IRB APPLICATION PROCESS

Claire V. Murphy, PharmD, BCPS
What is the IRB?

- Institutional Review Board responsible for the risks to research participants
- Mission is to protect the “rights, dignity, welfare and privacy of all participants in research”
- To ensure adherence to principles of the “Belmont Report”

At OSUWMC:
- Behavioral and Social Sciences
- Biomedical Sciences
- Cancer
- Western IRB (external)
Who is on the IRB?

- Dedicated group of volunteers from OSU and surrounding community
- At least 5 members
- Varying backgrounds to promote complete review
  - At least one member with scientific background and one with non-scientific background
- Chair
- Vice-chair(s)
- Members
- Alternate(s)
Options for IRB Applications

- Minimal risk (or less)
  - Exempt
  - Expedited
- Greater than minimal risk
  - Convened (full IRB Board) review
Exempt Research

• Meant for short term projects
• Multiple categories
  • Most of our studies fit in category 4
  • “Research involving the collection or study of existing data…..if the information is recorded…in a manner that subjects cannot be identified…”
• Data MUST already be existing and cannot rely on information that has yet to be generated or collected
• CANNOT be used if mix of collection of existing data (i.e. retrospective) and prospective data collection.
• CANNOT retain linked codes that can identify patients (i.e. Master Key)
Data Collection Under Exempt Approval

- CANNOT collect any data on our prisoner population
- CANNOT have patient identifiers on data collection tool
  - This includes the 18 identifiers dictated by HIPAA
  - Name
  - All geographical subdivisions smaller than a State
  - All elements of dates (except year) for dates directly related to an individual (i.e. DOB, admission date, date of antibiotic administration, etc.)
    - Can collect age except for those patients over 90 years, must collected as simply >90yrs
  - MRN
  - Device identifiers and serial numbers
  - Biometric identifiers, including finger and voice prints
  - Full face photographic images and any comparable images
  - Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data)
Approval of Exempt Applications

- According to OSU HRRP, determination with 5-7 business days, up to 2 additional weeks for review by Privacy Board
- Does not expire and does not require annual continuing review
- MUST be conducted as proposed (i.e. cannot amend your protocol)
- If you require revisions must submit a new application prior to initiating changes in research
Most Common Obstacles for Exempt Research

- Someone in the research group didn’t complete CITI training
- Someone in the research group didn’t complete or renew their COI
- Identifiable data points on data collection tool:
  - Dates- must revise as Hospital Day or Post-injury Day, etc.
  - Protection of Privacy clarifications:
    - Must destroy master key linking patient to reference number after data collection is complete, **prior** to data analysis
Participants will be identified by an order for continuous insulin infusion while admitted to the medical or surgical intensive care unit, and data will be collected through Essentris, the information warehouse, IHIS and patient charts using the structured data collection sheet. Data will be entered into a password protected electronic database for statistical analysis. Data will be coded and de-identified, and stored in a locked cabinet inside a locked office in Doan 332 in the department of pharmacy. The coding list containing identifiable information will be password protected and stored on a password protected computer within the P drive of Dr. Murphy in the department of pharmacy.
Dear Dr. Murphy,

In order to make a determination, I reviewed your exempt request for the protocol above. The following elements need to be addressed before your application can receive a determination.

Please clarify--is this project being done only for internal quality purposes, or is it also to be used for research purposes? If only for internal purposes, no review is needed: please confirm and I will close the exemption request. If also for research, please address the following:

1. Question #13a--revise for clarity as all identifiers (e.g., keys) must be destroyed immediately after collection, prior to analysis.
2. Question #13b--revise for clarity as the master list of coding cannot be retained beyond the collection phase.
3. Question #13c--revise as start date has passed.
4. Question #20a--revise as identifiable information cannot be collected/retained with the data, even temporarily. Only a temporary subject list or key can be utilized.
5. Protocol page 3--revise as only a sample key can be created (e.g. MRN = Random study number). If a more complex key is needed with additional PHI, then IRB review (rather than exempt review) is required.

As applicable, your clarifications and/or modifications should be submitted as follows:
- Provide a cover letter or reply email with a detailed, point-by-point response to each of the items.
- Revise all applicable documents with changes underlined.

Once the above elements are satisfied, you will be notified with a determination. Please let me know if you have any questions.
Expedited Research

- IRB review carried out by IRB Chairperson or by at least one experienced IRB member
- Research cannot present more than minimal risk to subjects
- Research involves procedures listed in categories 1-7 (see online for full descriptions)
  - Collection of data through non-invasive procedures routinely employed in practice
  - Research involving materials already collected for non-research purposes
- Requires signature from both PI and Department Chair
- Reviewed outside of the convened IRB meeting
- Requires annual continuing review
What and who is a PI?

- Principal Investigator
- Co-investigator
- Key Personnel
The Actual Paperwork!

• Need to include a research proposal/protocol that details
  • See http://orrp.osu.edu/irb/guidance/ “guidelines for writing a research protocol:
  • Remember to write for lay people
• Include data collection form
• Exempt:
  • Application for IRB Exemption
  • Appendix A1 (Co-investigators and key personnel)
  • Appendix N (Waiver or Alteration of HIPAA Research Authorization)
• Expedited
  • Initial Review of Human Subjects Research
  • Appendix A1
  • Appendix B (Expeditedi review- initial review)
  • Appendix M1 (Waiver or Alteration of Consent Process)
  • Appendix N (Waiver or Alteration of HIPAA Research Authorization)
SUBMIT ONLINE!!