# Minutes

Human Subjects Institutional Review Board (HSIRB)

October 1, 2021 from 11am – 12pm, A&S 1120 with Webex option

## Committee Members:

Patti Ayers, Matthew Fall, Susan Jepsen, Patricia McKay, James Owens, and Melinda Wilson

## Alternates:

Maryetta Dombrowski and Alicia Juskewycz

## Community Member:

Renee Brown

## Voting Participants:

Maryetta Dombrowski, Susan Jepsen, James Owens, and Melinda Wilson

## Other Participants:

Patti Ayers, Matt Fall, Patricia McKay

## Absent:

Renee Brown and Alicia Juskewycz

## Action Items:

* Add to HSIRB Policy.
	+ HSIRB Administrator can act as a voting member when needed to fill quorum or to break a tie vote
* Melinda to create a draft Consent Letter for the Cardio Exercise and Student Success Study.
	+ Susan Jepsen to help with wording of general cardio symptom risks
	+ Will send out to other members for review/comment via email
	+ Will give to researchers to edit as needed and resubmit for continuing review approval
* Request revised application, from the Cardio Exercise and Student Success Study, to encompass changed protocol when it goes into effect.
	+ Researchers can submit a new one if desired or revise their existing one
	+ Does not need to occur until protocol changes and can be handled via email outside of a formal board meeting
* Email out discussed wording of generic confidentiality statement for people to continue editing between HSIRB meetings.
* HSIRB website updates.
* Links from Matt’s scientific merit discussion sent out to group.
1. **Discussion - Dr. Fall, our HSIRB Administrator, designated an alternate voting member.**
	1. Only in effect when needed to fill quorum for a meeting and/or to break tie votes.
	2. Any objections/discussion, putting in HSIRB policy to allow the HSIRB administrator a vote if needed to make quorum or as a tie breaker?
		1. Question, Maryetta. As alternate does her vote count?
			1. Yes, whenever your presence is needed to meet quorum
			2. This fulfills the alternate role
			3. You are always welcome to all meetings and participate in discussions
		2. Originally Maryetta was to be the member and Patricia McKay the alternate but Pat finished her training first and was given the member seat
			1. At some point would like to discuss member options including reverting back to the original plan where Maryetta is member and Pat is the alternate
	3. No objections, motion stands approved.
		1. Will add to HSIRB policy that the HSIRB Administrator can act as a voting member when needed to fill quorum or to break a tie vote

## Approval of the September 3, 2021 Minutes.

* 1. Hearing no objections the minutes stand approved.

## Review approval to conduct continuing research for the Cardio Exercise and Student Success study.

* 1. Continue discussion from September meeting.
	2. The Informed Consent needs reworking.
		1. Needs to include information regarding two levels of risk:
			1. The risks of being involved in a study
				1. Including confidentiality of statements

Could be as simple as stating, “all information we collect will be kept confidential to the extent possible.”

* + - * 1. Clearly state voluntary nature of the study and that students can withdraw at any time
			1. The risks of receiving the independent variable in the study
				1. Including general cardiac risks such as chest pain, or headache
		1. Melinda to revise researcher submitted information into a recommended draft consent letter, for researcher edits
			1. Not usual, but offering this draft due to the fact this research group has been a partner with us since our beginning and we are both working and learning the technicalities of ongoing research projects together
			2. Susan Jepsen to help with some wording for some general cardiac risk factors
		2. Will be sent out to HSIRB via email for review and comment
		3. Will send to researchers for their review and edits before resubmission
	1. Request revised application, not new one unless they choose to do that.
		1. Understand they will want to continue the same study for longitudinal research potential
		2. If there are changes to the protocol they can revise the existing application and the board can look at it via email, no need to wait for next board meeting

## Confidentiality Statements for Surveys – status update.

* 1. Recap, Pat had good points on this from CITI training during last meeting.
	2. Research is broadly defined here, this would be for all LCC surveys not just research ones that go through HSIRB.
	3. Anonymous and confidentiality are not the same.
		1. Anonymous is not collecting identifiable information at the outset
		2. Confidential is using identifiable information but either keeping it safe (as possible) or de-identifying it once the research is completed
			1. Example: When need to know student id to cross reference information in Banner but once the data is collected the id can be removed.
	4. While it is important to let subjects know confidentiality cannot be 100% guaranteed it is also important to describe it in a way that does not deliver a chilling effect.
	5. Revised HSIRB wording:

Your privacy is important to Lansing Community College. Any identifiable information from your response(s) will be made anonymous and will be removed from the data set once analysis is complete. Information will only be maintained as necessary to maintain research purposes.

This survey will use the following methods for data storage and protection: [Researcher to insert survey specific information here].

While it is not possible to guarantee absolute confidentiality when using online surveys, all steps possible will be used to protect your information.

If you have any questions about this research study and/or survey please contact

[insert name, title, LCC division or program, email and/or office phone number here].

* 1. Next steps identified:
		1. Finalize via email discussion within HSIRB
		2. Present finalized statement to Provost Sally Welch for review
		3. Present final statement to Academic Senate
			1. Mindy will request it put on agenda when we are ready
		4. Communicate to LCC via Star
		5. Post on HSIRB website
			1. Create a toolbox area there and this will be one of the items included

## HSIRB Website update

* 1. Create a toolbox portion of the website.
		1. Add the finalized HSIRB confidentiality statement there
		2. Move the Informed Consent Checklist, Application statements there
		3. Remove IRB Policy from site
	2. Will then work on communicating to Academic Senate and LCC in general the updated site location for their future reference.
		1. Want to be first and easiest to use source when research questions come up

## Define and document the boundaries within which the IRB judges “scientific merit” of a project.

* 1. Reference sites worth looking over:
		1. [IRB Solutions website at https://www.solutionsirb.com/scientific-merit/](https://www.solutionsirb.com/scientific-merit/)
			1. The following is directly copied from this site

**“Why is scientific merit important?**

Research ethics and scientific merit are closely related. Ethical research begins with the conceptualization of the study and ends when the results and findings of the study are disseminated. Scientific merit refers to the sound design of the study. Broken down to the most simplistic concept, can the proposed study answer the research questions?

Institutional Review Boards (IRBs) may also review the merit of the study to comply with federal research regulations and to make decisions that support the ethical principles in accepted ethical codes such as the Nuremberg Code and the Declaration of Helsinki. Researchers and IRBs must carefully consider the study design and overall scientific quality of each study. Below are three key areas to consider:

1. According to OHRP the IRB must consider scientific merit when evaluating the risk and benefits of studies. According to the regulations, the final authority on whether or not the study design or methodology demonstrates sufficient merit to justify the risk rests with the IRB. In other words, the final review for scientific merit is part of the IRB review.

2. Studies must be able to answer the research questions. If the purpose of the study is to answer certain questions and the study, because of its design, will not be able to answer those questions, then we know the study cannot achieve its purpose.

3. This does not mean each study is perfect. If the study can answer the research questions, the purpose is accurate, and there is minimal risk, we can make suggestions on improvements but can’t require them as a condition of approval.”

* + 1. [APA website at https://www.apa.org/advocacy/research/defending-research/review-boards](https://www.apa.org/advocacy/research/defending-research/review-boards)
			1. Note: On 10/5/21 this link did not work, there is an internal error on their website at this time, members may not be able to follow the above link
		2. Mayo Clinic Scientific Review on our [LCC-IRB SharePoint site](https://lansingcc.sharepoint.com/sites/Interdivisional/IRB/Shared%20Documents/Resources/For%20reference%20only/MayoClinic_ScientificReview.pdf).
		3. [BYU IRB website at: https://irb.byu.edu/scientific-review](https://irb.byu.edu/is-irb-approval-required)
	1. As risk increases so does the need for IRB review.
	2. Projects can be defined as investigations that do not need to go through IRB review verses research which would need review.
	3. Do we increase HSIRB purview to include risk review of projects that normally would not need IRB approval?
		1. Would only occur if requested, totally voluntary submissions to the HSIRB
		2. This would be outside of looking at exempt or nonexempt research proposals
		3. LCC faculty or staff could ask the IRB to look over how their project is set up before moving forward with it
			1. Example: First time the employee engagement survey (HESEE) came through might be sent to HSIRB for risk review
		4. Not a minor change
		5. Currently people who are thinking they might want to publish or do presentations about the project results down the road are requested to submit the research proposal to the HSIRB as an exempt project
			1. Then the HSIRB will review
			2. Putting the information in our application helps researchers get their project thoughts in order
				1. There have been times when the HSIRB review determines the research is outside of the current IRB purview
		6. Will put this question in a parking lot at this time
			1. Current system is working but worth keeping this as a future option if needed

## Future Agenda Items.

* 1. Will remove the “Revisit LCC Checklist” item at this time.
		1. Melinda to modify one and present when completed at a future date
	2. Revisit scientific merit discussion with emphasis on adopting or modifying language from the IRB Solutions website quoted in section 6.A.1.

## Other items/next meeting/meeting adjourned. 12:15pm

* 1. Next meeting is scheduled November 12, 2021, 11-12pm Room TBD

*Respectfully submitted by HSIRB Secretary Terri Christian*

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