University of North Florida
Institutional Review Board Meeting

May 6, 2015
2:03pm – 3:42pm
ORSP Conference Room
Building 3, Room 2502

Voting members present: Richard Buck, Christopher Joyce, Krista Paulsen, Jennifer Wesely, and Ray Wikstrom
Alternate member present (observing only, did not count towards quorum or voting): Stephen McCoy
Quorum: yes (5 of 9 attending)
Non-voting meeting attendees: John Kantner, Dawn Harmon-O’Connor, Kayla Champaigne, and Eva Espique-Bueno

Minutes

I. Review and Discussion of Full Board Project IRB#15-034 (727234-1) “Examining a Triadic Approach to Decision Making in Adolescents” submitted by Dr. Tracy Alloway
   - Materials:
     - Associated material was shared with all IRB members in IRBNet
   - Background:
     - The study population includes teenage boys who are enrolled in the Safe Harbor Maritime Academy (at-risk teenage boys who are under 18). According to the Safe Harbor website they are specifically called a Christian boarding school and they offer behavior modification program. It is not clear if the boys have been routed through the juvenile justice system.
     - According to Attachment A the researchers were invited by the director (Dustin Johnson) to work with all of the boys registered at this facility. It appears that Mr. Johnson has legal guardianship over the boys.
     - In Attachment A, the PI said that the aim of the pilot study is to develop an understanding about how at-risk youth make decisions and a sample size would be about 10. There are two aspects to the study. The first aspect is the cognitive part that will consists of tests and surveys, which focus on the working memory and self-reflection. The testing sessions will be done on Qualtrics and should last no longer than 30 minutes with a researcher present. The second part of the study includes observations and written recordings during weekly group sessions where the youth discuss reasons for their behavior.

   - Initial IRB Discussion
     - An IRB member started the discussion by identifying some concerns: insufficient information about the Safe Harbor Maritime Academy (e.g., what kind of agency is Safe Harbor Maritime Academy?, lack of clarity about number of participants in each portion of study and how many group sessions will be attended for research, do boys have the freedom to leave the facility, potential for undue influence/coercion, extent of Mr. Johnson’s investment in the research, clarity about how group session information will be recorded and how those who did not assent will be excluded from research).
     - Another IRB member identified concerns regarding the group sessions (e.g., need for clarity about the types of question asked, extent of PI’s role in developing group session questions, ability of boys to opt out, could the effectiveness of group sessions be compromised by presence of researchers).
A third IRB member suggested changes to some of the language on the assent form and wanted to know whether or not the boys have access to email (since the PI stated in the assent form that the boys could opt out by email).

**Initial Discussion of “Wards” According to Regulations:**
- IRB reviewed section on wards in federal regulations (45 CFR 46.409), including the following statement which helps to define wards as “Children who are wards of the state or any other agency, institution, or entity…” The federal regulations do not include a formal definition of the term “ward”
- One IRB member indicated that the boys at Safe Harbor may not actually be “wards.” This IRB member also indicated that the use of the word “ward” in the power of attorney document does not mean that the children are legal wards. This determination was based on the IRB’s understanding that the boys were not taken away from their parents and the parents/guardian willingly gave guardianship for the boys to Safe Harbor. As long as there is a power of attorney document for each boy and the boys were voluntarily enrolled in the program then they are unlikely to be wards under the federal regulations. This IRB member also confirmed that the Power of Attorney documents that were submitted were valid and granted Mr. Johnson the authority to grant permission for the boys to participate in the research. However, the boys must still assent to participate in the research. Finally, this IRB member indicated that a child advocate who is not invested in the research, agency, or the program may still be valuable.
- No other IRB members expressed disagreement about the above information (i.e., boys not considered “wards” and power of attorney document could grant authority to Mr. Johnson to serve as guardian for boys to participate in research).

**An IRB administrator reminded IRB member of concern identified for this project at a previous meeting: dual role of Safe Harbor director as both director and guardian (potential for conflicting roles/interest). Several IRB members indicated that this could still be a potential concern that should be addressed by the PI**

**An IRB member expressed concern that the risks to participants may be greater than the potential for benefits. Additional study information is needed including information about the necessity of this research with a vulnerable population.**

**An IRB administrator asked the IRB members if they had concerns about references within the IRB documents to interviews or reports from the Safe Harbor staff even though there was no other information about staff involvement in the research. Several IRB members indicated that they would like additional information about the Safe Harbor staff involvement in the research.**

**Discussion with Dr. Alloway**
- Dr. Alloway attended a portion of the meeting.
- The PI was asked to provide additional information about Safe Harbor and whether the boys are free to leave the facilities. The PI said this is a new kind of project to her (e.g., doesn’t usually conduct pilot studies or work with this type of population). She also indicated that the director of Safe Harbor approached Dr. Alloway because she was featured in a UNF magazine. Mr. Johnson reached out to the PI because he wanted to provide additional support for the boys. The PI met with Mr. Johnson and he provided a tour of the facility. The PI also indicated that she believed the facility to be a replacement for a juvenile detention home for boys who have committed a crime. The facility is limited to 12-14 boys at any one time. She also indicated that there was a residential component (i.e., boys live on boats). Although she believed that boys may have some free time, she was not certain if the free time could be spent off site and/or unsupervised. The PI said that the privileges may be different based on
the terms the boys are serving. According to the PI, Mr. Johnson said their mission statement is to provide a more positive environment for the boys to facilitate rehabilitation.

- **The PI was asked to describe Mr. Johnson’s investment in the research:** The PI said that Mr. Johnson currently uses a self-developed behavioral approach with the boys. For instance, if punitive actions are necessary (e.g., don’t follow the rules, don’t clean up after meal time), Mr. Johnson may institute a time out. During the time out, Mr. Johnson gives them a shovel to dig holes and tells the boy to think about what they have done. The PI stated that Mr. Johnson’s approach is more self-taught and wants to bring in an evidence-based approach to the program. The PI said that her goal as a researcher is to get a better understanding of the boys at the facility including what is driving their decision making and their cognitive and social/emotional perspectives (e.g., are they being directed by peer influence). With regard to the group discussions, the PI said that the discussions will be led by Mr. Johnson and data will be obtained from the conversations during the group sessions without PI interaction. The research team will be observers who will review the language used in the group sessions and then compare that data to the data obtained from the tests and surveys.

- **For clarity, an IRB administrator asked for more information about whether the boys can leave the Safe Harbor facilities:** The PI said that there is a no smoking/alcohol policy, so Mr. Johnson doesn’t want the boys leaving the facility to purchase those items. Based on her understanding, the boys stay on site. The PI is not entirely sure of the rules, but knows that it is residential and the boys are responsible for the care of the boat in which they reside.

- **The PI was asked to explain the relationship between potential risks posed to subjects and the benefits of the research and to indicate whether there is an alternative to using this vulnerable study population:** The PI explained that research on decision making with young adults tends to focus on the peer influence. She also indicated there hasn’t been actual research on memory in decision making with young adults who have already committed a minor crime but are not in prison. The PI also indicated that she is interested in examining how attachment may be related to working memory. The PI research for the past 15 years primarily focuses on educational settings and she strongly believes this research is important because there isn’t much information on the multidimensional approach in decision making with these kinds of teenagers who are already being rehabilitated. Most of the times researchers are looking at the teenagers prior to committing the crimes or those who have already committed a more serious crime. The PI said it’s a goal of hers to understand and map on the quantitative aspects about how the boys are making the decisions. Although the PI has worked with controlled and vulnerable populations (e.g., minors, individuals with autism spectrum disorder and Down syndrome, and students who have been expelled from school), she has not worked with minors required to attend a rehabilitating boys home.

- **The PI was asked to address potential issues of undue influence:** Several IRB members were concerned that the boys may not have the freedom to decide whether or not to participate. The PI said that the data collection for the tests/surveys will be done online, but thinks the director may know who participated because it’s such a small group and he is invested in their day to day activities. However, upon additional discussion the PI indicated that it could be possible to ensure that the director does not know who participated in the tests/surveys. With regard to the group sessions, those are required as part of the program and led by the director. The PI does not have control over the group sessions and attending the sessions will allow the researchers to obtain information. When asked about the potential for her presence to affect the focus groups, the PI expressed that she was open to alternatives but was unsure about how all bias could be avoided.

- **The PI was asked to provide additional information about the group sessions:** The PI said that she hasn’t attended any group sessions and doesn’t know the nature of the questions asked of
the study population. However, from the information provided by Mr. Johnson it appears that the scheduled group sessions are like a support group. There is a school on site and a vocational aspect of the program (e.g., boys taught mechanical skills in a separate building where the boys work on boats). The PI thinks it’s a self-objective process and not sure of the specific questions asked during group sessions, but could ask Mr. Johnson to provide sample questions used during the group sessions. The PI said the questions may change on a weekly basis and could be open ended. She also indicated that she thought there was only one group session that included all boys in the Safe Harbor boys home. The PI informed the IRB that she will need to look into the confidentiality of information and expectations of privacy during group sessions.

- The PI was asked to describe how she will ensure that data obtained from boys who did not assent to the research would be excluded from data used for research if those boys are still required to attend group sessions: The PI said that researchers would just record the information that is provided by individuals who assented to the research and would not take notes on any information provided by non-participants. Other options were presented by the PI (e.g., PI not present during group sessions and would audio record the group sessions, PI not present during group sessions and ask Mr. Johnson or other staff to take notes on the sessions, have research assistant collect data). However, there are problems with those other methods (e.g., audio recordings would obtain responses of the whole group and it would not be possible to distinguish those who opted out, Asking Mr. Johnson or someone else to take notes at the group sessions may require too much manpower, disrupt the group sessions, or result in notes that are not usable). The reiterated that she was open to suggestions but believes her proposed procedures will be the least disruptive. An IRB member said that the director doesn’t have to know who assented and suggested that the PI includes a check box on the assent form to indicate assent and dissent and then ask that the boys return the form to the researchers either way. This would make it less likely that the director knows who assented to the research. However, this won’t solve the question of how the PI will know who assented to this research so she only obtains information from those who assented. The indicated that she could ask for photos and corresponding names of the boys to ensure that data was only recorded from those who assented to the research. An IRB member suggested name tags for the boys instead of photos with the list of names.

- The PI was asked to consider the inclusion of a child advocate to safeguard the study population. The advocate would be a person who is not invested in the research or program, and would be there solely to provide support for the youth. The PI was open to the suggestion, but was not sure who could serve as child advocate. An IRB administrator brought up the regulations on the screen for review (45 CFR 46.409) “The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.” The PI said that conflicting roles is a valid concern and doesn’t want Mr. Johnson to push or chastise the boys for not participating in the research. The PI indicated that she could conduct assent procedures when the director is not in the room. She also suggested that she could obtain assent and conduct testing when boys have computer time since assent and data will be obtained on the computer. This would allow non-participants to remain in the room and do whatever they wanted on the computers while other individuals participate in the research. By obtaining assent and data via this method, it would be difficult for participants, Safe Harbor staff, and researchers to know which individuals assented to the online portion of the research and which did not.
- Additional IRB Discussion (after PI left)
  - An IRB administrator said that because the facility is an alternative to a juvenile detention and boys could not leave the facilities, the boys might be considered prisoners according to the regulations. The IRB reviewed the federal definition of prisoner (45 CFR 46.303(c)):
    “Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration on a penal institution, and individuals detained pending arraignment, trial, or sentencing.”
  - IRB also reviewed federal guidance on the definition of prisoner. This guidance included this statements “Individuals are prisoners if they are in any kind of penal institution, such as a prison, jail, or juvenile offender facility, and their ability to leave the institution is restricted. Prisoners may be convicted felons, or may be untried persons who are detained pending judicial action, for example, arraignment or trial.” and “Individuals who are detained in a residential facility for court-ordered substance abuse treatment as a form of sentencing or alternative to incarceration are prisoners; however, individuals who are receiving non-residential court-ordered substance abuse treatment and are residing in the community are not prisoners.”

- The PI was asked to discuss the potential for boys to be chastised by other boys in the group because of their participation or non-participation: The PI said there is potential for negative peer interactions and influence regardless of the research and it is difficult to stop it entirely.
- Several IRB members indicated that they would like more information about the group sessions and the types of questions asked during the group sessions: The PI responded that she believes Mr. Johnson directs the session and in the spirit of collaboration she thinks he would agree to share information about the types of questions asked at the sessions.
- An IRB member asked about the boys in the study and whether the same boys would participate in the research throughout the study or if there could be some turnover: The PI said that it depends on the terms the boys are serving. The PI hopes to have the same group of boys with regard to the qualitative and quantitative components of the study so the data can be matched. The PI doesn’t want any lag time between matching the data.
- The PI was also asked to provide some additional information about the data collection setting and procedures: When asked about how many sessions the PI anticipated for the testing/surveys, she indicated that she planned to have 2 session of testing and surveys on Qualtrics. However, the exact amount of time depends on how fast participants respond and how long they choose to reflect on a topic. Also, with regard to the group sessions the PI indicated that she planned to be part of multiple group sessions in order to provide a bigger picture of the feedback that is provided by the boys during those sessions. When asked, the PI also indicated that she was not sure whether or not the boys have access to email and/or internet and would need to discuss procedures with Mr. Johnson. An IRB member suggested that the PI adjust the language on the assent form regarding withdrawal from the research. Currently, participants must withdraw via email and this should be changed if the boys do not have access to email and/or internet. This IRB member also indicated that boys should be able to withdraw from the research by informing the PI of their intent to withdraw in-person.
- An IRB member wanted to know why Mr. Johnson was not listed on the Safe Harbor website as the current director: The PI said that she first talked to Mr. Johnson in the fall (August/September of 2014) and that was when he became director of Safe Harbor. Mr. Johnson told the PI that the previous directors were looking to retire. The PI did not meet the previous executive director or the previous program director.
• Several IRB members felt that the boys would likely be considered prisoners if their ability to leave the institution is restricted.

• An IRB member also indicated that the boys may be wards if they are committed to Safe Harbor rather than being voluntarily placed there by their parents. This IRB member also had some concerns based on the study population and setting (e.g., confidentiality, potential for role conflicts with director and the fact that the directors’s information is not on the website, potential for undue influence, lack of information about group sessions). It was also unclear to this IRB member why this research was necessary if the director only wanted to improve the program since the director could always read about evidence based approaches or visit other facilities instead of conducting a research project involving these boys.

• Another IRB member felt that the PI provided a good basis for the need of the research but indicated that the PI would need to include that information in the IRB documents and back it up with citations and references.

• An IRB administrator reminded the IRB that they would have to decide which category in subpart D could apply to this research since it involves minors.

• Discussion of child category for research (Four Options: 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, or 45 CFR 407):
  o One IRB member indicated that the study does not qualify under 46.406 because the boys do not have a disorder or condition. Another IRB member asked if there was a definition of “condition” for 45 CFR 46.406. IRB reviewed 45 CFR 46.406 and looked in federal guidance but could not find a definition.
  o Another IRB member said the boys are really not encountering any great risk outside of their everyday lives. However, this IRB member also indicated that the everyday lives of the study population are exceptional.
  o An IRB administrator said the UNF IRB has not had a project fall under subpart D 46.407 to her knowledge and reminded the IRB of the additional approval criteria if that category is selected (e.g., need to consult the HHS secretary). The IRB reviewed content of 45 CFR 407. Administrator also reminded the IRB that the UNF IRB did not “check the box” for subpart D (or C) for UNF’s federal wide assurance with the government. Because of that and the fact that this research is unfunded, the UNF IRB has some flexibility with regard to the subparts. The IRB administrator then offered to consult with the Office of Human Research Protections (OHRP) and Health and Human Services (HHS) if the IRB believes this project requires 45 CFR 407. This would ensure that the IRB is fully aware of the requirements. No IRB members indicated that OHRP and HHS should be contacted at this time.
  o An IRB member questioned whether the benefits outweigh the risk and emphasized that this is very vulnerable population (i.e., both prisoners and minors) and the instigator of the research is the guardian.
  o An IRB member said that if the PIs goal is to better understand how at-risk youth make decision she could pursue that question with a non-incarcerated population (e.g., teen court, diversion program, youth who have not yet been arrested but have been identified). The benefits of the research would need to be more clear before the IRB could determine category.
  o An IRB member suggested that the PI could try to address all items identified in the pre-review and at the meeting or would need to consider an alternative procedure that could provide benefits to the boys at Safe Harbor without increasing potential risks. For example, the PI could collect some data about the boys but then only use it internally to inform the director of ways to therapeutically treat the youth without using the data for research.
An IRB administrator reminded the IRB of their power to disapprove the study (45 CFR 46.109(a), UNF IRB SOPs).

Another IRB member said that a kinder approach would be to provide the PI with the list of issues and concerns from the pre-review and IRB meeting, let the PI know that the IRB requires a great deal of revision before approval could be considered, and inform the PI that approval may not be possible even if the PI successfully addresses the identified items. If the PI would like to resubmit to the IRB, the IRB will consider those updated documents at another IRB meeting. However, there is no guarantee that the project could receive approval.

There was a suggestion to have an in-person meeting with the PI to discuss this project and the identified concerns. This would allow a few IRB members to discuss the review items and concerns and then help the PI to come up with solutions if possible. This may be more beneficial than simply generating a review memo and not meeting to discuss the items. Several IRB members liked this idea and confirmed that all the pre-review items and items discussed at this meeting should be discussed with the PI in-person. An IRB administrator confirmed that a meeting will be scheduled between a sub-committee of the IRB (1-3 members), at least one IRB administrator, and the PI. An administrator reminded the board that those IRB members who attend the meeting will not be able to make decision on behalf of the board. However, the sub-committee could make suggestions for changes that the PI could make to her documents before resubmitting those documents for review by the UNF IRB. The topics for the sub-committee meeting include all items discussed at this IRB meeting, the pre-review items, and federal regulations and guidance. After the sub-committee meeting, the IRB will need to meet again at a full board meeting to review and discuss this project.

- Vote (5 of 5 attending in favor of tabling this project without action, 0 against, 0 abstained, 4 not present):
  - PI will be asked to update IRB documents and resubmit those documents for review. The updated documents will need to be reviewed at another IRB meeting.

II. Update on training for employees in the Public Opinion Research Lab (PORL)
- An IRB administrator had a meeting with Dr. Binder and he liked the idea of not having his employees do CITI training for exempt projects. However, the IRB didn’t discuss training for employees assisting on expedited or full board projects. An IRB administrator suggested an exception for those expedited and full board projects submitted for PORL. Although PORL employees would not be required to complete CITI training, those employees would still need to complete a teaching tool that is similar to the FSU training. Due to lack of time, discussion of potential alternatives for PORL could not be fully discussed and no determination was made.

III. Review, discussion, and vote on past meeting minutes from the 4/22/2015 meeting
- 4/22/2015 minutes unanimously approved as-is (5 in favor, 0 against, 0 abstained, 4 not present)

IV. Due to time limitations, the IRB was not able to discuss the following items that were on the Agenda:
- Discussion of training for employees in the Public Opinion Research Lab (PORL) when a project is Expedited or Full Board rather than Exempt
- Confirmation and clarity about IRB requirements for Exempt projects
- Discussion of documents required for Expedited or Full Board review for updates to the UNF Standard Operating Procedures
- Discussion of subgroup topic: 90 day deadline for PIs to respond to memos
- Update and discussion of other subgroup topics
  - Class Projects
  - Incidental Findings and Contingency Plans
  - Serious and Continuing Non-Compliance

The above items will be discussed during the next IRB meeting if time allows.

IRB Projects Approved since last convened meeting:

**Original Approvals**

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**Expedited**

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**Full Board**

NONE

**Contingent Approvals**

NONE

**Amendment Approvals**

NONE

**Contingent Amendment Approvals**

NONE

**Extension Approvals**

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Full Board

NONE
Extension & Amendment Approvals
NONE

Waived or Not Engaged

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Class Project Waivers
NONE