Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

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

UGA Compliance Assurance

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

Getting Started

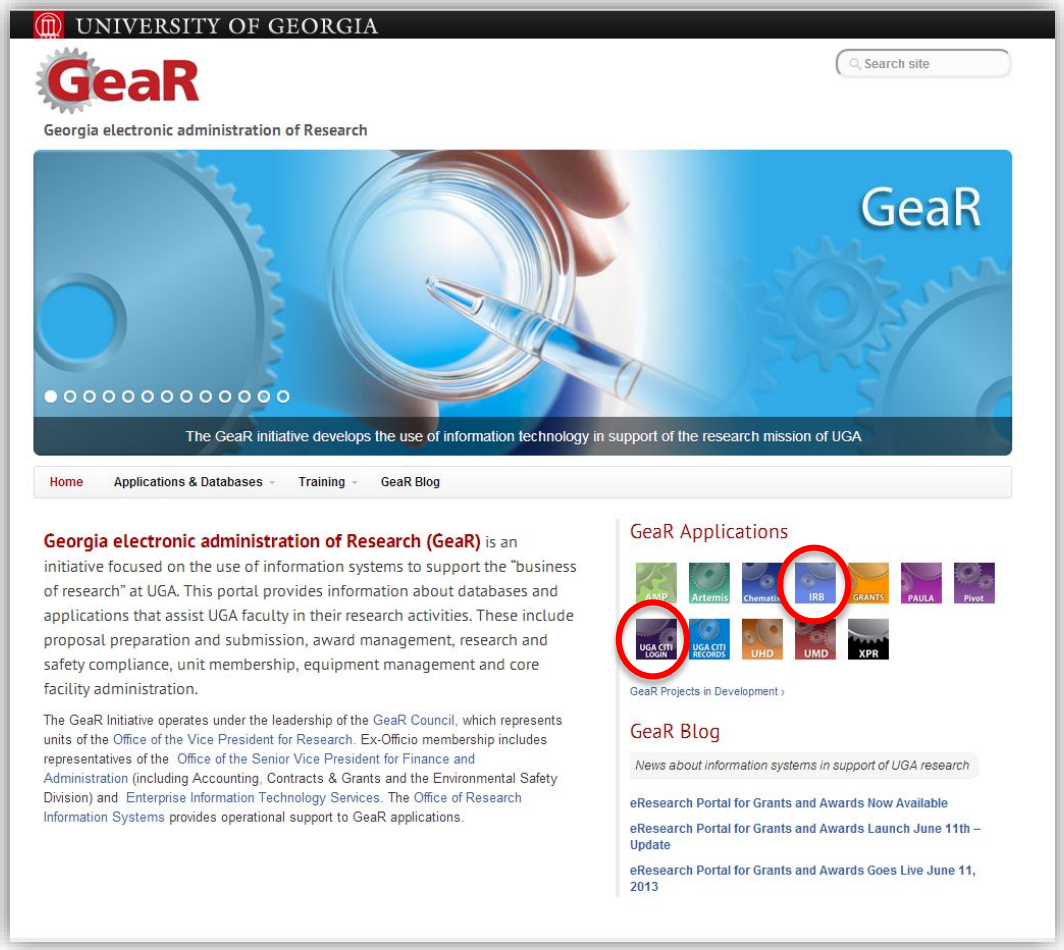
CITI Training

- 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

gear.ovpr.uga.edu



Practice vs. Research

Practice

Research

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

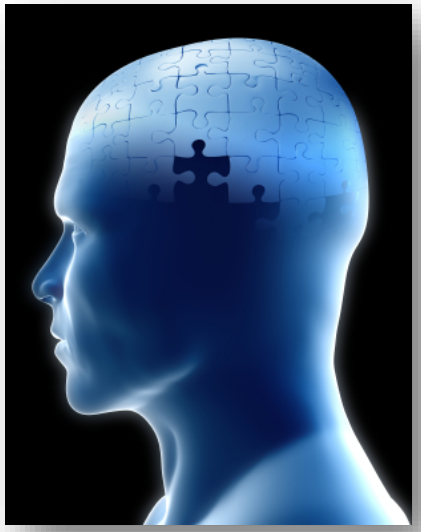
Research is a systematic investigation designed to develop or contribute to generalizable knowledge.

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

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.

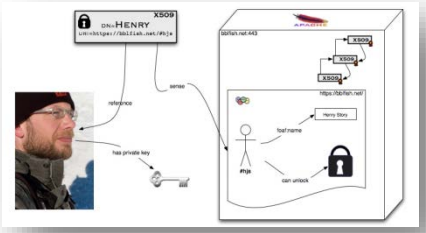
Identifiable Private Information

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

Individually identifiable

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



Private information or specimens are <u>individually identifiable</u> 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

Selection of Subjects

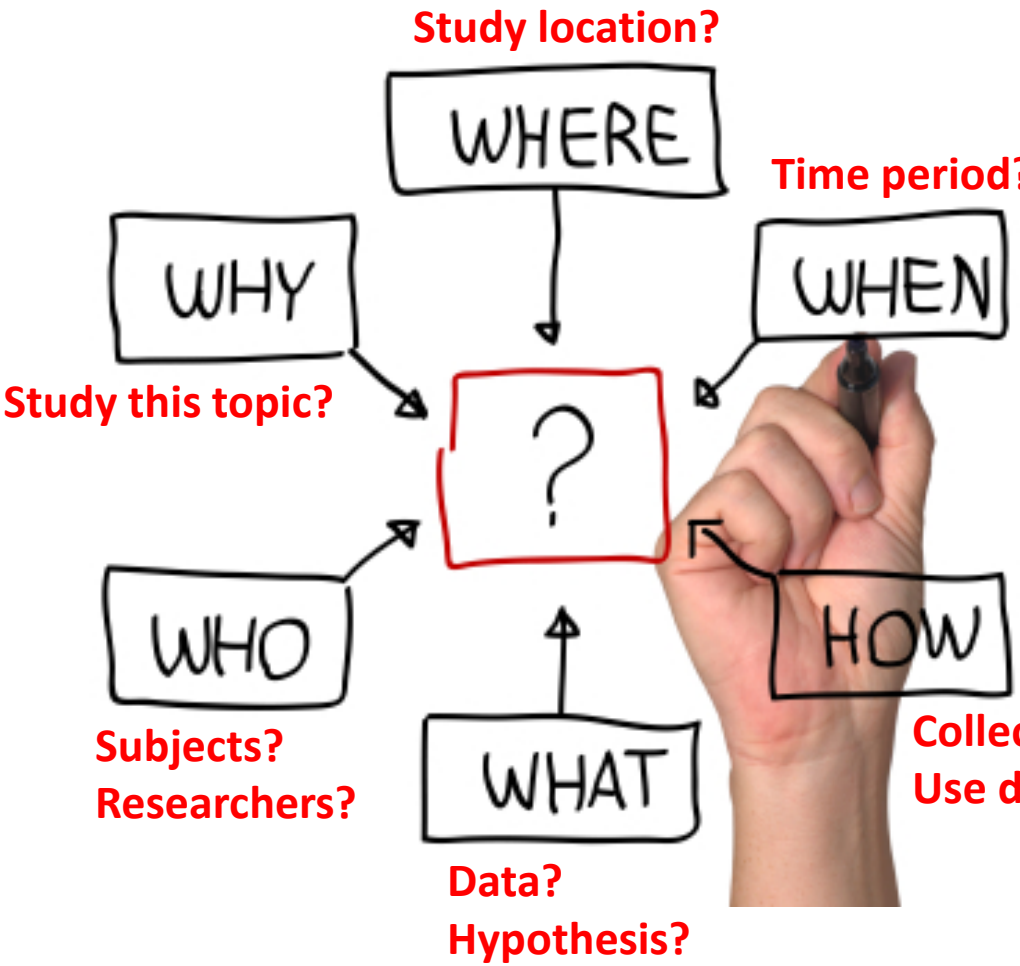
Beneficence

Risks vs. Benefits

Respect for Persons

Consent

What does the IRB need to know?



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?

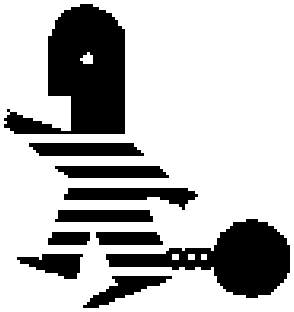
- People taking part in an educational activity, medical treatment, a program activity, an outreach activity?

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.



Justice

def. *– Individuals and groups should be treated fairly and equitably in terms of bearing the burdens of research and receiving the benefits*

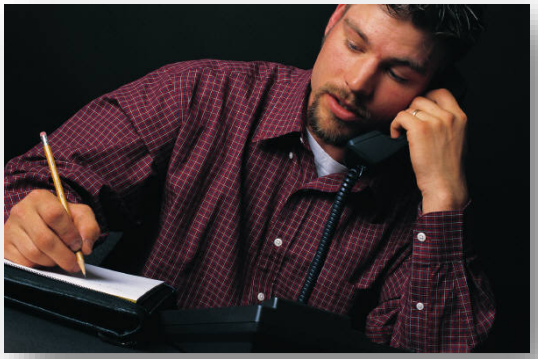
“Recruiting” = Invitation

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?

No really, where?

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)

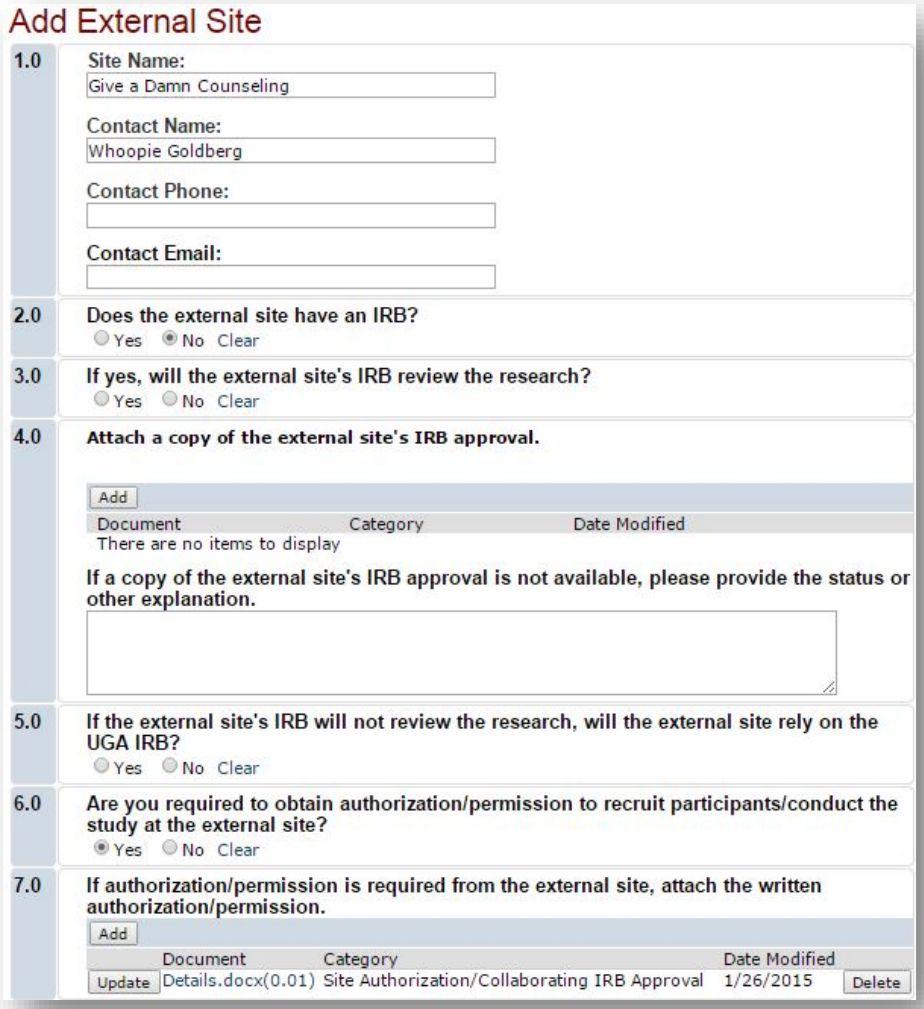
Public **Private**

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



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?

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

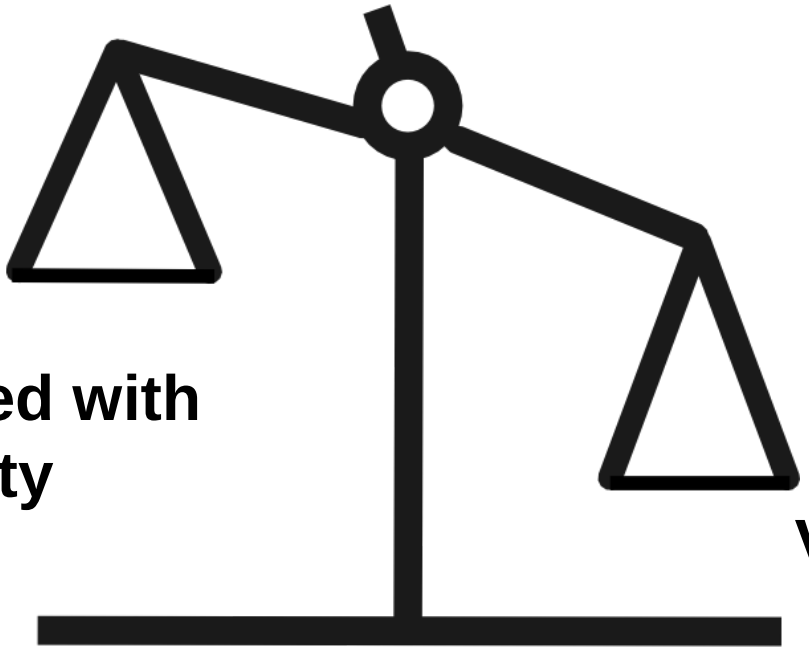
- Is extra time required to complete an activity?

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

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.

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

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”

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.

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

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.

What makes Good Research?

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

Human Subjects

Office of Research

UNIVERSITY OF GEORGIA

research.uga.edu