IRB Workshop:
Creating an IRB Submission

Kim Fowler, CIP  Interim Director
Mysti Scheuer, IRB Analyst II

January 9, 2017
Belmont Report and the “Common Rule”

- Describes the types of research subject to regulation
- Defines key terms
- Requires a written assurance of compliance (Federal Wide Assurance – FWA)
- Requires an IRB
- List general requirements for informed consent
At the University of Georgia (UGA), all human subjects research activities come under the purview and oversight of the Human Subjects Office and the Institutional Review Board, irrespective of whether the research is funded or non-funded, minimal risk or more. The human subjects policies apply to all UGA affiliated faculty, staff, and students conducting human subjects research on or off-campus (domestic or international sites) as well as visitors conducting research at UGA.
Types of Human Research

- **Exempt**
  
  Examples (6 federally defined and 2 institutional-specific):
  
  - Certain types of educational research
  - Certain projects involving collection of data by survey or interview
  - Certain types of low-risk research limited to analysis of identifiable data
  - Most research involving taste, food quality or consumer acceptance studies
  - A full, detailed listing can be found here: [Exempt Policy](#)

- **Expedited**
  
  - No more than minimal risk and fits within certain categories described in the federal regulations (9 categories)

- **Full Committee**
Learning Check

Do I have to submit to the IRB if I am a student?

Do I have to submit to the IRB if my project is not sponsored?

Do I have to submit to the IRB if I think my project is Exempt?
Getting Started
CITI Training

- CITI Training is required of the principal investigator (PI) and all study team members prior to the submission of a human research protocol.

- PI - The PI (Principal Investigator) is a faculty or senior staff member who has primary responsibility for overseeing the design and conduct of a research project
IRB Software Applications on GeaR

[Image of GeaR website]

GeaR Applications

GeaR Blog

Georgia electronic administration of Research (GeaR) is an initiative focused on the use of information systems to support the "business of research" at UGA. This portal provides information about databases and applications that assist UGA faculty in their research activities. These include proposal preparation and submission, award management, research and safety compliance, unit membership, equipment management and core facility administration.

The GeaR Initiative operates under the leadership of the GeaR Council, which represents units of the Office of the Vice President for Research. Ex-Officio membership includes representatives of the Office of the Senior Vice President for Finance and Administration (including Accounting, Contracts & Grants and the Environmental Safety Division) and Enterprise Information Technology Services. The Office of Research Information Systems provides operational support to GeaR applications.
Practice vs. Research

Practice

Research

Action research

Planning
- identifying
- informing
- organising

Acting
- trialling
- collecting
- questioning

Observing
- analysing
- reporting
- sharing

Reflecting
- evaluating
- implementing
- revisiting

A+ Teacher
Boundaries: Practice vs. Research

**Practice:** interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success.

**Research:** an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).
Research

Research is a systematic investigation designed to develop or contribute to generalizable knowledge.
Systematic Investigation Protocol

- Has a hypothesis
- Involves a prospective plan
- An activity that is methodologically driven
- Data or information is collected in an organized and consistent way
- The data or information is analyzed in some way, usually quantitatively or qualitatively
- Conclusions can be drawn from the results
Generalizable Knowledge

**def.** – *information or themes that can be transferred to other situations*

Add to our body of knowledge

Useful to people outside of the research group
Learning Check – Is it research?

- If I am a student and my research methods class is teaching me how to construct and deliver surveys, am I doing research?
- If I am evaluating a program and I will write up my experiences as well as share my results with the program stakeholders, am I doing research?
- If I am evaluating a program and I also want to determine if the program services are as valuable to the older children as they are to younger children, am I doing research?
Human Subject

• A Human Subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
Identifiable Private Information

Information about behavior occurring in a context where public observation or recording is not expected, or information given for a specific purpose that is expected not to be made public.

Identity of subject is or may be readily ascertained by an investigator.

Private information or specimens are individually identifiable when they can be linked to specific individuals directly or indirectly through coding systems.
Ask for a Determination

- Can request a letter through the Human Subjects Office
Belmont’s
3 Key Ethical Principles

- Justice
- Beneficence
- Respect for Persons

Selection of Subjects
Risks vs. Benefits
Consent
What does the IRB need to know?

1. Subjects?
2. Researchers?
3. Study location?
4. Time period?
5. Study this topic?
6. Collect data?
7. Use data?
8. What?
9. Hypothesis?
10. Data?
11. How?
S.M.A.R.T.

S.M.A.R.T. is an acronym that is used to guide the development of measurable goals.

Each **objective** should be:

*Specific* – target a specific area for improvement.
*Measurable* – quantify or at least suggest an indicator of progress.
*Assignable* – specify who will do it.
*Realistic* – state what results can realistically be achieved, given available resources.
*Time-related* – specify when the result(s) can be achieved
Who are the participants?

- People taking part in an educational activity, medical treatment, a program activity, an outreach activity?

  OR

- People you want to invite to take part in an educational activity, medical treatment, a program activity, an outreach activity?
Vulnerable Populations

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, students, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
def. – Individuals and groups should be treated fairly and equitably in terms of bearing the burdens of research and receiving the benefits
“Recruiting” = Invitation

1. Must indicate that Study is “Research”
2. Investigator
3. Investigator’s Affiliation
4. Purpose of the Study
5. What will be expected (e.g. time, action)
6. Eligibility criteria (i.e. age range)
7. Risks and benefits associated with participation
8. May want to mention compensation
Who are the researchers?
You are engaged if you...

Consent subjects or answer questions about the research

Interact with subjects to get data

Analyze private, identifiable information
Collaborations

If I plan on collaborating with colleagues at other sites, will they need IRB approval at their own institutions?

• It depends on what they are doing

• There are options:
  ▪ Rely on one IRB
  ▪ Each institution reviews the activities they are engaged in
Where?

- In the US?
- At UGA?
What is the research setting?

• A place where something else normally happens (e.g., a school or hospital)

OR

• A place specifically for research (e.g., a lab)

Public  Private
Working outside UGA

What if you have no collaborators and you just want to recruit people from another organization?

Obtain Site Authorization if the study is conducted at or targets a specific population at a location where you don’t have research privileges.
# External Site

## Add External Site

### 1.0 Site Name:
- Give a Damn Counseling

### 2.0 Does the external site have an IRB?
- Yes  
- No  
- Clear

### 3.0 If yes, will the external site's IRB review the research?
- Yes  
- No  
- Clear

### 4.0 Attach a copy of the external site's IRB approval.

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If a copy of the external site's IRB approval is not available, please provide the status or other explanation.

### 5.0 If the external site's IRB will not review the research, will the external site rely on the UGA IRB?
- Yes  
- No  
- Clear

### 6.0 Are you required to obtain authorization/permission to recruit participants/conduct the study at the external site?
- Yes  
- No  
- Clear

### 7.0 If authorization/permission is required from the external site, attach the written authorization/permission.

<table>
<thead>
<tr>
<th>Document</th>
<th>Category</th>
<th>Date Modified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
External Site Authorization

- Person conducting Research
- Specific detail of what research entails
- Time period approved for research
- Signed by someone with authority to grant research privileges
Sharing data or samples between sites/institutions

• Obtain a Data Transfer or Materials Transfer Agreement from Innovation Gateway (gateway@uga.edu)
What will participants be doing for research? How will you collect data?

- What procedures will be followed?
- How will data be collected?
- How will researchers analyze data?
- What data will you collect?
WHEN: What is the expected time commitment for research activities?

• Is it during something that would happen anyway so there is no extra time required for research participation?  

  **OR**

• Is extra time required to complete an activity?

  *How long will the study take from start to finish?*
Beneficence

def. – Weighing the benefits of research to the risk of harm to the participants
What are the risks and benefits?

Risk associated with the activity

Value to Research Participants and Society

Must mitigate the Risks
Privacy and Confidentiality

- The IRB must determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
What is the difference between Privacy and Confidentiality?

Privacy is...

• About people
• A sense of being in control of access that others have to ourselves
• A right to be protected
• Is in the eye of the participant, not the researcher or the IRB

Confidentiality...

• Is about identifiable data
• Is an extension of privacy
• Is an agreement about maintenance and who has access to identifiable data
• protects patients from inappropriate disclosures of "Protected Health Information" (PHI)
IRB Protocol Types

- **Exempt**
  
  Examples (6 federally defined and 2 institutional-specific):
  
  - Certain types of educational research
  - Certain projects involving collection of data by survey or interview
  - Certain types of low-risk research limited to analysis of identifiable data
  - Most research involving taste, food quality or consumer acceptance studies
  - A full, detailed listing can be found here: [Exempt Policy](#)

- **Expedited**
  
  - No more than minimal risk and fits within certain categories described in the federal regulations (9 categories)

- **Full Committee**
**Common Federal Exempt Categories**

**DHHS Exempt 1**: normal educational practices in established or commonly accepted educational settings

**DHHS Exempt 2**: educational tests, survey procedures, interview procedures or observation of public behavior, unless:

The information obtained is identifiable AND any disclosure of identifiable responses outside the research could harm the subjects legally, financially, or reputationally.  
**OR**
Surveys or interviews involve children OR children are observed and the investigator takes part in the observed activity

**DHHS Exempt 4**: obtaining and analyzing existing datasets, documents, records, or biological specimens, if these sources are publicly available or if the information is recorded by the investigator so that subjects cannot be identified

**DHHS Exempt 6**: Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed
UGA Flex Exempt Categories

**FLEX Exempt 7:** Minimal risk research involving established qualitative or quantitative data collection procedures and non-physically invasive tasks and manipulations/interventions that are not meant to induce moods or emotional states.

**FLEX Exempt 8:** Minimal risk research where activities are limited to the analysis of existing or prospective data/documents/records/specimens.
Learning Check

How does the IRB assess risk?

What factors other than procedures might influence the risk assessment?

How does the IRB assess benefits?
Respect for Persons

def. – right of a person to choose or decline to participate in research, without undue influence or coercion
What is “Consent”?

Consent is a process.

Questions

Agreement to Participate
The Consent Process

To meet regulatory and ethical requirements, consent must:

• Be legally effective

• Give sufficient time and opportunity to think about it before making a decision

• NOT be coercive or unduly influential

• Be understandable

• NOT contain exculpatory language
“Consent” must include...

1. Information that clearly identifies study as “Research”

2. Clear information that participation is voluntary and volunteers can drop from the study anytime without penalties or loss of benefits to which they would otherwise be entitled

3. Purpose of the Research

4. What is expected of Research Participants (i.e. time commitment)

5. Risks associated with the Research including ways in which those risk will be mitigated

6. Benefits of the Research

7. What compensation will be provided and how it will be distributed

8. Detailed information on how Research data will be handled, including how confidentiality will be protected

9. Contact information for questions related to the research or questions about their rights as research participants
Special Considerations in Consent

Informed Consent is an active process...

- Adult Consent
- Parent/Guardian Permission
- Assent from someone not capable of giving Consent

Consent required at “18”
Waiver of Signed Consent

One of these criteria must apply...

- Linking the volunteer to the study creates the sole risk they face in participation
- There is no more than minimal risk and the activity doesn’t usually require signed consent outside of research
Consent Waiver/Alternation Conditions

- **All** conditions must be met
- No more than “minimal risk”
- Will not adversely affect the right and welfare of the subjects
- Could not be practically carried out without the waiver or alteration
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation
Learning Check

What is the Belmont principle that is addressed through the consent process?

How can I ensure that someone understands the consent process?

Do I always have to have a signed form?
After approval, what happens?

• Comply with IRB’s review requirements for any continuing reviews and modifications. *exempt exceptions*

• Report any adverse events, unanticipated problems, and/or complaints to the IRB.

• If research activities will continue beyond five years, submit a new IRB application (with some exceptions).

• Comply with IRB’s record-keeping requirements.
If the study is Exempt...

- Do not need to notify IRB for most minor modifications of exempt protocols.
  - Except...
    - If the modification disqualifies the study for exempt review
    - If there is federal funding or support
    - If there are changes to study team personnel

- Do not have to request a continuing review for continued data analysis.
What makes Good Research?

Good Science
- Problem selection
- SMART objectives
- Proper methodology
- Proper analysis

Good Ethics
- Fair subject selection
- Favorable Risk-Benefit Ratio
- Independent Review
- Informed Consent
CLICK IRB Library

https://irb.ovpr.uga.edu

Click on Library Link for:

- Policies & Procedures
- Templates
- Checklist & Worksheets
- User Guides
Online Resources

• HSO/IRB website: http://research.uga.edu/hso/

Investigator Resources

• GeaR website: http://gear.ovpr.uga.edu
• Click IRB Login Portal: http://irb.ovpr.uga.edu
• CITI Training Login and Instructions: http://gear.ovpr.uga.edu/applications-and-databases/uga-citi-login-portal
• Office for Human Research Protections (OHRP): www.hhs.gov/ohrp
Contact Information

- Human Subjects Office
  206 Tucker Hall
  706-542-3199
- Kim Fowler - kfowler@uga.edu
- Mysti Scheuer - mysti@uga.edu
IRB@uga.edu
research.uga.edu