GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS IN SPA RESEARCH

Parties Involved and Responsibilities

- **Institutional Review Board (IRB) Responsibilities**
  - Makes sure risk is minimized
  - Makes sure there is equitable selection of research participants
  - Makes sure informed consent is obtained
  - Research protocol (plan) protects the data and confidentiality of the participant as well as privacy of the participant
- **Human Research Protections Office (HRPO) Responsibilities**
  - Support the research community (IRB, investigators, and participants)
  - Ensure applications are complete so they can be reviewed by the IRBs or chairs
  - Provide education and training initiatives
- **Principal Investigator (PI)**
  - Responsibilities
    - Makes sure the research is valid and well-written.
    - Makes sure no research related activities start until after the IRB approves the research (cannot contact prospective participants).
    - Valid research design and making sure research is approved prior to any research activities.
    - PI must take on additional responsibilities if there is no other "investigator."
  - *Who* can be a PI?
    - Main Campus-PIs can be students but they must have a responsible faculty member.
- **Investigator**
  - Responsibilities (between the PI and Investigator, these must be handled):
    - Submitting documentation to the IRB
      - Annual progress reports for full or expedited research
      - Reporting adverse events, protocol deviations and unanticipated problems within 5 days of occurrence
    - Requirement to comply with IRB approved protocol (research plan).
    - Protecting participants from harm- privacy and confidentiality
  - Who is an investigator?
    - Co-investigators
    - Anyone else (including faculty, staff, and students) working with the research that has access to identified data, the participants in the research, etc.

Levels of Review by IRB

- A majority of the time SPA submissions fall under the 'exempt' category, or do not require IRB monitoring (this will be determined after submission of Initial Review Form, protocol, and other supporting documents).
    - Exempt: requires a staff member and at least a single IRB member to review. Must pose less than or equal to minimal risk to participants.
    - Expedited: requires staff member and at least a single IRB member to review. Review is not necessarily 'quick,' but it does not go to full committee. Must pose minimal risk.
    - Full Committee: requires review of the convened meeting of the IRB. Considered more than minimal risk.

Application Process

- Go through either HRP or CITI Training.
    - These trainings show the importance of minimizing risk to participants.
        - UNM's HRP office suggests HRP Training for SPA students, as the CITI training contains information more relevant for scientific and medical studies.
    - Access to training can be found at: http://hsc.unm.edu/som/research/hrrc/training.shtml.
    - Everyone on your research team needs to also have gone through training (including your responsible faculty member).
- Go through Click IRB Training
    - Click IRB is where you will submit documents and track the progress of your submissions.
    - Access to training can be found at: http://hsc.unm.edu/som/research/hrrc/click.shtml
    - Your sponsor faculty member needs to have gone through this training also.
- Documents that you will want to submit initially:
    - Initial Review Form (IRF), also referred to as the application. The IRF is the 'create new submission' process on Click IRB.
    - Protocol
        - There *is* a difference between the IRF/application (one-time submission) and the protocol document (living document that changes as your research changes).
        - Can be found on the HRPO website at: http://hsc.unm.edu/som/research/hrrc/forms.shtml, or in Click IRB (IRB tab > IRB Library > Templates)
    - Human Research Determination Worksheet
        - Not required, though it is encouraged for SPA submissions.
        - Can be found at: http://hsc.unm.edu/som/research/hrrc/forms.shtml, or in Click IRB (IRB tab > IRB Library > Worksheets)
    - If you are certain that your study involves human research then you should send in the supporting documents as listed on the IRF.

- Word Document version of the IRF provides a more comprehensive list of supporting documents than does the Click IRB new submission process.

- After submission of the above documents, the HRP Office will determine the level of review.
  - This process generally takes 2-3 weeks.
  - You will be notified which level of review your study falls under. The HRPO will ask for any additional documentation that was not submitted previously, if the study falls under 'exempt' review or above.
- Once approved, work on the study can begin!

Helpful Documents

- Initial Review Form, Protocol, and other Documents: http://hsc.unm.edu/som/research/hrrc/forms.shtml
- List of additional forms, including human research determination form: http://hsc.unm.edu/som/research/hrrc/forms.shtml
- What is a Protocol? http://hsc.unm.edu/som/research/hrrc/docs/Protocol.pdf
- Click IRB, IRB Study Submission Guide: https://irb.health.unm.edu/IRB/Doc/0/BUIUQO5P7KJKJ8NIJQ9KOO78BA/IRB_Study_Submission_Quick_Ref.pdf
- How to determine if your project will be considered 'exempt': http://hsc.unm.edu/som/research/hrrc/docs/Worksheet_ReviewLevel.pdf
- Consent form generator: http://hscapp.unm.edu/createhrrcdocs/index.cfm?act=app.consentform
- UNM Investigator Conflict of Interest electronic submission: https://www.surveymonkey.com/s/FCOI_Annual_Disclosure_2012
- Non-UNM Investigator Conflict of Interest electronic submission: https://www.surveymonkey.com/s/Non-UNM_Investigator_FCOI_Disclosure

***You should also be able to find all documents on the Click IRB website in the IRB Library**