Research at Lifespan-Getting Started

Introduction

Welcome to conducting research at Lifespan! The HRPP Team and the IRB Committee Members are committed to helping Lifespan investigators conduct scientifically sound research which meets the ethical standards required by the federal regulations, state laws, and hospital policies.

Communication with HRPP- Ticket System

For all HRPP-related inquiries and communications, submit a ticket through the HRPP Ticket System: Submit a Ticket. Here, you can efficiently communicate with the HRPP Team through one, streamlined mechanism. The following ticket types can be submitted:

1) Request a status update
2) Get general Guidance on variety of IRB-related topics
3) Get guidance regarding an Existing IRB Submission
4) Learn about Reliance submissions (either Lifespan is the Reviewing IRB for up to two additional sites OR Lifespan is relying on an external IRB for IRB review; but Lifespan's IRB is still responsible for the local context/conduct of the study)
5) Report Time Sensitive Issues/Situations (Emergency Use, Unanticipated Problems, Major Deviation, HIPAA Breach)
6) Submit an Extension Request to Complete Requested edits (Pre-Review Unlock letter and/or Action Required Outcome letter)

Tickets will be resolved/responded to in the order in which they are received. Please do not submit multiple tickets for the same issue; this will result in longer wait times for everyone.

IRBNet

IRBNet is Lifespan's electronic protocol management system for the submission and administration of applications to the IRB. All key study personnel (meaning you are interacting with study subjects and/or their identifiable data/specimens) must be registered in IRBNet to be added to a project. IRBNet is a self-registering web-based platform. Link to IRBNet - Innovative Solutions.

First Steps

Getting Started: In order to participate in research, you will need to complete the following minimum requirements (see corresponding instructions for each requirement below):

1. Have an IRBNet Account that is Affiliated with Lifespan: Have an IRBNet Account that is Affiliated with Lifespan
2. Complete Lifespan-Required Citi Training: Complete Lifespan-Required Citi Training
    a. Basic Human Subjects Training
    b. Conflict of Interest
3. Link Your Citi Account within Your IRBNet User Profile: Link Your Citi Account within Your IRBNet User Profile

Once you have completed all requirements it is *highly recommended* that you schedule a "Navigator-New Researcher Training" appointment via the HRPP Booking Calendar, here: HRPP Booking Calendar This appointment will introduce you to the Navigator, walk you through how to use IRBNet, teach you about the role of the HRPP office and will explain the HRPP submission process.

Before beginning any IRB submissions, **download the appropriate** submission checklist from the IRBNet Forms and Templates library

Forms and Templates (F&T) Library

The Lifespan F&T can be accessed from the left-hand side menu within IRBNet. This library contains all of the necessary Forms, Templates, and Guidance documents needed for your IRBNet submission package. Note that there are libraries for each type of research conducted at Lifespan, including IACUC (animal studies research), Institutional Biosafety committee and the Institutional Review Board (IRB). If you are affiliated with more than one type of research, make sure you are selecting the "Lifespan Institutional Review Board-documents for Researchers" library from the drop down in order to get the documents you need for Human Subjects Research.

Always download applicable documents from the library before each use. The library is updated regularly and may be subject to change.

General Layout

We recognize that your first visit to the Forms and Templates can be daunting. It's important to understand the basic layout so that the resources you need for any given task can be easily found. This is a rough guide to help you do so:

- At the top of the library list you will find items with asterisks- these are typically announcements/general tools (e.g., Calendar of Meeting Dates and Deadlines for full board review, new policies, etc).
- **Sections 01 – 7 will be where you find a bulk of what you need for your submissions**
  - Section 01 contains all submission checklists—these are absolutely key to successful submissions and keeping within your desired timeline. See more about checklists below!
  - Sections 02 – 06 contain the various forms and templates required, depending on the type of submission.
  - Section 07 contains documents related to Reliance Studies, including when Lifespan is the Reviewing IRB for other sites and when Lifespan is Relying on an external IRB
  - Section 08 contains educational resources, guidance documents and videos
  - Toolkit: QI/QA is a zipfile with the application and project description template for a QI/QA submission
  - Section "Z" at the bottom contains regulatory information

Becoming familiar with the checklists and the library layout in general will be extremely helpful for all of your IRB submissions.

Checklists

The following checklists are available in the **F&T Library.** The submission-specific checklists provide detailed guidance for ***each type of submission***. Once you hit "Submit this Package" your package contents and signatures will be compared to the corresponding checklist, so ***download and complete the appropriate checklist for all of your submissions***. Read the entire checklist from guidance at the top through the FAQs at the end—these are a great resource.

Lifespan Research Requirements

Researcher Responsibilities

1. The **Principal Investigator (PI)** is responsible for the conduct of the research
2. PI must be either a Lifespan employee or affiliated employee (ex. A Brown Physicians Inc. physician) AND have a masters degree or above
3. Residents, students and fellows can NOT serve as the PI
4. The PI is responsible for all key study personnel on the study
5. All researchers (PIs and all KSP) are responsible for creating an IRBNet account and linking their CITI training
6. All researchers (PIs and all KSP) are responsible for making their new project, annual, and updated Financial Conflict of Interest disclosures.

Signatures

The PI is required to sign every submission package. Packages cannot be processed without the appropriate signatures. For the New Project package this includes the PI and the Department Chair.