The IRB Messenger

Vol. 4, Summer 2018

UofL Human Subjects Protection Program and the Institutional Review Board

Research Using Retrospective Subject Data

Using human subject data for research generally requires IRB approval prior to collecting the data. The level of IRB review will depend on the specific circumstances of the project. The following information describes various levels of IRB review for data collection projects. For additional guidance on how to submit your project, please contact an IRB Analyst.

1) Data collection research that could be considered Expedited Category 5:
   - The data to be used in the research has been (or will be) collected solely for non-research purposes (such as medical treatment or diagnosis).
   - Under this expedited category HIPAA identifiers may be collected as part of the research data collection.
   - The IRB must approve a HIPAA waiver of authorization as part of the IRB submission to access subject medical records to use the data in the research.
   - If not obtaining informed consent from subjects, you must request a "waiver of informed consent" in the IRB application and provide justification for all four criteria for a waiver of consent.

2) Data collection research that could be considered Exempt Category 4:
   - All of the data existing at the time of exemption.
   - No identifiers are recorded (note: researchers may have access, and see identifiers in the medical record, but none of the 18 HIPAA identifiers may be collected under this category).
   - The IRB must approve a HIPAA waiver of authorization as part of the IRB submission to access subject medical records to use the data for research.
   - If not obtaining informed consent from subjects, you must request a "waiver of informed consent" in the IRB application and provide justification for all four criteria for a waiver of consent.

   #1 and #2 IRB Submission Instructions
   - An IRB Application must be submitted in iRIS, along with a written protocol, data collection sheet, and HIPAA waiver of authorization form for IRB review and approval.
   - Study Team Requirements: All study personnel must have CVs loaded in iRIS, completed ADF form, and have current CITI Human Subjects & HIPAA Research Training (training not required for Exempt research).

3) Data collection research that could be considered Non-Human Subjects Research (NHSR):
   - The data to be used in the research was not collected solely for the particular research study at hand.
   - The researchers will not view or collect any of the 18 HIPAA identifiers (i.e. the data is completely de-identified before the researcher is given access).
   - There is no way for the researcher to link the data back to the subject identities (e.g. if the data is coded, the researcher cannot access the link to the subject identities).

   #3 IRB Submission Instructions: The NHSR application along with a written description of the project may be submitted in iRIS for the IRB to formally make this determination.

4) Data collection that may be considered a Case Report:
   - University of Louisville defines a case report as medical information collected and presented on up to five patients to highlight an interesting treatment, presentation, or outcome.
   - If an author develops a case report with no prior research intent, IRB review is still required prior to publication to confirm the case report determination.

   #4 IRB Submission Instructions: The Case Report Application must be submitted in iRIS with the written case report.

Program Dates

IRB Submission Workshop

July 19, August 9, and September 13

9am-noon

MedCenter One, Suite 200

RSVP at hsppofc@louisville.edu

Consent Writing Workshop

Please join us for information on how to construct a consent form and the different types of consent forms approved by the IRB.

July 25

12:30-1:30

Lunch and Learn

Keep a look out for updated information on Fall topics.

August 29

TBD

September 26

TBD

11:30-12:30

MedCenter One, Suite 200

https://www.surveymonkey.com/r/8TXVPL1

RSVP at hsppofc@louisville.edu

For more information on any of the topics included in this newsletter, please contact the HSPP office at hsppofc@louisville.edu

2018 Quarter IRB Metrics

2018 Quarter 1
Turn-Around Times by Review Type

Calculations based on the working days from receipt of submission to approved as submitted.
Industry sponsored studies do not take into account the time for pending fee.

NHSR	Exempt	Expedited	Full Board
4	12	15.5	26
Total Submissions: 58	Total Submissions: 23	Total Submissions: 120	Total Submissions: 15
Target 10	Target 10	Target 10	Target 30

Research Involving Students

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The regulations define children as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted" (45CFR46.402(a)). All but three states use 18 as the age of majority, and all states have differing criteria for considering a minor emancipated. While most college students are 18 or older, some may be less than 18. It is reasonable to grant younger college students a waiver of parental permission for minimal risk research, as it is a matter of justice to be considered equal with their classmates. Such a waiver is difficult to justify in high school students and parental permission should be obtained.

Research conducted in classrooms, which is a common way research on students is done, can take several forms:

- A teacher or professor may be conducting research on their students for the purpose of producing generalizable knowledge. This can be a challenging situation for IRBs because of the power differential between professor and students and the possibility of undue influence. When IRBs consider this a problem they may require another professor to obtain consent and potentially conduct the study. While a student's professor may have authority over them in a classroom, the student must still be afforded their rights, to say no and not to suffer any untoward effects of a decision to say no or withdraw from research.
- A teacher or professor may conduct, or may have the students conduct, research within the classroom to teach the students about research methodology or research on the subject of the class. The intent is educational and not to produce generalizable knowledge. This type of research is usually minimal risk and since it does not meet the definition of human subjects is not reviewed by the IRB. Many professors have the students act as an IRB for research to teach about human research protection.
- A teacher or professor may have the students conduct research externally from the classroom on other students or subjects. If the study meets the definitions of research and human subjects, the IRB must be involved, although the IRB may use its discretion on the level and mechanism of review. Much of this type of research is usually exempt or expedited.

Many universities and colleges have "student research pools," where professors or graduate students submit research studies into a "pool" of studies and utilize the student population "pool" as subjects. Such studies are used to produce generalizable knowledge (including theses and dissertations) although many professors also use such research to educate students about research. This research must be reviewed by the IRB. The IRB must consider the following:

- That the research is voluntary. The student can say no with no untoward consequences. If the student signs up for a study and does not show up, this is considered withdrawal and within the rights of the student and thus there should be no untoward consequences.
- Some professors may offer a non-research alternative, like reading and reporting on an article, or writing a brief paper. While the IRB may find this acceptable, the alternative must be equal to the research effort, for example the alternative to a 10 question multiple choice survey should not be writing a 20 page paper—this would constitute undue influence to be in the research.
- One of the most challenging student research issues for IRBs is when the research is required for class credit or extra credit. In a student's situation, this can certainly be considered undue influence to participate in the research. Non-research alternatives are critical to receive the same credit. This situation should be carefully reviewed and considered by the IRB to ensure the student's rights are protected.

Look Out!

If you stop by the HSPP office, you may see a new face. We are pleased to welcome Jenn Hay as our new IRB analyst. Jenn was previously a research coordinator at UL. She will be working, largely, with our Pediatric departments once she gets settled into her new role. We are so excited to have you Jenn!

IRB Meeting Dates

Biomedical

July: 5, 19, and 26

August: 3, 17, and 24

September: 7, 21, and 28

Social/Behavioral/ Educational

April: 4

May: 2

June: 6

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