A Deeper Look at the IRB: Social & Behavioral Research

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The birth of the Institutional Review Board resulted from an unfortunate history of crimes against humanity in the name of science and research.
NATIONAL RESEARCH ACT OF 1974

- Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- Charge to the Commission:
  - Identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects
  - Develop guidelines which should be followed to assure that such research is conducted in accordance with those principles
BELMONT REPORT

- Issued April 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- Made necessary due to a long history of various questions, concerns, difficulties and problems that arose in medical experimentation and other forms of research efforts involving the enrollment of human subjects

- Distinguished between medical practice (treatment) and research

- Established the responsibility of the investigator to submit research activity for review by an Institutional Review Board
THREE PILLARS OF BELMONT REPORT

Respect for Persons

Beneficence

Justice
RESPECT FOR PERSONS

- The freedom and capacity of subjects must be protected
- Each subject is an autonomous agent
- Special measures must be taken to protect the rights and welfare of persons with diminished autonomy
- Informed consent is central to protecting the autonomy of human subjects
Researchers have the obligation to secure the well-being of subjects.

Possible benefits must be maximized and possible harms must be minimized.
Researchers question who receives the benefits of research and who bears its burdens.

There must be fairness in the distribution of the risks and benefits of the research.

Each person must equally share in the distribution of risks/benefits according to individual need, individual effort, societal contribution, and merit.
The IRB is responsible for the review and approval of all research involving human subjects
- Scientific validity
- Ethical review

Per Federal regulations (45CFR46) IRBs are mandated to maintain a specific composition
- 5 Members, Scientists, Non–Scientists, Community Members, Non–Affiliated party – minimum
Per Federal regulations (45CFR46.102(d)), research is defined as the **systematic investigation**, including research development, testing and evaluation, **designed to develop or contribute to generalizable knowledge**.
Definition for IRB purposes: (Contributing to) generalizable knowledge means that (1) conclusions are drawn from particular instances, and (2) the information from the investigation is to be disseminated.

To be considered research, the generalizable knowledge must be drawn from the results of a systematic investigation of participants.

http://research.brown.edu/rschadmin/hrpo_generalizable.php
Per Federal regulations (45CFR46.102(f)), a human subject is defined as:

- A *living individual* about whom an investigator (whether professional or student) conducting research obtains
  - Data through *intervention or interaction* with the individual, or
  - *Identifiable private information*
Individually Identifiable, as it pertains to research involving human subjects

- defined in 46.102 within the Human Subject definition – the *identity* of the subject is or may be *readily ascertained* by the investigator or readily associated with the information

- In addition, OHRP generally considers private information or specimens to be individually identifiable when they *can be linked* to specific individuals by the investigator(s) either *directly or indirectly* through coding systems

WHAT MAKES INFORMATION PRIVATE?

- defined in 45CFR46.102 within the Human Subject definition – includes:
  - information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and
  - information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)

If your project fails to meet the criteria described, then it may not be research with human subjects.

**BUT**

*The IRB makes this determination*
REVIEW TYPES

- **Exempt**
  - Must meet certain criteria
  - Differs from “Not Human Subjects Research” (designation made by IRB)

- **Expedited**
  - Must meet certain criteria
  - Does not mean “fast”
  - Reviewed by Chair and/or Designee

- **Full Board**
  - Reviewed by fully convened Board
Anonymous Surveys

Data that is “already on the shelf”
- Recorded in a de-identified fashion
  - May require a Waiver of HIPAA Authorization
  - Cannot be “coded”

Research comparing standard practice methodology in an educational setting
- No radically new instructional strategy or use of random assignment of subjects
- Common practice in elementary, secondary, or post-secondary settings
Surveys that include identifiable information
Interviews
Analysis of data collected (or that will be collected) for non-research purposes
Secondary data analysis
Video or audio recordings
Focus Groups
FULL BOARD – EXAMPLES

- Studies involving prisoners, which includes data about prisoners

- Other vulnerable populations, including children

- Information that could place the participant at risk of civil or criminal liability or may cause other societal harms (stigma, ostracism, excommunication, etc.)
  - This determination is based upon IRB policy
NOT HUMAN SUBJECT RESEARCH

- Research utilizing data or specimens from decedents
- De-identified secondary data analysis
- Non-private information
  - E.g. – Information disclosed in a public forum or that is directory information
If your project does not meet the definition of “Research” as earlier described, then it does not require IRB submission or review.

If your project is “Research” but does not involve human subjects, the IRB will make a determination of “Not Human Subjects Research”.

≠ Research = No IRB Review

Research + NHS ~ IRB Determination

Research + HS = IRB Review
The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
WHAT IS INFORMED CONSENT?

- Informed consent is central to the protection of human subjects. It is both a *process* and a *procedure*.
  - The *process* is the exchange of information that takes place between the prospective subject, and the investigator and study staff, before, during and sometimes after the study.
  - The *procedure* includes the shaping and signing of an informed consent document.
  - There are also times the IRB can waive consent.
INFORMED CONSENT

- IC is founded on the principle of Respect for Persons, found in the *Belmont Report*

- Requires that individuals be treated as autonomous agents, and that the rights and welfare of persons with diminished autonomy be appropriately protected

- The *Belmont Report* states that an autonomous agent is “an individual capable of deliberation about personal goals and of acting under the direction of such deliberation”

- Respect for persons requires that prospective research subjects “be given the opportunity to choose what shall or shall not happen to them” and thus necessitates adequate standards for informed consent
MORE ON THE “PROCESS”

- Informed consent is not intended to be a singular event, but rather the recurring “give and take” of information between the investigator and the subject.

- Each subject should *always* be allowed the opportunity to consider participation.

- Throughout the study, the investigator is expected to address questions and concerns brought forth by the subject.

- The investigator is responsible for notifying the subject(s) of any new concerns that may affect their willingness to participate.
The IRB has developed several templates to ensure that informed consent documents include all of the required elements.

There are Tip Sheets located on the IRB website at:
http://www.research.usf.edu/cs/irb_Tips.htm
Per 45CFR46.166(a), the list of required elements includes:

- A statement that the study involves research, an explanation of the purposes, the expected duration, a description of the procedures, and identification of any experimental procedures

- A description of foreseeable risks/benefits

- Disclosure of appropriate alternatives

- A statement on the extent to which confidentiality will be maintained
ICD ELEMENTS, CONT.

- Discussion of compensation and explanation regarding availability of medical treatments for research-related injury (minimal risk research only)

- Contact information for questions about research subject rights and research-related injury

- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits, and the subject is free to withdraw at any time

- Other additional elements as appropriate (i.e., HIPAA Authorization for research performed by covered entities)
WHEN CAN THE INFORMED CONSENT PROCESS BE WAIVED OR ALTERED?

- Minimal risk

- Risky “link” to the subject

- Will not adversely affect the rights and welfare of the subjects

- Could not be practically carried out without the waiver of alteration
If the IRB determines that a research protocol is designed for conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the child, provided there is an appropriate mechanism in place for protecting the children who participate.
WHEN CAN ASSENT BE WAIVED?

- If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted; OR

- The intervention or the procedure involved holds out a prospect of direct benefit important to the health or well-being of the child AND is available ONLY in the context of the research
WHERE TO BEGIN

- The IRB mandates that all investigators complete a comprehensive course on Human Subject Protections
  - The list of available courses is available on the IRB website
  - The recommended course is delivered via Collaborative Institutional Training Initiative (CITI Program – www.citiprogram.org)
  - The IRB policy (HRPP Policy 711) on investigator education may be found on the IRB website: http://www.research.usf.edu/cs/irb_policies.htm
SPECIAL CONSIDERATIONS FOR S&B STUDIES

- The highest volume of studies seen at the USF IRB are Social and Behavioral studies
  - One Chairperson is assigned to the Social and Behavioral Board
- Remember when collaborating with external agencies or organization that additional approvals may be necessary (E.g. – public school system, DOH, other universities, etc.)
- Consider the appropriateness of the documentation of informed consent prior to submitting your application
- Is it appropriate to obtain a Certificate of Confidentiality?
- Have conflicts of interest been appropriately disclosed and managed?
The Principal Investigator ultimately shoulders the responsibility for the conduct of the study, including the actions or inactions of the study team, support staff, etc.
SUBMITTING A STUDY

The USF IRB has an electronic system, eIRB

*Account Activation Takes Approximately 48 hours
The eIRB system is a “Smart Form” driven system

As you or your study team answer questions on the application, the forms will be customized to ensure that only those questions that are likely to apply to your research will appear

- TIP: It’s a good idea to answer BOTH the required questions (*) AND the optional questions to ensure a more seamless review
eIRB TRAINING MATERIALS

The staff at the eIRB Help Desk have created several tutorials for working with eIRB, including new study submissions and the conversion of paper studies.
COMPREHENSIVE eIRB TRAINING AVAILABLE

- DRIC has created a schedule of eIRB Comprehensive Workshops for 2011
  - February 23, 2011
  - May 13, 2011
  - August 12, 2011
  - November 16, 2011

- Register via TRAIN™ website or through GEMS self-service
WHAT TO EXPECT DURING REVIEW

- Once your study has been submitted, a Research Compliance Administrator (RCA) will review the application
  - He/she will notify you if there are questions or necessary revisions

- The study will be reviewed per its “category”
  - Exempt & Expedited review studies are reviewed by the Chair and/or Designee
  - Full-board studies are reviewed at the convened meetings
    - A schedule of the convened meetings is available on the USF IRB website
HOW A BOARD MEETING “WORKS”

- Each new study is assigned a primary and a secondary reviewer.
- The reviewers will present the study to the board, and will make recommendations to secure approval based upon the categories of approval found in the federal regulations.
- The entire board will discuss any controverted issues arising from the review.
- The vote will be taken and recorded in the meeting minutes.
WHAT THE REGULATIONS SAY ABOUT APPROVAL

- Risks to subjects are minimized
- Risks to subjects are reasonable
- Selection of subjects is equitable
- Informed consent will be sought from each prospective subject
- Informed consent will be appropriately documented
- Provisions for monitoring the data, protect the privacy of subjects and data confidentiality
- Additional safeguards for vulnerable populations
- Research involving children must comply with the regulations
IMPORTANT NOTES ON TIMEFRAMES

- It is important to note that the review process requires careful collaboration with multiple parties.

- Departmental approval must be obtained prior to IRB review.

- Not all studies are approved on first submission:
  - *Allow at least 30–45 days to ensure adequate time for review*
Once the approval letter has been issued, the research may commence.

All protocol amendments and/or revisions MUST be submitted to the IRB BEFORE implementation.
- This includes increases in enrollment numbers.

Expedited and Full-board studies require annual review.

Exempt studies are approved for 5 years, after which they are closed.

Once the study is complete, a final report MUST be submitted to the IRB to officially close the study.
CHAIRS

SOCIAL & BEHAVIORAL
John Schinka, PhD

BIOMEDICAL
Barry B. Bercu, MD
Janelle Perkins, PharmD

VICE-CHAIRPERSONS
Verena Jorgensen, MD
Jose Montero, MD
QUESTIONS?