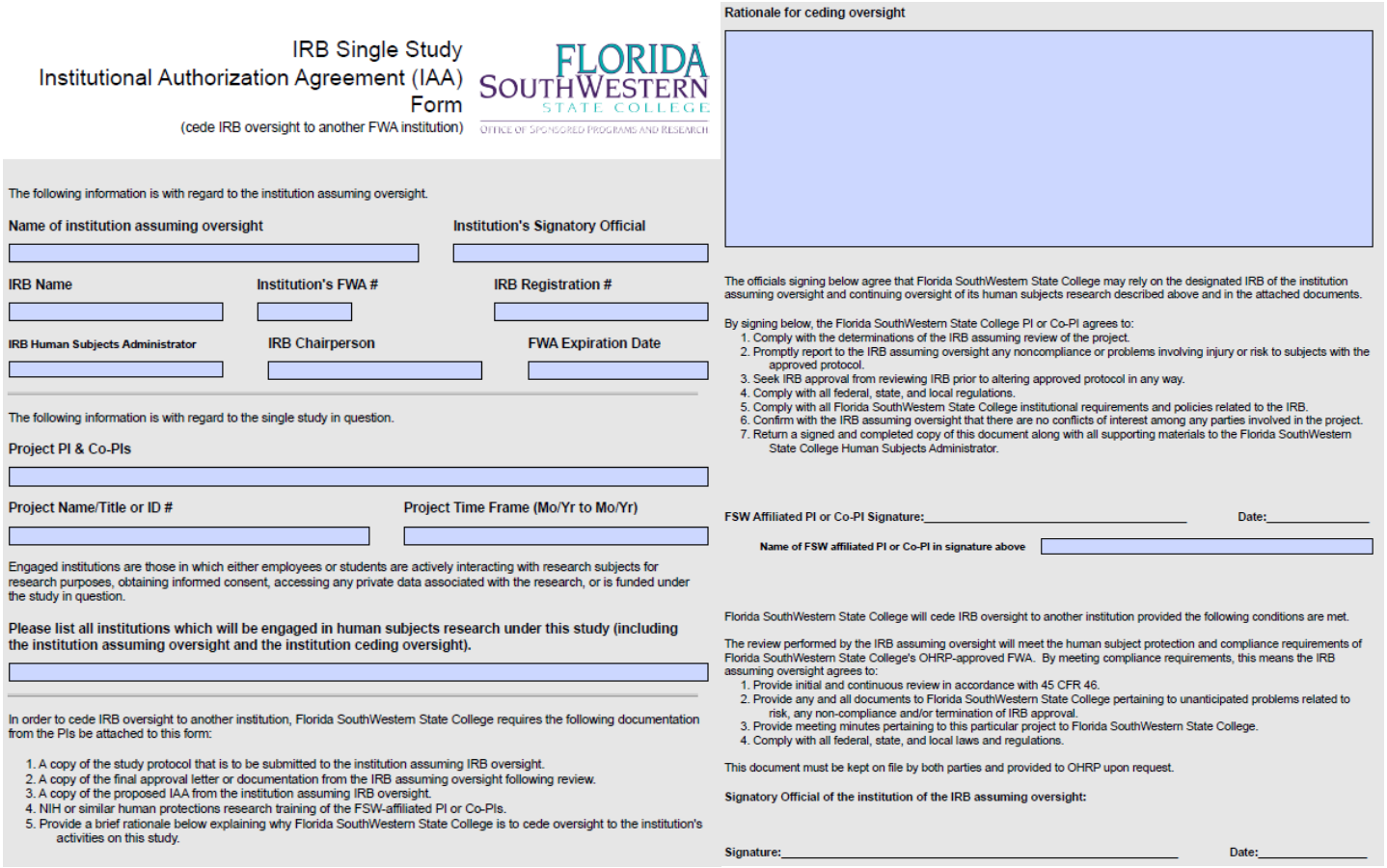
FSW Institutional Review Board Meeting
Friday, October 12, 2018
Thomas Edison Campus (I-228)

In attendance: Frank Dowd, Larry Miller (via phone), Roy Hepner (Chair), Sindee Karpel, Susan Marcy, Joseph van Gaalen (Human Subjects Administrator), Brian Just

- J. van Gaalen opened the meeting and welcomed everyone at 3:00pm.
- R. Hepner gave an update of the research proposals submitted
    - R. Hepner noted that most applications at FSW are exempt.
    - R. Hepner noted that some are non-exempt (Expedited) or not human research.
- J. van Gaalen shared that updates, revisions, and changes to FSW's IRB in terms of structure and function are dictated by the U.S. Dept. of Health & Human Services' Office for Human Research Protections. Revisions to the Common Rule, which requires a delayed general compliance by January 21, 2019, mandates the use of a single IRB as a contingency for federal funding of multi-center studies. In preparation for that potential, FSW's IRB is developing an Institutional Authorization Agreement (IAA) as a pathway for FSW to cede oversight to another FWA (Federal Wide Assured) institution. The below is the current draft of the IAA which is to be reviewed by the IRB with revisions/comments input to the HSA by November 1, 2018.



IRB Single Study
Institutional Authorization Agreement (IAA) Form
(cede IRB oversight to another FWA institution)

FLORIDA SOUTHWESTERN STATE COLLEGE
OFFICE OF SPONSORED PROGRAMS AND RESEARCH

The following information is with regard to the institution assuming oversight.

Name of institution assuming oversight | Institution's Signatory Official

IRB Name | Institution's FWA # | IRB Registration #

IRB Human Subjects Administrator | IRB Chairperson | FWA Expiration Date

The following information is with regard to the single study in question.

Project PI & Co-PIs

Project Name/Title or ID # | Project Time Frame (Mo/Yr to Mo/Yr)

Engaged institutions are those in which either employees or students are actively interacting with research subjects for research purposes, obtaining informed consent, accessing any private data associated with the research, or is funded under the study in question.

Please list all institutions which will be engaged in human subjects research under this study (including the institution assuming oversight and the institution ceding oversight).

In order to cede IRB oversight to another institution, Florida SouthWestern State College requires the following documentation from the PIs be attached to this form:

1. A copy of the study protocol that is to be submitted to the institution assuming IRB oversight.
2. A copy of the final approval letter or documentation from the IRB assuming oversight following review.
3. A copy of the proposed IAA from the institution assuming IRB oversight.
4. NIH or similar human protections research training of the FSW-affiliated PI or Co-PIs.
5. Provide a brief rationale below explaining why Florida SouthWestern State College is to cede oversight to the institution's activities on this study.

Rationale for ceding oversight

The officials signing below agree that Florida SouthWestern State College may rely on the designated IRB of the institution assuming oversight and continuing oversight of its human subjects research described above and in the attached documents.

By signing below, the Florida SouthWestern State College PI or Co-PI agrees to:
1. Comply with the determinations of the IRB assuming review of the project.
2. Promptly report to the IRB assuming oversight any noncompliance or problems involving injury or risk to subjects with the approved protocol.
3. Seek IRB approval from reviewing IRB prior to altering approved protocol in any way.
4. Comply with all federal, state, and local regulations.
5. Comply with all Florida SouthWestern State College institutional requirements and policies related to the IRB.
6. Confirm with the IRB assuming oversight that there are no conflicts of interest among any parties involved in the project.
7. Return a signed and completed copy of this document along with all supporting materials to the Florida SouthWestern State College Human Subjects Administrator.

FSW Affiliated PI or Co-PI Signature:_____ Date:_____

Name of FSW affiliated PI or Co-PI in signature above

Florida SouthWestern State College will cede IRB oversight to another institution provided the following conditions are met.

The review performed by the IRB assuming oversight will meet the human subject protection and compliance requirements of Florida SouthWestern State College's OHRP-approved FWA. By meeting compliance requirements, this means the IRB assuming oversight agrees to:
1. Provide initial and continuous review in accordance with 45 CFR 46.
2. Provide any and all documents to Florida SouthWestern State College pertaining to unanticipated problems related to risk, any non-compliance and/or termination of IRB approval.
3. Provide meeting minutes pertaining to this particular project to Florida SouthWestern State College.
4. Comply with all federal, state, and local laws and regulations.

This document must be kept on file by both parties and provided to OHRP upon request.

Signatory Official of the institution of the IRB assuming oversight:

Signature:_____ Date:_____

- J. van Gaalen also updated the IRB on the necessity for updates to the current FSW model for human research protections training. In response to the NIH's training being replaced by a training module

with a fee, FSW will implement a multipath strategy to ensure both PIs and IRB members receive adequate training for their roles in human research protections. The pathways are shown below:

- Option 1: PI (with IRB application already submitted) or IRB member can take NIH training at FSW's Office of Sponsored Programs and Research (OSPR) where the fee will be covered by OSPR. Or PI/IRB member can elect to take NIH training independently but fee must be self-funded.
- Option 2: PI (with IRB application already submitted) or IRB member can take CITI Social-Behavioral-Educational (SBE) Basic training course at FSW's Office of Sponsored Programs and Research (OSPR) where the fee will be covered by OSPR. Or PI/IRB member can elect to take CITI training independently but fee must be self-funded.
- Option 3: PI (with IRB application already submitted) or IRB member can take FSW's in-house human research protections training course (currently being developed jointly by the IRB and FSW's Teaching & Learning Center) where there is no fee and training can be administered at the leisure of the PI or IRB member. Transferability outside of FSW cannot be guaranteed, but FSW's IRB will ensure that training is as rigorous as that of the NIH (in which the training is based). This training, when complete, will be available for IRB to review and provide revisions/comments.
- J. van Gaalen noted the original COP for FSW assigned members to the IRB committee seats.

- J. van Gaalen adjourned meeting at 3:20pm

Minutes submitted by Joseph van Gaalen on Oct. 18, 2018.