STETSON UNIVERSITY

INSTITUTIONAL REVIEW BOARD ANNUAL REPORT 2018-19

The Institutional Review Board (IRB) works to elevate responsible research conduct and integrity related to research on human participants. The purpose of the IRB Annual Report is to present the board's review activity, challenges, accomplishments, and opportunities. The Research Integrity Officer issues a formal response to the IRB Annual Report in consultation with the Chair and the Provost.

Board Members

Rick Medlin, Ph.D., Professor of Psychology, Chair
Deborah Goldring, Ph.D., Associate Professor of Marketing
Peter May, Ph.D., Professor of Biology
Page Thanasiu, Ph.D., Assistant Professor of Counselor Education
Meryl Baker, Ph.D., Community Representative

Official Charge

The IRB is charged with protecting human participants involved in research by Stetson University faculty, staff, and students. The IRB reviews research protocols, the informed consent process, and the procedures used to enroll participants to ensure that research is conducted ethically and in compliance with Federal Policy for the Protection of Human Subjects and university regulations.

Policies and Procedures

All research involving human participants is subject to IRB review. Such research is defined as "a systematic investigation designed to develop or contribute to generalizable knowledge that involves obtaining information about living individuals through intervention or interaction with those individuals." Research that does not involve direct contact with participants may also require IRB review if the information obtained is identifiable (it can be associated with a particular person) and private (people could reasonably expect that their behavior will not be observed or that the information they provide will not be made public).

The IRB policies and procedures are specified by the U. S. Department of Health and Human Services in the Code of Federal Regulations Title 45 Part 46 (45 CFR 46), Federal Policy for the Protection of Human Subjects (see https://ecfr.io/Title-45/pt45.1.46).

Levels of Review

The IRB conducts three levels of reviews: determination that research is Exempt from further review or requires only limited review, Expedited reviews, and Full Board reviews.

IRB actions include approving a research protocol, requiring revisions, and denying a protocol.

For certain kinds of research, investigators may request an exemption from IRB review. Exempt research involves no anticipated risks, does not include a vulnerable population, and falls into one of eight specific categories. Some Exempt research requires limited review to ensure that there are adequate provisions to protect the privacy of the participants and the confidentiality of the data. Exemption requests are subject to administrative review by the IRB Chair and the head of the principal investigators' department.

Expedited reviews are permissible for research on individual or group characteristics and behavior if the risk involved is no more than minimal. Other categories of research are also eligible for expedited review. Expedited reviews are conducted by two members of the IRB who may approve protocols outside of convened meetings of the board.

Full Board reviews are required for research that is not Exempt and does not qualify for Expedited review. Such research may involve more than minimal risk, deception, or testing participants from a vulnerable population such as children, prisoners, pregnant women, people with mental or physical disabilities, or people who are educationally or economically disadvantaged. This kind of research is reviewed by all members of the IRB and voted on at a convened meeting of the board. A simple majority is required for approval.

Continuing Reviews (annual renewals of ongoing research) are completed by the IRB Chair. Amendments are reviewed at the same level of review as the original protocol if they involve substantive changes and by the Chair alone if they do not.

MentorIRB, the online IRB management software we use, helps researchers determine what level of review their project requires, but the final decision is made by the IRB Chair. The software automatically assigns protocols, annual renewals, and amendments to the appropriate reviewers.

Review Activity

The IRB met once in the fall semester and twice in the spring semester to discuss and vote on Full Board reviews and conduct other business (see attached condensed minutes). From 6-1-2018 to 5-31-2019 the IRB reviewed 151 protocols. More than half of these were Expedited reviews, and the great majority of principal investigators were students in the College of Arts and Sciences (see tables below). The board also processed 3 annual renewals, 17 amendments, and 2 authorization agreements with other institutions.

Number of Protocols by Level of Review

Exempt	Expedited	Full Board	Total
51	85	15	151

Number of Protocols by Principal Investigators' Academic Unit

Arts & Sciences	Business	Music	Other
135	5	1	10

Number of Protocols by Principal Investigators' Status

Student	Faculty/Staff
118	33

Most (2/3) of the protocols reviewed at the Expedited and Full Board levels required revisions, which made a second (or third) review of these protocols necessary. Therefore, the 151 protocols processed by the IRB in the 2018-19 academic year generated about 300 initial reviews and more than 170 subsequent reviews of revised protocols. As the community representative participated primarily in Full Board reviews, the other four members of the board completed well over 100 reviews each. The Chair also communicated individually with more than 50 researchers outside the MentorIRB system.

CHALLENGES AND ACCOMPLISHMENTS

Compliance with New Federal Regulations

Federal regulations governing the ethical treatment of human subjects were revised in 2017 and took full effect in January 2019. According to the Office of Human Research Protections, the purpose of the changes was to "strengthen protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment." Rules governing exempt research, continuing reviews, informed consent documents, and more were substantially revised.

Therefore, the first priority of the IRB in the 2018-19 academic year was to bring Stetson into compliance with these new regulations. The text of the MentorIRB Info Page (https://www.axiommentor.com/pages/irb/info.cfm) and Stetson University IRB web page (https://www.stetson.edu/other/institutional-review-board/) was rewritten, and 15 new forms, templates, and instructional documents for researchers were developed. These materials were designed to be not only consistent with the revised rules but also simple, clear, and attractive (for example, see Figure 1). A summary of the most relevant changes in the regulations was distributed via email to all faculty at the DeLand campus.

The Chair gave brief presentations to the Psychology Department faculty (psychology majors account for most of the student protocols submitted to the IRB) and to IRB members, who also watched HHS videos explaining the new rules.

Human Subjects Education

In September 2018, the NIH Office of Extramural Research stopped offering free online training and certification in the protection of human research participants. Since then, Stetson has been out of compliance with the federal requirement that all researchers, including students, complete human subjects education. Furthermore, when the new regulations governing the ethical treatment of human subjects took effect in January 2019, all previous training became obsolete.

Therefore, the second priority of the IRB was to procure Collaborative Institutional Training Initiative (CITI) training for the Stetson community (see https://about.citiprogram.org/en/homepage/). A basic subscription offers courses in biomedical research, social/behavioral/educational research, conflicts of interest, responsible conduct of research, and other topics. With the help of a generous donation by Dr. Meryl Baker, the IRB community representative, this training will be available for the 2019-20 academic year.

Administrative Support

Lynn Monahan, Project Manager for the Brown Center for Faculty Innovation and Excellence, was tasked with providing administrative support to the IRB. She resigned in October 2018, and since then the IRB Chair has assumed her responsibilities.

Therefore, another priority of the IRB was to work with Dr. Rosalie Richards, Associate Provost for Faculty Development, to restore administrative support. The IRB Chair participated in interviewing candidates for this position, and Terri Bassett was hired in May 2019 to provide part-time administrative support to the IRB, the Office of Faculty Engagement, and the Adult Degree Completion Program.

OPPORTUNITIES

Goals for the 2019-20 Academic Year

- Complete IRB by-laws
- Create forms that can be completed entirely online
- Teach Terri Bassett to administer the MentorIRB system
- Develop clearer, more consistent guidelines for reviewers
- Consolidate and summarize Full Board reviews for researchers
- Require CITI training for researchers, faculty advisors, and IRB members
- Produce instructional materials for faculty such as how to use MentorIRB, what kinds of research must be reviewed by the IRB, etc.
- Register the IRB with HHS (see (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html)

The Role of the Chair

The role of the IRB chair is always demanding, but this year, with new federal regulations and no administrative support, it was crushing. (I spent more time on IRB work than on all six of my courses put together.) Even apart from these unusual circumstances, however, the increasing number of protocols to review has created a heavy workload for everyone on the board.

Therefore, in addition to the five members already appointed to the board for the 2019-20 academic year, the Chair recommends that:

- Dr. Meryl Baker be retained as the community representative
- Dr. Michael Eskenazi, Assistant Professor of Psychology, be appointed to the board as Chair-Designate
- one additional at-large member be added to the board, bringing the total number of IRB members to eight

The Chair-Designate would be mentored during the 2019-20 academic year and assume the role of chair in 2020-21. This is, however, only a temporary solution. Managing the IRB properly requires thorough, specialized training and experience. It is not unlike being in charge of Title IX or NCAA compliance, but to put it bluntly, we have entrusted the IRB to part-time amateurs (like me) who rotate in and out every two or three years. This model is inconsistent with Stetson's emphasis on research.

A Final Note

All the 2018-19 members of the IRB were hard-working, conscientious, and professional in their service to the board and to the university.

Minutes of IRB Meetings (Condensed)

9/26/2018

Members present: Medlin, May, Thanasiu, Goldring, Baker, Monahan, Davis (via phone)

Actions Taken

Approved protocols requiring full board reviews (unanimously):

484	Johannessen	Male Dating Preferences
485	Lake	How Does Psychedelic Drug Use With/Without Stimulant Drug Use Relate to Factors of Mood, Behavior and Relationships
488	Garcia	Pain Measurement Development
495	McCaffrey	The Effect of Nonverbal Communication on the Accuracy of Memory Recall from Different Event Stimuli

Other Business

Discussed criteria for approval, training for new faculty and faculty advisors, workflow for protocol reviews and revisions, and updating IC templates.

February 7, 2019

Members present: Medlin, May, Goldring, Thanasiu, Baker.

Actions Taken

Approved protocols requiring full board reviews (unanimously):

536	Langhorn	Stress and drug use
540	Colamarco	Alcohol use by first-year students
543	Morales	Creativity and drug use (pending addition of information that the survey includes questions about illegal drug use to the risks section of the IC document)

Agreed to require the following on protocol description forms for expedited and full board reviews:

- Citations/references for measures used and study rationale
- Revisions if errors are excessive or they affect integrity of the IC document and to use "approved pending revisions" if errors are not excessive. It was noted that the responsibility of reviewing student protocols and materials before they are submitted to the IRB needs to be communicated to faculty advisors.

Other Business

- Discussed finding a replacement for NIH training and certification
- MentorIRB Info page and all linked documents have been updated to be consistent with the 2019 federal regulations.
- Rosalie has submitted a request for part-time administrative assistant whose job description will include administrative support for the IRB.

4-17-2019

Members present: Medlin, Baker, Goldring, May, Thanasiu

Actions Taken

Confirmed approvals for full board reviews (unanimously):

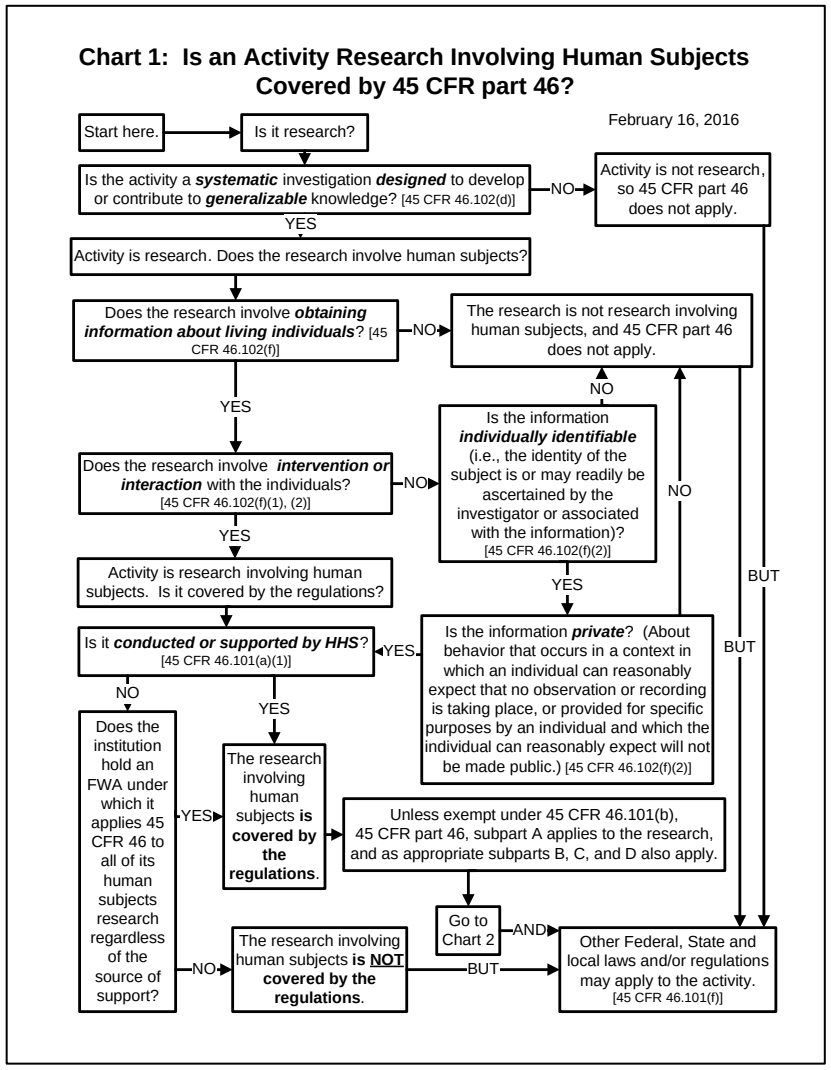
582	Ramos	Life behind Bars: Family Involvement and Work Release
543	Morales	Identifying Predictors of Creativity
540	Colamarco	Consequences of Stress
536	Langhorn	Factors Correlated with First-Year Students' Alcohol Consumption and Alcohol Consequences

Other Business

Discussed possible goals for 2019-2020:

- CITI training
- training in using MentorIRB
- administrative support
- register IRB with HHS
- add new members with 1 representing the School of Law
- completion of by-laws
- improved feedback to PI's and FA's
- clearer guidelines for reviewers
- explore alternative apps to MentorIRB
- presentation for SOBA faculty on what kind of research needs to be reviewed by the IRB
- offer reviews during the summer months?
- offer forms that can be completed entirely online
- configure MentorIRB to notify reviewers when new documents are uploaded

Before



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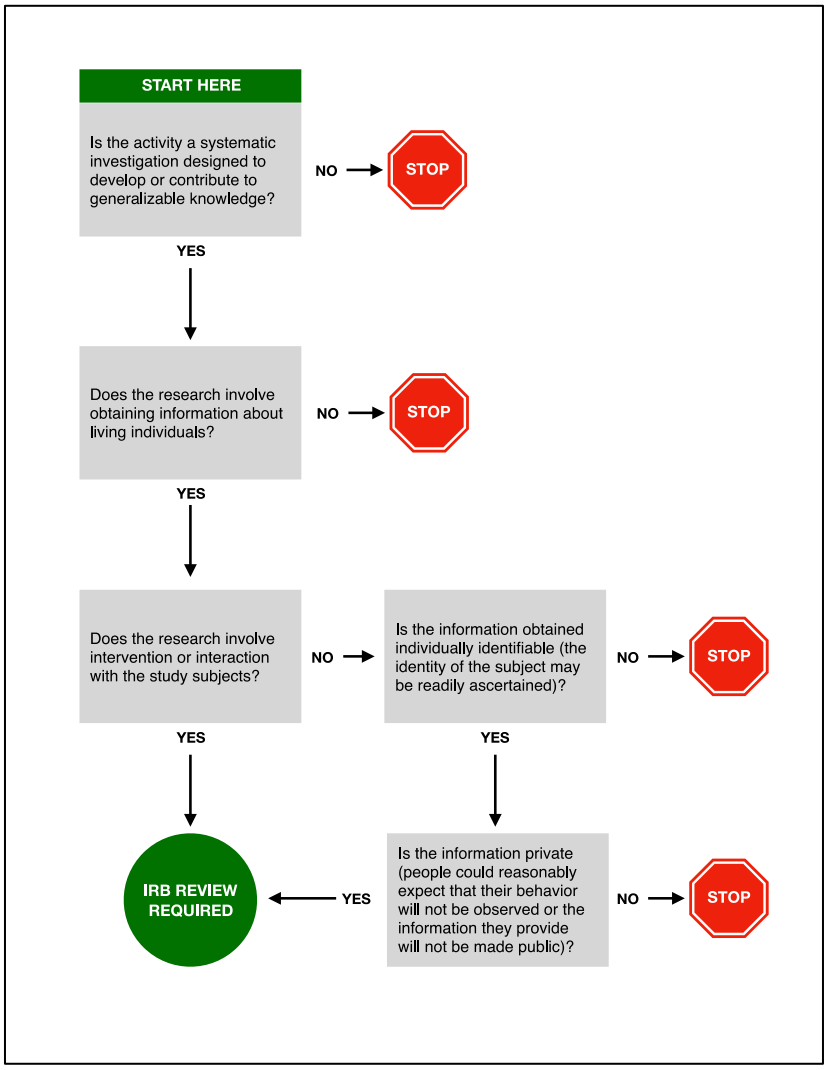

Figure 1. "Is It Research Involving Human Subjects?" charts before (developed by HHS) and after (developed by Rick Medlin).