

# PGI Dissertation IRB Flow-Chart

Designed for students using human participants in their research.

## 1 The Pre-Proposal Stage

1. Once you enter the dissertation writing phase, email the Dissertation Office to complete the **Investigator Agreement** via DocuSign.
2. You, Cottage Health, and the Dissertation Office will receive a copy of your completed Investigator Agreement.
3. Dissertation Office then sends the CITI Training and HIPAA training to you via email.
4. Complete the trainings and send the **CITI** and **HIPAA Certificates of Completion** to the Dissertation Office.
5. Afterwards, send a current signed and dated **CV** to the Dissertation Office.

## 2 The Proposal Stage

1. Submit your dissertation proposal draft to your Chair, along with a **Proposal Approval Form**.
2. Following your Chair's approval, send the same files to your Reader and External Reader. They will sign form and send back to your Chair.
3. Your Chair will send all three signed Proposal Approval Forms to Dissertation Office.
4. You'll then complete and send the **Intellectual Property and Copyright Infringement Form** to Dissertation Office.

## 3 The IRB Stage

- With your Chair's support, you'll complete the **IRB packet**, which includes the following 6 items, as well as any extra materials.

### 3.1 IRB Packet Checklist

- An initial submission checklist.

### 3.2 IRB Cover Page

- Who is involved in the study: your Chair, and any other participants.
- You are the "Principal Investigator," and all other personnel are "Key Research Personnel."
- A new Cover Page will need to be drafted for any amendments made to the study.

### 3.3 HIPAA Waiver of Authorization or Alteration

- A HIPAA-compliance statement notifying the IRB of your sensitive data-storage practices.

### 3.4 Protocol Development Plan

- You can use the development outline template of your choice to detail how you will develop your own protocol (3-10 pages)
- The protocol explains the purpose of the study.

### 3.5 Written Responses to 10 items

- Written brief summary of your research design, protocols, and procedures for the IRB.

### 3.6 PGI Research Addendum

- Includes your contact information, your Research Coordinator's approval of your study.

### 3.7 Additional Materials

- This can include consent documents, surveys, questionnaires, recruitment materials, and any other research documents.

## 4

1. Following completion, your Research Coordinator will review your packet.
2. Please note: The Dissertation Office is unable to submit a Research Protocol all **CITI Certifications** and signed and dated **CVs**.
3. The Dissertation Office verifies and submits your application to Cottage Health IRB.
4. **Allow 1 month for review.**
  - a. Refer to IRB meeting dates and deadlines on PGI's Dissertation Office webpage.
5. IRB notifies the Dissertation Office of their approval or request for revision.
6. The Dissertation Office sends the IRB decision to you, your Chair, and your Research Coordinator.

## 5 The Revision Stage

1. If a request for revision has been made, you'll submit any revisions to your Chair and Research Coordinator for approval.
2. Your Research Coordinator will then submit your revised packet to the Dissertation Office.
3. The Dissertation Office will submit your revisions, per the instructions of Cottage Health. *Allow at least two weeks for review.*
4. Cottage IRB sends decision to Dissertation Office.
5. The Dissertation Office sends IRB decision (and your IRB approval date) to you, your Chair, and your Research Coordinator.
6. Once approved, you'll receive access to a secured drive for your data collection processes.

## 6 Receiving Proposal Approval

1. Dissertation Office confirms all forms were submitted
  - a. **Proposal Approval forms** [3x]
  - b. **Intellectual Property Form**
  - c. **IRB approval from Cottage**
2. Dissertation Office grants Proposal Approval by sending Student, Chair, Research Coordinator, Financial Aid, and Registration the Proposal Approval date.
3. Proposal Approval date will be considered the IRB approval date.