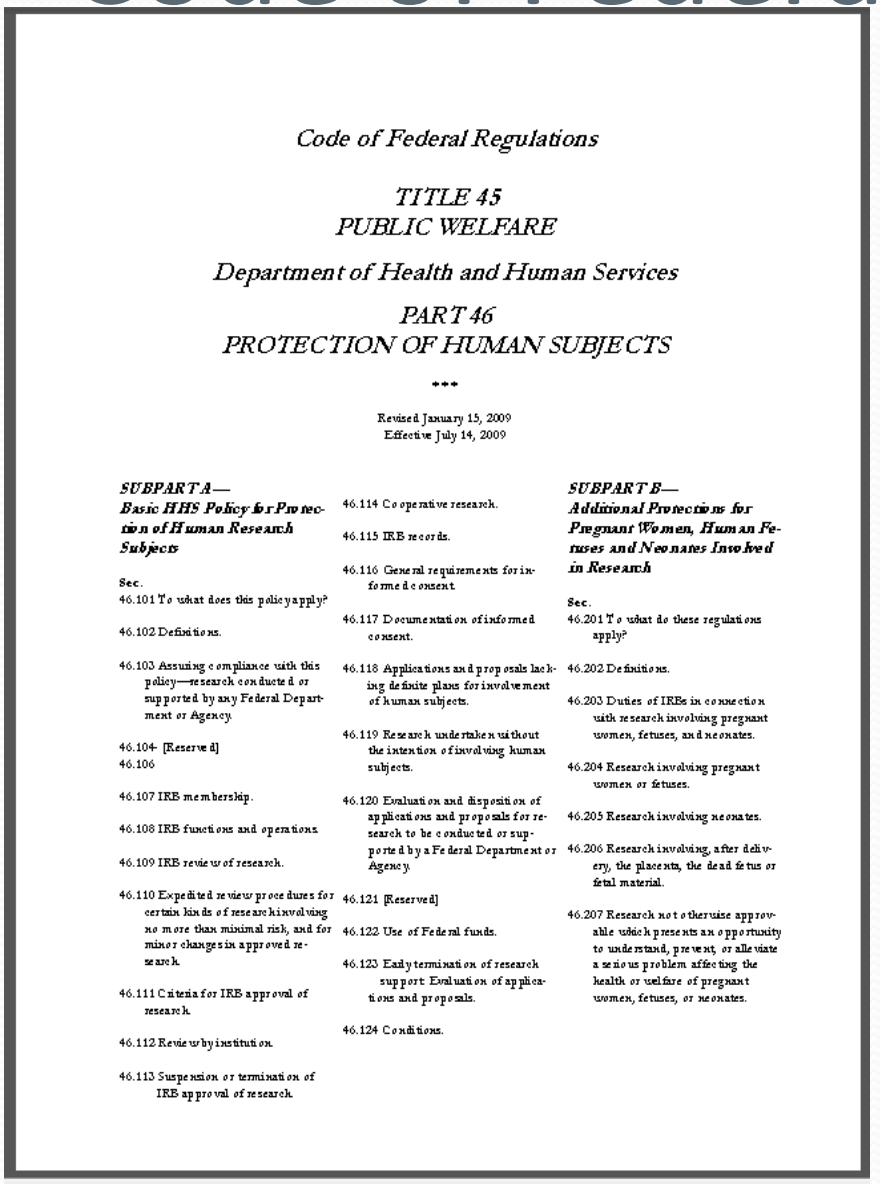
Students As Researchers STARS in the IRB Sky

September 25, 2014

Ethics in Human Subject Research

Respect for persons	Acknowledge autonomy, Protect those with diminished autonomy
Beneficence	Maximize benefits Minimize harms
Justice	Fairness Non-discrimination

Code of Federal Regulations



Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

Department of Health and Human Services

PART 46
PROTECTION OF HUMAN SUBJECTS

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Revised January 15, 2009
Effective July 14, 2009

SUBPART A—
Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101 To what does this policy apply?

46.102 Definitions.

46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

46.104- [Reserved]
46.106

46.107 IRB membership.

46.108 IRB functions and operations.

46.109 IRB review of research.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

46.111 Criteria for IRB approval of research.

46.112 Review by institution.

46.113 Suspension or termination of IRB approval of research.

46.114 Cooperative research.

46.115 IRB records.

46.116 General requirements for informed consent.

46.117 Documentation of informed consent.

46.118 Applications and proposals lacking definite plans for involvement of human subjects.

46.119 Research undertaken without the intention of involving human subjects.

46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

46.121 [Reserved]

46.122 Use of Federal funds.

46.123 Early termination of research support: Evaluation of applications and proposals.

46.124 Conditions.

SUBPART B—
Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.
46.201 To what do these regulations apply?

46.202 Definitions.

46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

46.204 Research involving pregnant women or fetuses.

46.205 Research involving neonates.

46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

- 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

Respect for persons	Acknowledge autonomy, Protect those with diminished autonomy	Informed consent Language is understandable to subjects Privacy and confidentiality Protection of vulnerable populations
Beneficence	Maximize benefits Minimize harms	Scientific rationale Appropriate study design Competent investigators Risks are reasonable in relation to anticipated benefits Safety monitoring
Justice	Fairness Non-discrimination	Selection of subjects is equitable

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.

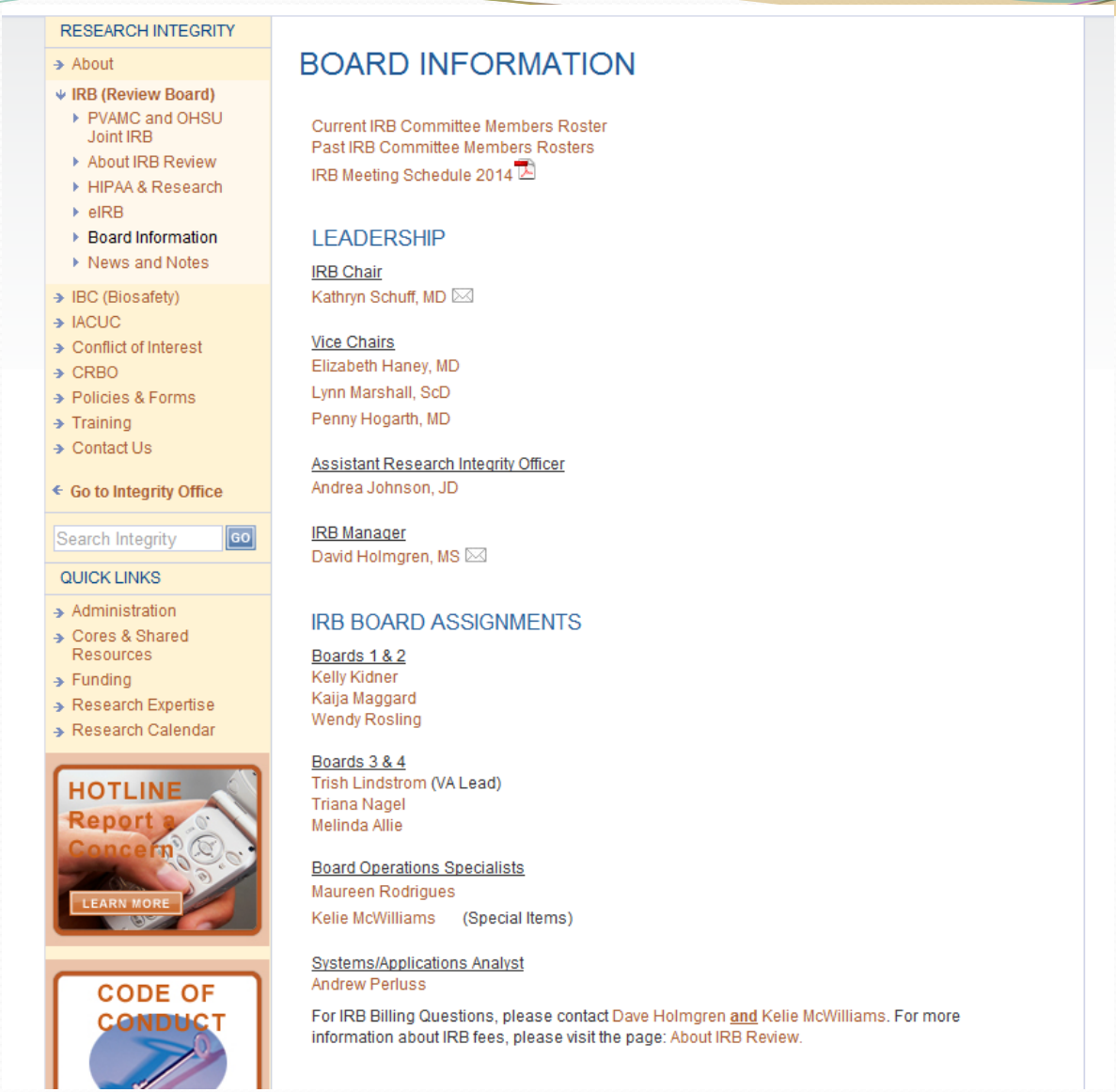
Responsibilities

- 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

OHSU Board Information



http://www.ohsu.edu/xd/research/about/integrity/irb/board_information.cfm

Research Submission Process

- We are here to help!

Research Submission Process

Research Team

Idea

Grant/Support

Collaborators

Protocol

IRB staff

Details

- describe how this project will meet the criteria for approval

Revisions

IRB Board /Chairs

Revisions

Approval!

Submission includes:

- Protocol
- Brief Project Description
- Consent or Waiver/Information Sheet
- Other documents potentially…

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Review details of the proposal

- How will this project will meet the criteria for approval?

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- How will this project will meet the criteria for approval?

Revisions

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

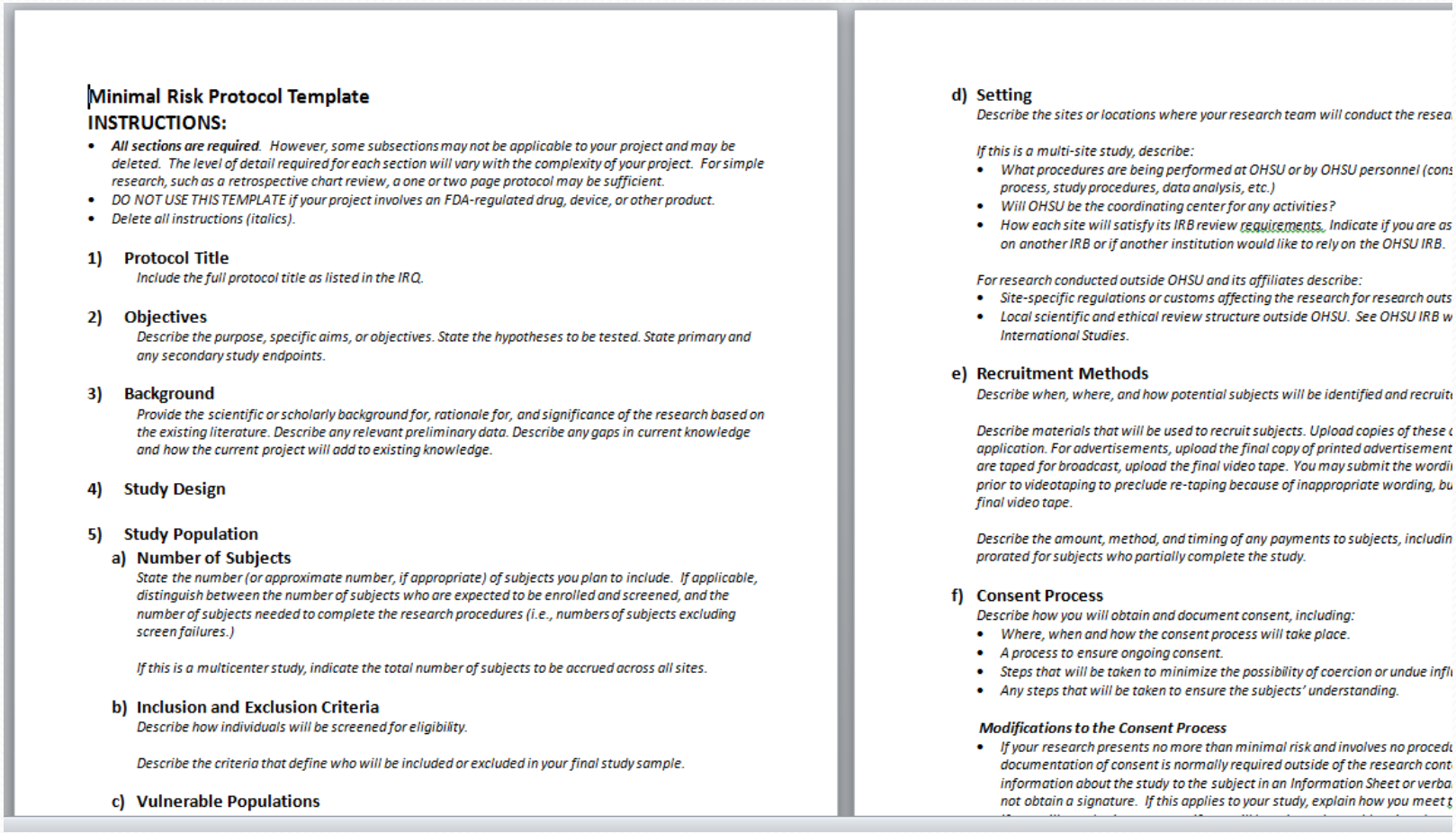
Some Minimal Risk Activities

- 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



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 IRQ.

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 appropriate) 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

d) Setting

Describe the sites or locations where your research team will conduct the resea

If this is a multi-site study, describe:

- *What procedures are being performed at OHSU or by OHSU personnel (cons 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 as on another 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 outs*
- *Local scientific and ethical review structure outside OHSU. See OHSU IRB w International Studies.*

e) Recruitment Methods

Describe when, where, and how potential subjects will be identified and recruit

Describe materials that will be used to recruit subjects. Upload copies of these application. For advertisements, upload the final copy of printed advertisement are taped for broadcast, upload the final video tape. You may submit the wordi prior to videotaping to preclude re-taping because of inappropriate wording, bu final video tape.

Describe the amount, method, and timing of any payments to subjects, includin prorated for subjects who partially complete the study.

f) 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 infl*
- *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 proced documentation of consent is normally required outside of the research cont information about the study to the subject in an Information Sheet or verba not obtain a signature. If this applies to your study, explain how you meet*

Telephone Script Template

eIRB #____

Telephone Recruitment and Screening 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

OREGON HEALTH & SCIENCE UNIVERSITY	**Brief Project Description**

Principal Investigator:		IRB#:	
Protocol Title:			

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 3.5.2014

Research Integrity Office
Mail code L106-RI
Portland, Oregon 97239-3098
Phone: 503-494-7887
Fax: 503-346-6808

	eIRB Number:	
Researcher Name:	First	Last
Study Title:		
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.	A. ☐ B. ☐ C. ☐ D. ☐ **Must fill out Section I D below.
	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 required HIPAA element would affect the results of the study.	☐
SECTION I D: **IF APPLICABLE: Description of partial waiver from Part 1.D. 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 zip digit 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

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

OREGON HEALTH&SCIENCE UNIVERSITY

Information Sheet

IRB#_____

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

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 _____. [*For example, "have asthma."*] The purpose of this study is to _____. [*For 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 Number]*.

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.

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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:

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

- You have questions about your rights as a research subject.
- You want to get more information or provide input about this research.

You may also submit a report to the OHSU Integrity Hotline online at https://secure.ethicspoint.com/domain/media/en/gui/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