For Students Using Human Participants in their Research

Proposal Stage

- 1. Student, Dissertation Chair, and Research Coordinator each emails the Dissertation Office with their interest in completing the **Investigator Agreement**, once the student enters the dissertation writing phase.
- 2. Dissertation Office sends Investigator Agreement to Student, Chair, and Research Coordinator via DocuSign.
- 3. Student, Chair, and Research Coordinator each complete their Investigator Agreement on DocuSign.
- 4. Cottage Health IRB, Dissertation Office, and Student/Chair/Research Coordinator receive a copy of the completed Investigator Agreement.
 - a. Only one Agreement needs to be filed regardless of the number of projects Chair and Research Coordinator may supervise.
- 5. Dissertation Office sends credentials for CITI Training and HIPAA training (both available through Cottage Health IRB) to Student, Chair and Research Coordinator via email.
 - a. All dissertation Chairs supervising new data collections involving human participants are required to complete CITI training (or equivalent training) and HIPAA training.
 - b. All Research Coordinators are also required to complete CITI training (or equivalent training) and HIPAA training.
- 6. Student, Chair and Research Coordinator each completes CITI Training and each sends **CITI and HIPAA certificates of completion** to the Dissertation Office. Copies of the certificates will remain on file until the certificates expire. CITI *Certificate is valid for three years and valid for multiple protocols.*
- 7. Student, Chair and Research Coordinator each send signed and dated **CV** to the Dissertation Office.
- 8. Student submits their dissertation proposal draft to their dissertation Chair, along with a copy of the **Proposal Approval Form**. (*This form remains the same*)
- 9. Once Chair is close to approving student's proposal, Student submits dissertation proposal draft to committee Internal Reader and External Reader, along with a copy of the Proposal Approval form.
- 10. Chair signs Proposal Approval Form.
- 11. Committee Internal Reader and External Reader sign and send Proposal Approval Form to dissertation Chair.
- 12. Chair sends all three Proposal Approval Forms to Dissertation Office.
- 13. Student submits Intellectual Property and Copyright Infringement Form to Dissertation Office.

IRB Stage

- Student (with Chair's support) completes IRB packet including Packet Checklist, IRB Cover Page, HIPPA Waiver, correct Data Protocol Development Outline, Responses to 10 Items, Pacifica Addendum, and any Attachments (e.g., consent forms), and submits to Research Coordinator.
- 15. Research Coordinator reviews packet, requests revisions if need be, and submits final packet to the Dissertation Office.
 - a. Dissertation Office will not be able to submit a research protocol without the CITI certifications and a signed and dated CV for both student and dissertation Chair.
- 16. Dissertation Office verifies application and submits to Cottage IRB. Allow 1 month for review.
 - a. Refer to IRB meeting dates and deadlines on PGI's Dissertation Office webpage.
 - b. <u>Protocols submitted through the end of the 2023-24 academic year will require a 10-</u> <u>min. introduction of the project to the IRB by the student (on site or via video</u> <u>conference).</u>
- 17. Cottage returns review to Dissertation Office with approval or request for revision.
- 18. Dissertation Office sends Cottage IRB decision to Student, Chair, and Research Coordinator.
 - a. Student submits any revisions to Chair and Research Coordinator for approval. *Up to student for timeline to resubmit.*
 - b. Research Coordinator submits to Dissertation Office for resubmission to Cottage IRB.
 - c. Dissertation Office submits revisions, per instructions of Cottage Health. *Allow at least two weeks for review.*
 - d. Cottage IRB submits decision to Dissertation Office.
 - e. Dissertation Office sends Cottage IRB decision to Student, Chair, and Research Coordinator.
- 19. Once approved, student receives access to secured drive for ALL data storage and management processes.

Proposal Approval Stage

- 20. Dissertation Office receives IRB approval date from Cottage.
- 21. Dissertation Office confirms all forms were submitted to Dissertation Office (Proposal Approval forms [3x], Intellectual Property Form, & IRB approval from Cottage).
- 22. Dissertation Office grants Proposal Approval by sending Student, Chair, Research Coordinator, Financial Aid, and Registration the Proposal Approval date.
 - a. Proposal Approval date will be date noted as IRB approval from Cottage Health.