University of North Florida  
Institutional Review Board Meeting  
December 11, 2013  
10:39am – 12:06pm  
ORSP Conference Room  
Building 3, Room 2502

Voting members present: Steven Ames, Richard Buck (non-scientist), Kathaleen Bloom, Catherine Hough, Krista Paulsen, Susan Perez, Janice Seabrooks-Blackmore  
Quorum: yes (7 of 7 attending)  
Non-voting meeting attendees: John Kantner, Cheresa Boston, Jennifer Wesely, Dawn O’Connor, and Kayla Champaigne

Minutes

I. Review and approval of minutes from 11/01/13 IRB meeting  
   - 11/01/13 minutes unanimously approved with modifications (7 approved).

II. Discussion of IRB leadership change  
   - Due to time constraints, Dr. Paulsen approached Dr. Kantner to see if it would be possible to step down as IRB chairperson 1 year prior to the end of her 2 year appointment. With her duties as the chair of the Sociology, Anthropology, and Social Work department, she felt that she could not devote as much time as was needed to her duties as the UNF IRB chairperson.
   - Dr. Jennifer Wesely has agreed to serve as the new UNF IRB chairperson beginning in January 2014. Dr. Susan Perez will continue to serve as the vice chair and Dr. Paulsen will assist Dr. Wesely with the transition process.
   - IRB members did not express concerns with the transition

III. Discussion of Authorization Agreements (AAs)  
   - Background:
     • An authorization agreement is a legally binding agreement that allows one or more IRBs to rely on the IRB review of another institution thereby reducing the amount of effort needed for researchers who are interested in collaborative research.
     • The UNF IRB has been entering into an increasing number of these authorization agreements. At the 10/17/2012 IRB meeting the UNF IRB decided that individual authorization agreements were acceptable on a case by case basis if the project meets the following criteria (other criteria may also be considered):
       o Other institution has an IRB and a valid FWA
       o IRB at other institution has standard operating procedures that the reviewer deems robust.
       o The research activity will take place at the non-UNF institution using a non-UNF population.
     • At this time, the UNF IRB has only been entering into authorization agreements on a case by case basis and each authorization agreement is limited to just one specific project
     • The IRB at Flagler Hospital has requested that the UNF IRB consider issuing a blanket authorization agreement for all research conducted in their facility involving UNF faculty, staff or students. With this blanket AA, the UNF IRB would be relying on the Flagler
Hospital IRB for all IRB oversight of projects at their facility that involve UNF faculty, staff or students as researchers.

- Authorization agreements are allowable under 45 CFR 46.114 of the federal regulations. However, that section of the regulations also includes the following statement “In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.”

**Discussion of Authorization Agreements (including Blanket Agreements for multiple projects):**

- One IRB member wanted to know about the potential downside of entering into a blanket authorization agreement with another institution. Potential downsides identified at the meeting include the following:
  - The UNF IRB would not even know if UNF faculty, staff or students were conducting research at the other institution which could cause problems if there was misconduct or adverse events that took place. By getting authorization agreements for each project, the UNF IRB is given some information about the project activities and can ensure that each project has been reviewed and approved by the collaborating institution before relinquishing oversight of that project to another institution.
  - Potential for increased institutional liability for UNF in the event of misconduct or adverse events

- One IRB member wanted to know how time consuming authorization agreements can be for both administrators and researchers. Administrator Response:
  - The process heavily relies on administrative action so the researchers often have to commit much less effort for an AA than they would for an IRB submission.
  - Generally speaking, authorization agreements are not very time consuming for administrators because there is a standard template. However, it varies depending on the collaborating institution.

- One IRB member asked how common these types of arrangements are with other IRBs. Administrator Response:
  - Authorization agreements in general seem to be on the rise
  - OHRP and the federal regulators are considering revising the regulations to require one institution to be the IRB of record so it is expected that AA will continue to be prevalent

- IRB members discussed the kinds of documents needed when entering into an AA:
  - The IRB discussed whether it would be necessary to obtain all the approved protocol documents, just the IRB approval memo from the relied upon IRB, or no documentation at all.
  - If all project documents are submitted, it could cause tension if the UNF IRB did not agree with the other IRB’s determination on the project
  - One IRB member felt that receiving no documentation was problematic in terms of the IRB’s accountability for projects involving human subjects. Obtaining the approval memo from the relied upon IRB is a happy medium between obtaining all the protocol documents and not obtaining any documentation.
  - One IRB member remarked that it might be helpful to receive the IRB approval documents for some projects during the first year of an agreement to see if the UNF IRB feels comfortable with the quality of the IRB review at the relied upon institution. This would be particularly valuable for projects covered under a blanket AA. A blanket
authorization agreement could be generated with an annual expiration date so it would have to be renewed every year. The relied upon institution could also provide a monthly or yearly report to update the UNF IRB on all projects covered by a blanket AA. An agreement can be generated with any additional conditions or requirements the IRB requires.

- One IRB member asked about what the UNF IRB would review on an annual basis if deciding whether or not to renew a blanket AA.
  - Another IRB member said that it may not be necessary to review anything on an annual basis after the first year
  - Another IRB member indicated that it would be up to the UNF IRB to decide what to review but the annual expiration date would serve as a forced mechanism to ensure that the UNF IRB reviews the agreement each year.

- Conclusions:
  - The UNF IRB is not opposed to blanket authorization agreements and is also open to continuing individual authorization agreements on a case by case basis when appropriate.
  - Research integrity administrators in conjunction with the IRB chair and UNF general counsel will generate draft requirements and language for a blanket authorization agreement if such an agreement is requested by another institution.
  - The UNF IRB is comfortable with the current UNF procedures for when another IRB relies on UNF IRB review and approval. An additional note will be included on the approval memos for applicable collaborative projects such as “It is the Principal Investigator’s responsibility to share approval documents and IRB requirements with all study personnel responsible for the conduct of research for this project.”
  - Vote (Blanket authorization agreements are allowable by the UNF IRB and the logistics of such an agreement can be finalized by research integrity administrators in conjunction with the IRB chair and UNF general counsel without coming back to the full board) 7 approve

IV. Discussion of UNF Standard Operating Procedures (SOPs)

- This discussion is the beginning of a longer and more detailed process to delve into the UNF IRB standard operating procedures. The broader UNF community will also be consulted for feedback once a draft document has been generated.
- The standard operating procedures would be used in the event of a federal audit so they must be detailed enough to be useful while still allowing the necessary flexibility to conduct the various business under the purview of the UNF IRB.
- IRBNet needs to be incorporated throughout and the list of required documents for submission needs to be updated as well.
- Discussion of the exempt review process
  - Current Standard Operating Procedures regarding exempt review does not entirely reflect current procedures so it must be updated.
  - At a minimum, the UNF IRB needs enough information to confirm that the project is eligible for exempt review.
  - One IRB member remarked that researchers should not be responsible for identifying the final review type for their own projects
  - In the event that the UNF IRB moves to an exempt review model where the IRB was only making a determination of exempt status, more than one IRB member felt that the consent form and measurement tools would still be important for the review process.
Attachment B has already been implemented and iterative changes will help the IRB determine what changes might be effective in the future.

Many new projects originate from UNF student researchers and use UNF students as participants. Additionally, faculty advisors differ greatly in the amount of oversight and guidance they give their students when working with regard to research conduct. One IRB member suggested that the IRB consider the UNF IRB’s role in serving as a potential check on the human subjects facet of research before students interact with participants.

One option is to have the IRB chairperson review all exempt projects in conjunction with research integrity staff.

One administrator commented that many review items pertain to issues with the North Florida – IRB Protocol document so revising and clarifying that document would be very helpful in improving the review process. This is something that the UNF IRB already indicated they would like to do in the future.

Future discussion about the review of exempt projects will be needed before a final determination about the process can be made.

Discussion of class projects

Prior to the class project procedure, those projects went through the formal IRB review process. Class project waivers are now valid for three years rather than the original one term period. The turn-around period for review of class projects is no more than 5 business days. The documentation required for class projects is limited to the course syllabus, a brief description of the class project topic/activities, a signed instructor checklist, and verification that the instructor has completed the required CITI training.

Class projects also serve as a control mechanism to ensure that instructors and students are aware that class project data cannot be used to contribute to generalizable knowledge and ensures that the course instructors are trained in the protection of human subjects.

One IRB member had issue with the special review process for class projects. One suggestion was to use a decision tree to determine if the class project activities fit the definition of human subject research. If the project was not human subject research, nothing would be needed and a waiver could be generated. If it was human subject research, UNF IRB review and approval would be required prior to initiation.

Future discussion about class projects will be needed before a final determination about the process can be made.

IRB members were asked to forward any SOP comments to the IRB chairperson for future discussion.

IRB Projects Approved since last convened meeting:

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<td>Ryndak, Karen (FA: Toglia, Michael)</td>
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**Amendment Approvals**

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**Contingent Amendment Approvals**
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**Extension Approvals**

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Contingent Extension Approvals
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Extension & Amendment Approvals

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<td>Balasubramanian, Chitra</td>
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Withdrawn Projects
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