|  |
| --- |
| **AGENDA & NOTES** |
| **Name of Committee:Human Subjects Institutional Review Board (HSIRB)**Members: Patricia Ayers, Matthew Fall, James Owens, Katrina Steinsultz, Matthew Van Cleave, Melinda Wilson, Kari Richards, and Susan JepsenAlternate: Anna MitterlingCommunity Member: Renee Brown |
| Committee Members Present: Patricia Ayers, Matthew Fall, Katrina Steinsultz, Matthew Van Cleave, Melinda Wilson, Kari Richards-by phone, and Susan JepsenCommittee Members Absent: Renee Brown, Anna Mitterling, and James OwensGuests: Sally Pierce and Carlotta Walker |
| Date: May 3, 2019 | Time: 11am – 12pm | Room: ADM 200 |

| **Agenda Item** | **Discussion** |
| --- | --- |
| Approval of the March 1, 2019 minutes (4/5/19 mtg was canceled) | * The 3-1-19 Agenda & Notes were approved.
 |
| Discuss Proposal for Exemption from Dr. Carlotta Walker. | * Group discussion with Dr. Carlotta Walker regarding her HSIRB research application.
* Determined that the project is exempt per category 2 (45 CFR 46.104).
* Exemption is contingent upon approval of the Benedictine University IRB.
 |
| Discuss research being done by LCC employees (faculty or staff) on other LCC employees (faculty or staff). | * Is it possible (or even desirable) to have a general policy in place for the LCC-HSIRB on this topic?
	+ This discussion is focusing on the internal researcher vs external researcher
	+ Types of concerns from previous discussions
		- Confidentiality is different when internal
			* researcher may know identity of participants
				+ Bias may occur during research
				+ Potential for harmful effects outside of research
		- HSIRB members may know the researcher which might bias their decisions
			* Is information not included in the application allowed to affect HSIRB decision?
				+ Needs to be determined on a case-by-case basis
				+ Internal vs. External application should not affect HSIRB functions – to protect human subjects in research projects
				+ Application process establishes the parameters HSIRB needs to review
			* How can we ensure we are not approving by person instead of the research?
				+ Part of the HSIRB administration and training to be aware of this potential bias and work against it
		- To flatly disallow LCC employees to do research on other LCC employees brings a pre-existing bias into the HSIRB review process and should not happen
	+ Application question #6 addresses the conflict of interest potential
		- If power dynamics are not addressed well in the application the HSIRB will ask follow up questions
		- The researcher can to speak to the potential issue and solution
		- If applicant does not see the power structure it is the board’s responsibility to inform them
	+ Suggestion: Have a sample document ready for applicant review
		- Would detail answers to questions on the application and some thought processes involved
	+ Suggestion: Create a preamble for the HSIRB Proposal to Conduct Human Subjects Research at LCC application
		- Explain the review process for non-exempt projects might take several months to complete
		- Mention that an example application document can be requested
		- Suggest that research should attend a HSIRB meeting previous to submitting their proposal application
* Bringing in other information during the research proposal review is what the HSIRB is charged to do.
	+ This committee is required to be from varied backgrounds to ensure many ways of looking at a project, and its potential effect on human subjects, are represented
 |
| IRB Proposal form - LCC –in process | * Due to the Revised Common Rule that went into effect January 21, 2019 we will need to change many IRB documents.
	+ Large project will require several steps to complete
	+ Drafts will be sent via email for review and feedback outside of this meeting
 |
| Other items/next meeting  | * Revised Common Rule Citi Training over summer.
	+ Request that all HSIRB members complete this training
	+ This training should also be sufficient as a refresher course
* Members requested to check their email over the summer so that any time sensitive issues can be discussed via email.
	+ Items that should not wait until September to address
* Next meeting is September 6, 2019, 11-12pm in ADM 200

  |