Reasonable in Relation to Benefits**
- **Selection of Subjects is Equitable**
- **Informed Consent will be Sought** for Each Prospective Subject
- **Informed Consent will Be Documented**
- Research Plan Adequately Provides for **Monitoring the Data Collected to Ensure Safety** of the Subjects
- Research Plan Adequately **Protects the Privacy of Subjects and Maintains Confidentiality**
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, **additional safeguards** need to be included in the protocol to protect the rights and welfare of these subjects.

THE IRB HAS THE AUTHORITY TO:

- **Require modifications** prior to approval
- **Approve**
- **Monitor**
- **Disapprove** all research activities including proposed changes in previously approved human subject research.

INFORMED CONSENT

- **Information** – includes research procedure, purpose, risks, benefits, alternatives, etc.
- **Comprehension** – presentation of information must be adapted to the subject's capacity
- **Voluntary** –requires conditions free of coercion and undue influence

CONSENT FORM REQUIRED ELEMENTS

- Statement that the study involves research
- Research is described
- Description of risks
- Description of benefits
- Disclosure of alternatives
- Confidentiality
- If more than minimal risk, description of any compensation and/or medical treatment
- Participation is voluntary
- Whom to contact

ADDITIONAL ELEMENTS OF INFORMED CONSENT

- Unforeseeable risks
- Early termination
- Additional costs to subjects
- Consequences of a subject's decision to withdraw from study participation
- Disclosing new findings that may impact a subject's willingness to continue participation
- Number of subjects involved

INFORMED CONSENT PROCESS

- Informed Consent is more than just the IRB-approved document
- Initial
- Ongoing

INITIAL INFORMED CONSENT

- Take the time at the initial discussion with subjects so that they have a thorough understanding of what they are making a commitment towards

- Test subject comprehension
  - Research versus standard of care procedures
  - Time commitment
  - Randomization
  - Alternatives
  - Potential costs
  - Risks and Benefits

- Taking time upfront with potential subjects will improve subject understanding and improve retention

ONGOING CONSENT

- Every time you have an encounter with a subject gives you an opportunity to continue the informed consent process

- Discuss new information that may impact a subject's willingness to continue study participation (i.e., new known risks, benefits, alternatives, changes in study design, etc.)

- Reminding subjects of study goals and objectives will improve subject compliance with the protocol and improve retention of subjects

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