Navigating the IRB

What You Need to Know About Human Subjects Research

For IRB Review

For the Life of Your Research

February 9, 2011

GW Research Conference 2010-2011
A new or better understanding of IRB determinations

Common Issues seen with submissions

How your research qualifies for types of IRB Review

IRB Research Review types

Requirements and expectations of all submissions

The definition and elements of Human Subjects Research

What we hope you take with you today:
First: What is an IRB?

1. An office: “I’m going to the IRB”
2. An ethereal location: “Has my project gone to the IRB?”
3. The paperwork for research project review: “I’m going to submit an IRB”
The Institutional Review Board (IRB): An ethical review panel established to protect the rights and welfare of all human subjects in research, in accordance with federal, local, and GW rules and regulations.

"IRB Designee" = Single IRB members

Conduct review and approval of non-high risk research

The Office of Human Research (OHR): The administrative support office for the IRB.

GW Human Research Protections Program
What IS Human Subjects Research?

So what
Uses of #1: It's Research?

Question #1: Systematic investigation designed to develop or contribute to generalizable knowledge.

Generalizable Knowledge = Theories, principles, statements of relationships, outside of local context, intended to publish, present, disseminate new knowledge expressed in hypotheses.

Systematic = Testing hypotheses, including objectives, research development, procedures, testing and evaluation designed to reach objectives.

Generalizable Knowledge = A systematic investigation designed to develop or contribute to generalizable knowledge.

**From the DHHS and The Belmont Report**
“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
**YES:**
- Research medical records review
- Research interventions
- Randomization to two existing therapies/procedures
- Observational data collection
- Comparative case studies
- Research survey/interview
- Research medical records review

**PROBABLY NOT:**
- Non-clinical pilot studies
- Internal program eval/QA
- A case study
- Secondary/aggregate data analysis
- Internal program eval/QA
- Non-clinical pilot studies
- Not intended for publication
The principles of medical ethics were extended into the realm of research.

Ethics go beyond 'do no harm' and beyond obligation.

"First, Do No Harm"
Historical atrocities in human research prompted formalized ethical premise.
The Belmont Report—written in 1979:

- Established ethical principles for biomedical and behavioral research involving humans.

Federal regulations for human research codified based upon these.

The “IRB” was established per federal regulations.
The Belmont Principles of Ethics

RESPECT FOR PERSONS -
• Research is voluntary and informed
  Application: Informed consent

JUSTICE -
• Equitable selection of subjects, fair distribution of risks
  Application: Equitable selection of subjects

BENEFICENCE -
• Risks to subjects do not outweigh benefits
  Application: Favorable Risk/Benefit Ratio
• Evaluate risks to subjects vs. potential benefits
• That risks to subjects are minimized
• Review plans for equitable subject selection
• Review plans for informed consent that is freely given
• Ensure plans for privacy of subjects and confidentiality of data
• Ensure additional protections for vulnerable populations
• Ensure adequate provisions for monitoring data
• The IRB MUST determine the following:
Identifying Risks: What is Harm?

**RISK:** "Probability of potential harm that may arise from a future event."

**CABLES:** Acronym for types of possible risks
- Cognitive/psychological
- Affective
- Biological/physical
- Legal
- Economic/financial
- Social
Examples:

Believe information could be used to identity a person or
“Data that can potentially identity an individual directly

Risk Examples: "Identifiers"

- Full face photographic images, comparable images
- Audio/Visual recordings
- Biometric identifiers
- Email and IP addresses
- Phone numbers
- All elements of dates - DOB, date of death (except year)
- Street address, city, county, zip codes
- Names
"Knowing is not enough; we must apply.

Willing is not enough; we must do."

- Johann Wolfgang von Goethe (1749-1832)
Avoiding Common Pitfalls

Applying Ethics in Research:

of Protocol Design
PEER REVIEW OF RESEARCH

What do I have in mind?

• Think your research through from the beginning
• Design your research to maintain scientific validity

How am I going to accomplish it?

• Provide valid support for risks. Consider methodology alternatives
• Work with your colleagues, advisors, and PI.

How do I want to accomplish it?

• Discuss research with your team, define roles in advance.
• Plan for potential resources, facilities, subject populations in mind

How can I?

• Design your research to maintain scientific validity
• Think your research through from the beginning

What do I have in mind?

SUCCESS = PREPARATION

Designing Your Research:
Consider: Magnitude of Risks
- Duration
- Frequency
- Cumulative effects
- Reversibility
- Culturally dictated

Make a Risk Assessment
- Evaluate the probability, frequency, magnitude of any harm

Actively Limit Risks
- Proactively monitor safety, document and report as needed

Create Plans to Minimize Risks
- Design study around reducing risks to subjects

Research Description:
Research Risk Requirements
Issue: Deficiencies are observed in research design or in the written protocol.

Tips:
- Recruitment and consenting processes
- Justification of sample size, screening procedures
- Inclusion/Exclusion criteria
- Disposition of records and data (physical and virtual)
- Confidentiality measures

Include:
- Recruitment and consenting processes
- Justification of sample size, screening procedures
- Inclusion/Exclusion criteria
- Disposition of records and data (physical and virtual)
- Confidentiality measures
Issue: Protocols are missing plans to manage unanticipated events due to participation in research.

Tips:
- Withdraw procedures for safe early end of participation
- Include stopping rules for necessary research termination
- Provisions for referrals to non-research professionals
- Proactive plans for handling identified potential risks.

Research Design

Handling Potential Study Issues
Issue: Assessing what information to provide can be challenging.

Tips:
- Do not include information not related to the research.
- Clearly identify what is research and what is practice.
- Identify specific data to be collected, procedures to be conducted as standard conducted.
- The information should be comprehensive but not exhaustive.
- Do not include information not related to the research.
Retrospective data collection:

- Information being viewed and analyzed for the study must already exist.
- No new data may be collected and added to the records for research under this category!

Prospective data collection:

- Data to be used in research is being or will be collected on an ongoing basis.
- Implies all current and future data collection, and may include retrospective data components.

Defining Types of Data Collection

Research Description
Potential for Undue Influence/Coercion

**Issue:**
Patients can feel pressure to participate in research due to investigator's position of authority (their physician, nurse, medical resident, etc).

**Tips:**
- Develop methods NOT to include treating/authority figures in your research when possible.
- Make a research team member responsible for recruiting, obtaining consent from patients, and collecting data as appropriate.
- Include consent statement that participation will not affect current or future care and treatment.
IRB Review and Submission Types
**Risk assessment involves population + study procedures**

Minimal Risk:

"The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life."

Full Board – Greater than Minimal Risk

Exempt – No greater than Minimal Risk to the subjects

Expedited – Less than Minimal Risk to the subjects

Types of IRB Review
Research activities present less than minimal risk to subjects

**EXEMPT research must fit within these categories of study:**

- Category 1 – Research in educational settings
- Category 2 – Educational testing, surveys, interviews, observing public behavior (not for surveys or interviews involving children)
- Category 3 – Research involving public officials
- Category 4 – Existing data (retrospective only)
- Category 5 – Demonstration projects
- Category 6 – Taste or food quality evaluation

*Review conducted by IRB Chair, OHR Director or designee*
Research will involve retrospective medical chart reviews of all orthopedic patients who had a hospital admission between January 2007 and January 2010. Patients who are found to have had at least one primary and one related follow-up surgery will be included.

Patient PMH, previous surgery data, demographics, operative details, and related lab results will be collected for data analysis. This information will all be recorded anonymously. Results are intended to be presented in aggregate at a regional conference.

Research will involve retrospective medical chart reviews of all orthopedic patients who had a hospital admission between January 2007 and January 2010. Patients who are found to have had at least one primary and one related follow-up surgery will be included.
Research activities present no more than minimal risk to subjects.

1. Eligible for Expedited Review if:
   - Meets one or more of the 9 Expedited review categories
   - Minor changes to previously IRB approved research
   - Previously approved by full board, study risk is downgraded.

2. Approval is granted for 365 days: Annual IRB review is required.

3. The review is carried out by the IRB Chair or IRB Chair designee.


1. Clinical studies of drugs and medical devices only when:

An IND or IDE are not required, device is FDA approved, used with approved labeling.

2. Blood samples by finger stick, heel stick, ear stick, or venipuncture.

3. Biological specimens through non-invasive means.

4. Data through non-invasive procedures.

5. Data, documents, records, specimens collected for non-research purposes.

6. Data from voice, video, digital or image recordings for research purposes.

7. Group characteristics or behavior, employing surveys, interviews, focus groups, program eval, human factors evaluation, or QA methodologies.

Collection of:

1. Expedited Review Categories 1-7
Prospective enrollment of current cardiology patients.

Identifiable data will be collected on subjects 12-50 years of age, who have a history of hypertension, have been newly diagnosed with diabetes mellitus and have started treatment.

Subjects will be asked to participate in 5 research clinic visits over a one year period. The research evaluation and data collection will include: collection of vital signs and one blood draw per visit; multiple time-point survey; and medical chart review for surveillance of medical condition and treatment side effects.
Research involving prisoners

Most research drug and device trials

Most research that includes deception of the research subject

(i.e., illegal activities that may implicate someone)

Research involving collection of very sensitive, high risk data

"Research activities present greater than minimal risk to the subjects" (high risk)
Prospective enrollment of patients 15 to 70 years of age and older, who have been scheduled for an elective (non-research) abdominal surgical procedure. Research will include randomization of patients to the use of either FDA approved staples or a non-FDA approved suture closure material during this surgery. Patients will be followed by the research team for surveillance of complications, subsequent surgery(s), safety data, and all data related to this surgery and surgical materials. Patients will be followed by the research team for surveillance of complications, subsequent surgery(s), safety data, and all data related to this surgery and surgical materials.
Specific Issues in Research
Certain persons/groups are at increased risk of exploitation.

Federal regulations define the following as "vulnerable populations:"

- Pregnant Women, Fetuses, & Neonates
- Prisoners
- Children
- Students, employees
- Ethnic groups
- Economically disadvantaged
- Educationally disadvantaged
- Elderly
- Cognitively impaired
- Other groups subject to vulnerability in research:

Vulnerable Populations
Some research can receive IRB approval to keep study data stored directly with the identifiers:

- Study code and data: JD-001. Diagnosis, admission date, address.

Some research is approved for storage of data separate from participant identifiers, using codes and a data key:

- Data key: JD-001 = John Doe

Data: 001. John Doe - diagnosis, admission date, address.

Some research can receive IRB approval to keep study data stored directly with the identifiers:
Confidentiality: Data Storage

**Issue:** No matter how well data is coded, it can be decoded if someone has access to your personal files.

**Tips:**

- Physically secure all identifiable data.
- Data not intended for secure archiving or future use should be destroyed.
- De-identify, eliminate links, and/or anonymize data whenever possible.
Informed Consent and Consent Process

- Is a person's voluntary agreement to participate
- Consent process contains disclosure of study participation
- Must be prospectively obtained
- Includes a conversation for questions before subject signs
- Can be altered or waived by the IRB under certain circumstances
- Is an ongoing process
- Consent process contains voluntary agreement to participate

- Can be altered or waived by the IRB under certain circumstances
- Includes a conversation for questions before subject signs
- Must be prospectively obtained
- Is an ongoing process
Requirements for a Consent Form

1. Purpose of the Research 

2. Statement the study involves research

• That participation is voluntary.
• Can discontinue participation at any time without penalty.
• That participation is voluntary.

3. Duration of Subject Participation

• Can discontinue participation at any time without penalty.

4. Description of the Procedures

• Procedures which are experimental

5. Forseeable Risks or Discomforts

• Alternate procedures/treatment

6. Benefits to the Subject or to Others

• Costs to the subject for participation

7. Costs to the Subject or to Others

8. Confidentiality of Records will be maintained

9. How Confidentiality of Records will be maintained

• Whom to contact for questions, rights, research-related injury
Subjects will be consented?

Full HIPAA Waiver
When consent and HIPAA Research Authorization is not feasible.

Partial HIPAA Waiver
Need Recruitment information, but will consent patients for research.

Full HIPAA Written Authorization
Subjects will be consented?

HIPAA: Guidelines for the Investigator
YES: "All ABG/Coag labs relating to the condition; Initial and repeat head CT and related diagnostic data, medications at time of admission;"

NO: "Medical chart information collected for (specific surgery) from 2006 forward."

YES: "Medical chart information collected for (a specific surgical procedure and/or follow-up) from (date of surgery) through December, 2010."

NO: "Medical chart information collected for (specific surgery) from 2006 forward."

YES: "All labs, patient CT reports, full PMH, all medications"
Keys Tips for the IRB Review Process
The ONLY way an IRB can conduct a complete and ethical review of your research, and understand potential risks to subjects, is if you tell them what you are doing for the research:

- What are the potential risks to subjects?
- What is your plan to minimize any risks?

If you tell them what you are doing for the research, it helps the IRB understand potential risks to subjects, and conduct a complete and ethical review of your research.

Why This Matters:
Providing sufficient information is crucial for an IRB to conduct a thorough review.

...
This is not what an IRB meeting looks like.
SUBMIT A COMPLETE IRB SUBMISSION PACKET!

- Research sites, location of activities, permissions
- Recruitment, consenting process
- Data collection tools
- Include HIPAA and other forms
- Identify the funding and sponsor
- Investigators, roles and responsibilities

Tips:

MISSING/INADEQUATE STUDY INFORMATION

Issue:

Submission Packet
We are not the experts in your field!

- Be clear and organized when completing forms.
- Do not skip sections by referring to the protocol.
- Explain terms/provide clarification where necessary.
- Use clear non-technical language to explain procedures.

IRB Review and Assessment:
Complicated language and wording create difficulty.
Changes to approved research

Modifications

No modifications, especially if it could increase the risk
determination, especially if it could increase the risk

Even if exempt, changes must be submitted for official

Changes must be submitted and approved PRIOR to implementing

- changing consent form language
- adding investigators, researchers, students
- increasing enrollment number above IRB approved
- adding/delisting or changing survey, interview

For review, including:

Any change made to the study must be submitted to the IRB office

Changes to approved research

Modifications
How do I begin the review process?

Go to: [http://www.gwumc.edu/research/human/index.html](http://www.gwumc.edu/research/human/index.html)

- Download and complete current submission forms/documents
- Complete all application and relevant forms
- Obtain necessary PI and Dept. Chair signatures
- Submit packet via email, mail or hardcopy to the OHR

How long will it take for my study to be reviewed?

* Exempt: 10-15 business days
* Expedited: 10-15 business days
* Full-committee: 4-6 weeks
1. Study submissions are assigned an IRB number and an IRB Analyst contact when received.

2. Pre-review of proposed research conducted by an IRB Analyst.

3. Communication with Analyst will continue to resolve all issues.

4. IRB full board or designee conducts final review and (usually) approves the research study.

5. The registration or approval email is generated, with:

   a. Signed IRB application that serves as this documentation.
   b. All stamped and approved documents (consent, survey, ...

OhR Review Process for all Research
Mandatory - "Basic Training Course" for all researchers

If you have completed an alternate form of Human Subjects Protection Training, please provide the OHR with this certification.

Please refer to the OHR website for CITI instructions:

http://www.gwumc.edu/research/human/citi.html

Human Subjects Protection Training

Required:

"CITI Training"
Who has to take CITI training?

CITI training must be completed by all GWU investigators, non-GW investigators, and research study staff conducting human subjects research under the authorization of the GWU IRB, (including “Exempt” research).

Which CITI courses do I need?

Either the Social-Behavioral or Biomedical “Basic Course” (Required)

CITI “HIPS” (HIPAA), is required for use of Protected Health Information (PHI).

How often do I need to renew my CITI training?

For all ongoing research activities, the Social-Behavioral Basic or Biomedical Basic or Data and Specimens module must be renewed every 2 years by taking the CITI “Refresher Course.”

Health Information Privacy & Security (HIPS) training does not require renewal.

Who do I contact with questions?

Contact the GWU Office of Human Research (OHR) at (202) 994-2715 or ohrirb@gwumc.edu.

See the CITI Registration Instructions on our website.
Welcome

The CILI logo and registration page

The CILI Program is a collaboration service providing various ethics education to members of the research community. To participate, all members must be affiliated with a CILI-affiliated organization. You must register to create a user account and access the site.

Your own username and password are assigned access to the site.

The CILI course site is best viewed with Microsoft Internet Explorer 6.0 or later or Firefox 2.0 or later.

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If you already have a user account, log in. There are currently 151 users logged in to the site.

To ensure full display of your required resources, access is temporarily limited to 2,000 concurrent users. As a result, you may need to refresh the page to ensure proper display.

You can log in and manage your user account.

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Your protocol is your contact with the Institution and the IRB.

As a researcher you agree to:

- Obtain IRB approval before conducting research.
- Follow the protocol as approved by the IRB.
- Report unanticipated problems to the PI and the IRB.
- Report changes to the IRB before implementation.
- To keep accurate records of the research.
We Welcome Questions!!

Office of Human Research
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Google Search: GW OHR
www.gwumc.edu/research/human

Contact Us