Guidance for PharmD Students Conducting Research with Human Subjects

Oregon State University College of Pharmacy

Drafted and approved by the OSU College of Pharmacy Research and Scholarship Committee; May 7th, 2018.

Background

PharmD students participating in experiential programs access patients and patient healthcare records as part of their professional education and practice. Students may wish to conduct research using patient data; for example, to evaluate prescription behaviors, medication adverse effects, or the effect of therapeutic guidelines. Most research involving humans or data collected from humans require approval from the Institutional Review Board (IRB). This guidance provides an interpretation of the existing guidelines available at http://research.oregonstate.edu/irb/policies-and-guidance-investigators/guidance/chart-review and http://research.oregonstate.edu/sites/research.oregonstate.edu/files/irb/comparison_research_v_non_research_v12292017.pdf.

Note that this document provides a general summary of IRB regulations but is specific to OSU. All COP students are required to follow OSU IRB policies. However, COP students access the patient records at many different healthcare and pharmacy facilities. Each of these settings will have an IRB, ethics board, or other regulatory processes in place to oversee use of patient data. All COP students must also comply with the regulations in place at the site at which patient records are obtained/accessed.

By and large, PharmD students in the experiential programs interact with patients and patient-related data in the following ways:

1. Access to patients and patient records to provide *healthcare to individual patients*. This type of activity is not considered 'human subjects research' and does not require IRB approval.
2. Access to patient records for the purpose of quality improvement or quality assessment.
    a. In this scenario, patient data collected as part of routine medical care are used to evaluate healthcare delivery and interventions. This can include drug use evaluations. Typically, for these studies the student/investigator does not intend to publish or present their work externally.
    b. This type of work is typically not considered human subjects research, although some exceptions may apply. Note that the IRB for some healthcare facilities (eg, VA Portland Healthcare System) maintain a separate process for approving quality improvement/quality assessment studies. A request for determination can be sent submitted to the IRB to assess if a particular project requires IRB oversight or is exempt.
3. Access to existing patient records for descriptive or analytic purposes with an intent to disseminate results (e.g., publication or presentation).
    a. In the case that personally identifiable data (i.e., data that can be linked in any way to individuals) or any of the 18 protected health identifiers (PHI) specified under HIPAA are included in the

collected data, the research activity is considered 'human subjects research' and requires IRB approval.[a] Please also refer to items 3a and 3b below for further guidance. Note, the student's mentor/preceptor may choose to fully de-identify the patient data by removing all PHI and personally identifiable information (for instance, by removing names, MRN, all dates, and other identifiers). If the mentor provides coded data to the student, the mentor must apply for and obtain IRB approval for the project since the mentor has access to the identifiers and the codes[b].

b. In the case that human data *cannot be linked in any way to individuals* (for instance, analysis published or publicly available datasets), the research activity is not considered to include 'human subjects' and would not require IRB review. When in doubt, a determination request can be submitted to the OSU IRB at IRB@oregonstate.edu or visit https://research.oregonstate.edu/irb.

4. Collection of data through direct interaction (includes phone calls, etc.) with patients or through intervention with the intention to disseminate the results is considered 'human subjects research' and requires IRB review[c]. A research study meets the criteria of a clinical trial if one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (see https://grants.nih.gov/policy/clinical-trials/definition.htm). OSU Students are not allowed to serve as Principal Investigators on such projects but they may participate as co-investigators after completion of human ethics training available through the OSU IRB office.
    a. Student presentations, such as posters, simply to document the educational experience or to fulfill programmatic requirements are not considered 'dissemination of results'.
    b. Student presentations, such as posters, at professional or scientific meetings outside OSU that make the results of the data collection publicly available are considered 'dissemination of results'. Students wishing to make patient-related data publicly available must have IRB approval.

Footnote Comments

[a] Note that HIPAA authorization and consent or a waiver from the site will also be required.

[b] If the Principal Investigator is an OSU person, that person would need to submit an IRB application only if identifiable or coded data were being provided to other OSU persons. If instead, a non-OSU person is de-identifying the data and then giving it to the student (so no one at OSU ever has identifiable data) it may not need IRB review. De-identification must be done by someone other than the student before the student accesses the data.

[c] If conducted at the clinical site/covered entity, HIPAA authorization or waiver from the site may also be required.

Glossary

Coded: Identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a study-specific number, letter, symbol, or combination thereof (i.e., the coded identifier); and a key linking the coded identifier to personal/medical identifiers exists, enabling linkage of the identifying information to the private information or specimens.

De-identified: When collected, data contained identifiers or information that would permit identification of the individual(s) about whom the data were collected, but the identifiers or indirect links to identity have been removed and no longer exist anywhere in any form. Exception: When coded data are shared between researchers and a data use agreement is in place between the institutions that no identifiers will be shared, these data are considered de-identified. This exception does not apply when the holder of the key is involved in the research. *For example, a PI sharing coded data with a student researcher is conducting research with identifiable data because it is their responsibility to oversee all aspects of the study.*

Individually Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information. Individually identifiable information is not limited to name, date of birth, or contact information.

For questions regarding this policy, please contact the OSU IRB Office at IRB@oregonstate.edu.