Students As Researchers
STARS in the IRB Sky

September 25, 2014
# Ethics in Human Subject Research

<table>
<thead>
<tr>
<th></th>
<th>Acknowledge autonomy, Protect those with diminished autonomy</th>
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<td><strong>Respect for persons</strong></td>
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Institutional Review Board (IRB)

- Committee established to protect rights and welfare of human research subjects
- Research at the institution complies with regulations
- Approved research continues to comply with regulations
Criteria for Approval

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects
3. Selection of subjects is equitable
4. Informed consent will be sought
5. Informed consent will be appropriately documented
6. Adequate provision for monitoring the data collected to ensure the safety of subjects
7. Protect the privacy of subjects and maintain confidentiality of data
# Mapping Ethics and Approval Criteria

<table>
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<th>Respect for persons</th>
<th>Acknowledge autonomy, Protect those with diminished autonomy</th>
<th>Informed consent Language is understandable to subjects Privacy and confidentiality Protection of vulnerable populations</th>
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<tr>
<td>Beneficence</td>
<td>Maximize benefits Minimize harms</td>
<td>Scientific rationale Appropriate study design Competent investigators Risks are reasonable in relation to anticipated benefits Safety monitoring</td>
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What is a human subject?

- “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.”

Brought to you by 45 CFR Part 46.
Responsibilities

• Protection of human subjects is our responsibility
  – Institutional officials, the IRB and researchers
  – Crucial distinct roles
Demystifying the “Full Board”

- At least 5 members
  - Varying backgrounds to promote complete and adequate review of research
- Expertise, Experience, Diversity
  - At least 1 scientist
  - At least 1 non-scientist
  - At least 1 member unaffiliated with the institution
- Voting
  - No vote without the non-scientist
Research Submission Process

- We are here to help!
Research Submission Process

Submission includes:
- Protocol
- Brief Project Description
- Consent or Waiver/Information Sheet
- Other documents potentially...

Research Team
- Idea
- Grant/Support
- Collaborators
- Protocol

IRB staff
Details
- describe how this project will meet the criteria for approval

IRB Board /Chairs
Revisions
Approval!
Research Submission Process

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IRB staff
- Review details of the proposal
  - How will this project meet the criteria for approval?
- Revisions

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IRB staff
- Review details of the protocol
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IRB Board /Chairs
- Revisions
- Approval!
Pitfalls:

- Premature submission
  - Grant ≠ Protocol
  - Use the templates available on the IRB website
  - Anticipate some revisions if this is your first submission (or even when it’s your 2nd/3rd)!
- Ideas are not clearly explained
  - Have others read the protocol to make sure it is understandable.
- Too late in the process
  - Don’t start the research before you have approval!
Types of IRB Review

- Full Board
  - Projects that are greater than minimal risk
- Expedited
  - Projects that are minimal risk
Level of Risk

- **Minimal Risk**
  - The probability or 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.

- **Greater than Minimal Risk**
Some Minimal Risk Activities

- Blood samples by stick or venipuncture in healthy non-pregnant adults or children that do not exceed certain amounts
- Biospecimens for research by non-invasive means (nails, saliva, hair)
- Non-invasive data collection procedures not involving general anesthesia and used in routine clinical practice (EKG)
- Materials that have been collected, or will be collected solely for non-research purposes
- Data from voice, video, digital or image recording for research purposes
- Individual or group characteristics or behavior (surveys)
http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm
http://www.ohsu.edu/xd/about/services/integrity/policies/all-irb-documents.cfm
### Minimal Risk Protocol Template

**INSTRUCTIONS:**
- All sections are required. However, some subsections may not be applicable to your project and may be deleted. The level of detail required for each section will vary with the complexity of your project. For simple research, such as a retrospective chart review, a one or two page protocol may be sufficient.
- **DO NOT USE THIS TEMPLATE** if your project involves an FDA-regulated drug, device, or other product.
- Delete all instructions (italics).

1) **Protocol Title**
   - Include the full protocol title as listed in the IRB.

2) **Objectives**
   - Describe the purpose, specific aims, or objectives. State the hypotheses to be tested. State primary and any secondary study endpoints.

3) **Background**
   - Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature. Describe any relevant preliminary data. Describe any gaps in current knowledge and how the current project will add to existing knowledge.

4) **Study Design**

5) **Study Population**
   a) **Number of Subjects**
      - State the number (or approximate number, if applicable) of subjects you plan to include. If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures (i.e., numbers of subjects excluding screen failures).
      - If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.
   b) **Inclusion and Exclusion Criteria**
      - Describe how individuals will be screened for eligibility.
      - Describe the criteria that define who will be included or excluded in your final study sample.
   c) **Vulnerable Populations**

6) **Setting**
   - Describe the sites or locations where your research team will conduct the research.

   If this is a multi-site study, describe:
   - What procedures are being performed at OHSU or by OHSU personnel (e.g., process, study procedures, data analysis, etc.)
   - Will OHSU be the coordinating center for any activities?
   - How each site will satisfy its IRB review requirements. Indicate if you are an other IRB or if another institution would like to rely on the OHSU IRB.

   For research conducted outside OHSU and its affiliates describe:
   - Site-specific regulations or customs affecting the research for research conducted outside OHSU. See OHSU IRB international studies.

7) **Recruitment Methods**
   - Describe where, when, and how potential subjects will be identified and recruited.

   Describe materials that will be used to recruit subjects. Upload copies of these materials. For advertisement, upload the final copy of printed advertisement. File for broadcast, upload the final video tape. You may submit the world in a video prior to videotaping to preclude re-taping because of inappropriate wording in the final video tape.

   Describe the amount, method, and timing of any payments to subjects, including payment to subjects who partially complete the study.

8) **Consent Process**
   - Describe how you will obtain and document consent, including:
     - Where, when and how the consent process will take place.
     - A process to ensure ongoing consent.
     - Steps that will be taken to minimize the possibility of coercion or undue influence.
     - Any steps that will be taken to ensure the subjects’ understanding.

**Modifications to the Consent Process**
- If your research presents no more than minimal risk and involves no procedure, documentation of consent is normally required outside of the research context.

   If this applies to your study, explain how you meet the consent process in your study.

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**Example: Minimal Risk Protocol**

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   If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.
   
   b) **Inclusion and Exclusion Criteria** Describe how individuals will be screened for eligibility.
   
   Describe the criteria that define who will be included or excluded in your final study sample.
   
   c) **Vulnerable Populations** |
| **Setting** | Describe the sites or locations where your research team will conduct the research. If this is a multi-site study, describe:
   
   What procedures are being performed at OHSU or by OHSU personnel (e.g., process, study procedures, data analysis, etc.)
   
   Will OHSU be the coordinating center for any activities?
   
   How each site will satisfy its IRB review requirements. Indicate if you are an other IRB or if another institution would like to rely on the OHSU IRB.

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Telephone Script Template

Hello, my name is __________. I’m calling from Oregon Health & Science University about a research study. Am I speaking to __________ (name of recruit)?

If “no,” wait for recruit to pick up, arrange to leave a message, or ask for a time to call back.

If “yes”:

I got your phone number from ______ (describe contact source). Is this a good time to talk? I expect this phone call will take about ____ minutes.

Arrange to call at another time, if appropriate.

I’m calling about a research study of __________ (describe condition being studied) called ________ (study title). The purpose of this research study is to learn more about __________ (state study purpose).

I’m calling to see if you are interested and if you might be eligible to participate. If you agree, I will ask you some questions to see if you can be in the study. If it looks like you might be eligible, we will ask you to come into the clinic, where we will discuss the study with you in more detail, and you can decide if you want to participate.

Before we go on to the questions, let me tell you a little bit about your rights as a research subject.
**Brief Project Description**

<table>
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<th>Principal Investigator:</th>
<th>IRB#:</th>
</tr>
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**Instructions:** Provide a brief (one page maximum) description, of the central question the research is intended to answer, the primary objectives, and the methods used. Use non-technical language. *IRB members, IRB staff, and others use this document to get an overview of your study. It is not to be distributed to research subjects.*
Consents and Waivers

- There are criteria that allow research to be conducted in special situations:
  - Without consent (Waiver of consent)
  - Without written documentation of consent (Waiver of documentation of consent)
Example: chart review – how many people with hip fractures have a vitamin D level before they leave the hospital?

- Data exist and were collected for clinical purposes, not for research
- You can get the data without knowing who the people are
- It would be nearly impossible to consent all the people that came into OHSU for a hip fracture over the span of 15 yrs time
- This should be minimal risk – inappropriate/accidental disclosure would not result in significant harm to the individual.
Application & Certification for Waiver or Alteration of the HIPAA Authorization requirement

Version 5.0  Updated 3.3.2014

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Portland, Oregon 97239-3083
Phone: 503-484-7687
Fax: 503-346-5803

Editor Name:  
First  
Last  
eIRB Number:  

SECTION I:  Purpose of Waiver or Alteration of HIPAA Authorization

1. PARTIAL WAIVER:
   A. Waiver is requested to disclose PHI from one covered entity to another for the purposes of contacting and recruiting individuals into the study.
   OR
   B. Waiver is requested to collect PHI over the phone, fax, internet or e-mail from study participants.
   OR
   C. Waiver is requested to use PHI for research purposes for individuals who are unable to provide authorization and no LAR is available.
   OR
   D. Waiver is requested for any other use and disclosure for ONLY part of the research project as described below**.

NOTE: In cases of a partial waiver, the researcher must obtain HIPAA Authorization from eligible subjects for any use or disclosure of PHI beyond what’s approved under the partial waiver.

2. FULL WAIVER: Waiver is requested for complete access, use, and creation of records containing Protected Health Information, but only as described in the IRB-approved application.

3. ALTERATION OF AUTHORIZATION: Permission is requested to remove some, but not all, of the required elements of an Authorization***. When requesting an alteration, a copy of the proposed altered authorization form must be submitted for review.

NOTE: Alterations are often needed in sham or placebo studies when identification of a non-HIPAA element would affect the results of the study.

SECTION I D: **IF APPLICABLE: Description of partial waiver from Part 1D. above

SECTION II: Description of health information to be collected (e.g. blood pressure, **x-rays**).

SECTION III: Will any of the following elements be recorded for the study?

- Patient/Subject Names
- Age information for those over 89
- Geographic subdivisions smaller than a State with first 3 digit ZIP exceptions.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Dates (except year)
- Device identifiers and serial numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints

**Must fill out Section 1D below.
Example: you want to measure knowledge after a lecture on HTN to see if people learned anything

- This should be a minimal risk study
- The lecture is standard for all learners
- The evaluation of the lecture is the research
- Consider whether an information sheet would suffice for consent:
  - Contains all the elements of consent
  - Waives the documentation of signature on the consent form
Consent - Information Sheet

TITLE: Name of the study. Use the same title as that on the IRB.

PRINCIPAL INVESTIGATOR: (503) 494-####

CO-INVESTIGATORS: (503) 494-####

FUNDED BY: Delete if unfunded.

PURPOSE: Include and complete the following sentences: You have been invited to be in this research study because you;

[Example, "have asthma."] The purpose of this study is to _______. [Example, "learn about a new drug that may help treat asthma."]

PROCEDURES: Describe succinctly and in chronological order the procedures for the research. It is not necessary to describe procedures that subjects would be receiving as routine care. Include a statement describing the duration of participation.

At the end of the procedures section, you must insert the following statement: If you have any questions, concerns, or complaints regarding this study now or in the future, or you think you may have been injured or harmed by the study, contact [Contact Name and Phone].

RISKS: Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. [Add other risks if necessary.]

BENEFITS: You may or may not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

CONFIDENTIALITY: In this study we are not receiving any identifiable information about you so there is little chance of breach of confidentiality. For studies that provide any type of compensation to subjects, state: We may request your social security number in order to process any payments for participation.

COSTS: NOTE: This is to be included only if applicable, otherwise delete it.

It will not cost you anything to participate in this study. If subjects will be provided any compensation, describe the compensation in detail: You will receive $10 for completing the questionnaire.

PARTICIPATION:
This research is being overseen by an Institutional Review Board ("IRB"). You may talk to the IRB at (503) 494-7887 or irb@ohsu.edu if:

• You have questions, concerns, or complaints that are not being answered by the research team.
• You want to talk to someone besides the research team.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gw/18915/index.html or by calling toll-free (877) 733-8313 (anonymous and available 24 hours a day; 7 days a week).

You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

For studies recruiting OHSU students or employees as subjects, please include the following language: The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator’s department, or your grade in any course. If you would like to report a concern with regard to participation of OHSU students or employees in OHSU research, please call the OHSU Integrity Hotline at 1-877-733-8313 (toll free and anonymous).
Example: Nursing student (DCP program) is submitting a protocol that will help improve practice at an agency; the agency has IRB approval for the project

- **Questions that the OHSU IRB is likely to have:**
  - If the student wears dual hats (ie is employed by the agency and also a student at OHSU), which hat is he/she wearing for THIS project?
  - What is the purpose of the project – if it’s for an OHSU degree then OHSU IRB will need to have oversight
  - Does the outside agency have an IRB, and if so have they approved?
Pitfalls:

- Student project not clearly delineated from the rest of the project
  - Might be a huge project, but need to state what is the piece that you are doing
- Inadequate explanation of security and confidentiality procedures, especially if data are being transferred outside of OHSU.
  - Use the template language available, and understand what it means for your study
Other IRB Determinations

- **Exempt**
  - Project is exempt from Federal Policy for Human Research Subjects

- **Not Human Subjects Research**
  - Project is research but does not involve human subjects

- **Not Research**
  - Quality improvement
    - Not intended to yield generalizable knowledge
    - For use in local context
Final thoughts

- If you have questions about whether you are doing research, or whether it involves human subjects – contact the IRB.
- Take pride in your submission.
  - Be consistent between documents
  - Put your best foot forward
- Then, go do the research!!
If in doubt, ask!

We’re here to help!

503-494-7887

http://www.ohsu.edu/xd/research/about/integrity/
Next IRB Brown Bag – VA Update

- November 17, 2014, 11:30-12:30pm
- UHS 8B60