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Preparing for your IRB submission and review

THE BASICS OF GETTING STARTED TO SUBMIT A RESEARCH PROJECT TO THE IRB

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Baystate IRB

Disclosure



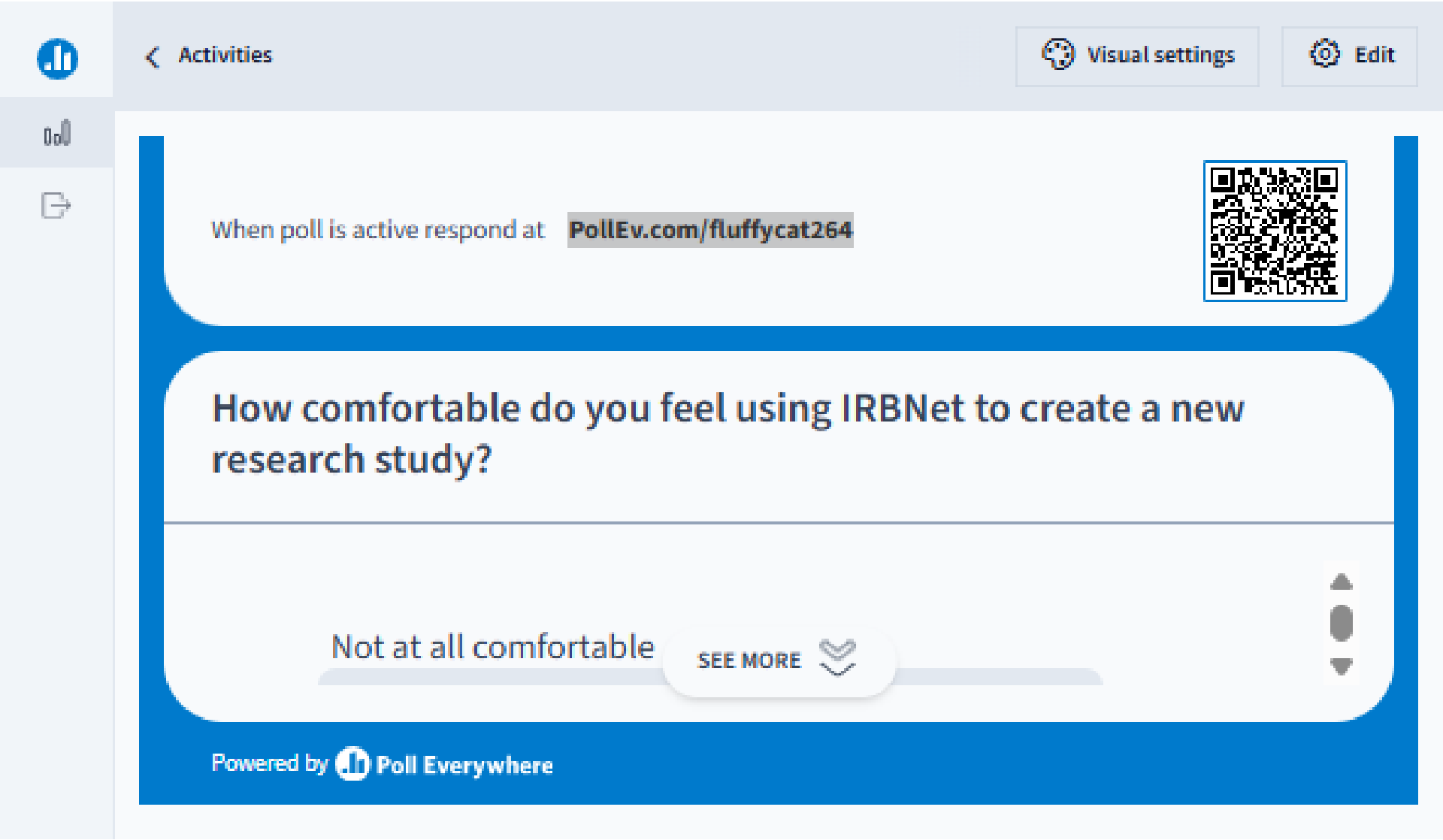
We have no financial disclosure or conflicts of interest with the presented material in this presentation.

Learning Objectives

Identify IRB-specific forms and documents and set up IRB Net profiles, including adding a CITI Program account and uploading CVs.

Illustrate how to submit a clinical trial through IRBNet, including the types of submissions.

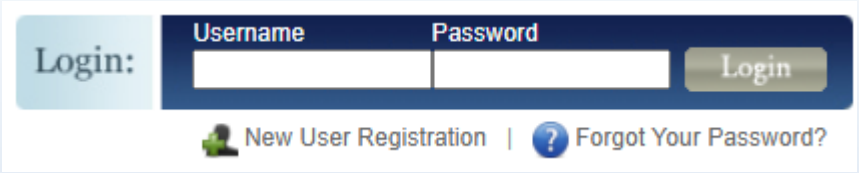
Review the purpose of ancillary reviews, including the Information Security Reviews, Unaffiliated Investigator submissions and more.


Activities
Visual settings
Edit
When poll is active respond at PollEv.com/fluffycat264
How comfortable do you feel using IRBNet to create a new research study?
Not at all comfortable
SEE MORE
Powered by Poll Everywhere

GETTING STARTED



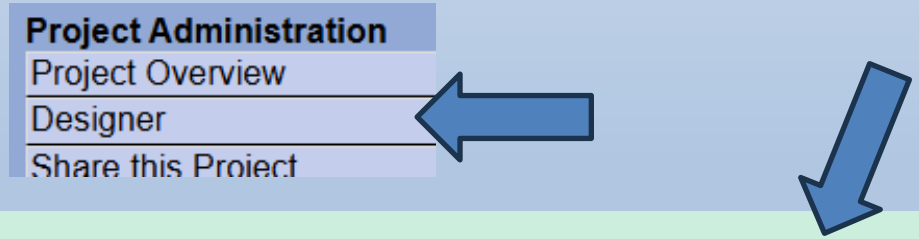
IRBNet Profile



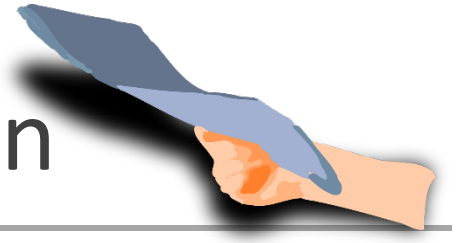
- **All Study Team Members need an IRBNet Profile.**



- **Manage Staff Credentials – CV's and CITI Training.**
  - **Link Credentials to Study Submissions in IRBNet.**



Preparing your IRB submission



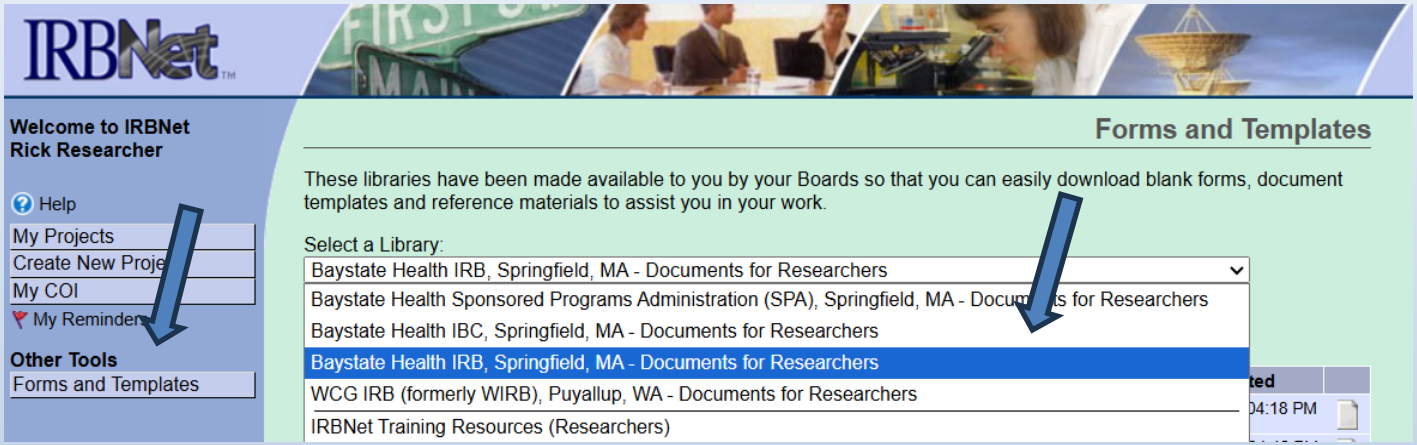
The IRB has created forms and checklists to assist you in preparing to submit to the IRB.

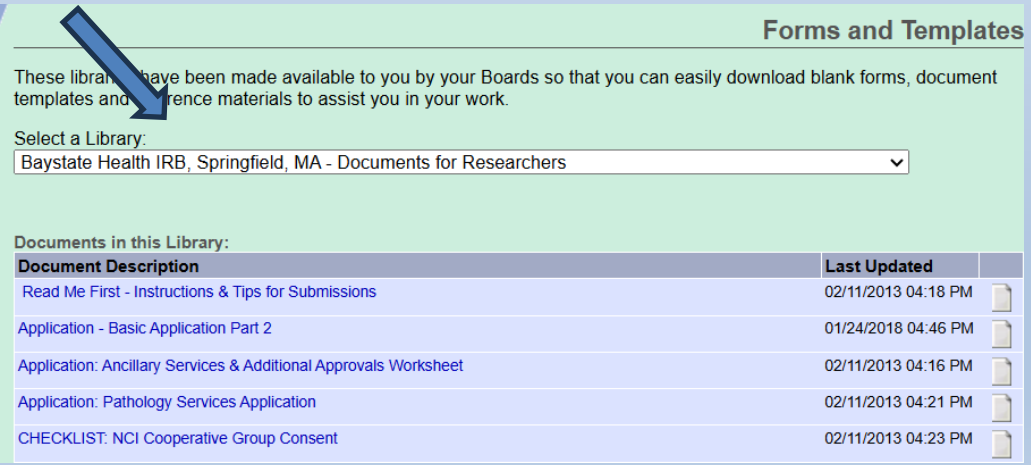
We are frequently reviewing and updating these forms as necessary and work to clarify confusing issues.

You need to know which forms to use and where to find them.

IRBNet Library









What Do I Need for a New Project?

- ✓ **Exception email from Jennifer Sabbagh Peirce**
- ✓ **SPA submission (package 1, with completed Core Data Form)**
- ✓ **Basic App 1**
- ✓ **ISRC/SSRC review (if applicable)**
- ✓ **The research protocol**
- ✓ **IS review (if applicable—see Basic App 2; Supplements H & I)**



Approval for Project

EXCEPTION EMAIL FROM JENNIFER SABBAGH PEIRCE

BEFORE ANY STUDY IS SUBMITTED TO THE IRB, THERE ARE QUESTIONS THAT MUST BE REVIEWED AND APPROVED BY THE DIVISION CHIEF, DEPARTMENT CHAIR AND OFFICE OF RESEARCH.

STANDARDIZED PRE-SUBMISSION ASSESSMENT PROCESS FOR ALL NEW CLINICAL TRIALS AND NON-NIH GRANT SUBMISSIONS.

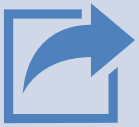
Linking Team Credentials



The IRBNet User Profile is a central location to house CITI Training and CV's.



Research team members can link all credentials to project packages in IRBNet.



This process will also trigger when any of the linked documents are set to expire (required to be updated every 3 years).

External Accounts

You can add your accounts from other organizations such as CITI to your IRBNet profile. Once you add an external account to your IRBNet profile, then external information such as training records can be automatically available to you in IRBNet.

| Learn More |

▸ Add an External Account

Account Type	Account ID	Status	
CITI Training Program	12381414	Verified	

Training & Credentials

IRBNet allows you to track and share your training records, certifications, resumes and other personal credentials. Once added to your profile, your training and credentials can be easily linked to your projects from the Designer, are accessible by your project teams and can be quickly accessed and tracked by the boards that review your projects. Some boards also permit you to directly submit your training and credentials without requiring you to link these records to specific projects.

▸ Add a New Training & Credentials Record

| Show all Versions |

Doc ID	Document Type	Description	Cr	Effective Date	Expiration Date	Last Modified	Status	
1135274.1	CITI - Basic Biomedical	CITI Training CR#56967288: Group 1347-Group 1.BIOMEDICAL, Stage 1-Basic Course		07/13/2023	07/13/2026	08/19/2025 01:34 AM	Accepted	| Submit |
1135275.1	CITI - Good Clinical Practice and ICH	CITI Training CR#56967289: Group 5153-Good Clinical Practice and ICH, Stage 1-Basic Course		07/17/2023	07/17/2026	08/19/2025 01:34 AM	Accepted	| Submit |
1120507.1	CV/Resume	Michael Boland resume.docx		06/24/2025	06/24/2028	06/24/2025 11:43 AM	Accepted	| Submit |

Go to your User Profile

CLICK

After attaching your CV, don't forget to click Submit

Conflict of Interest

The Principal Investigator and each member of the research team must complete and submit a Conflict of Interest/Commitment Questionnaire at initial and continuing review.

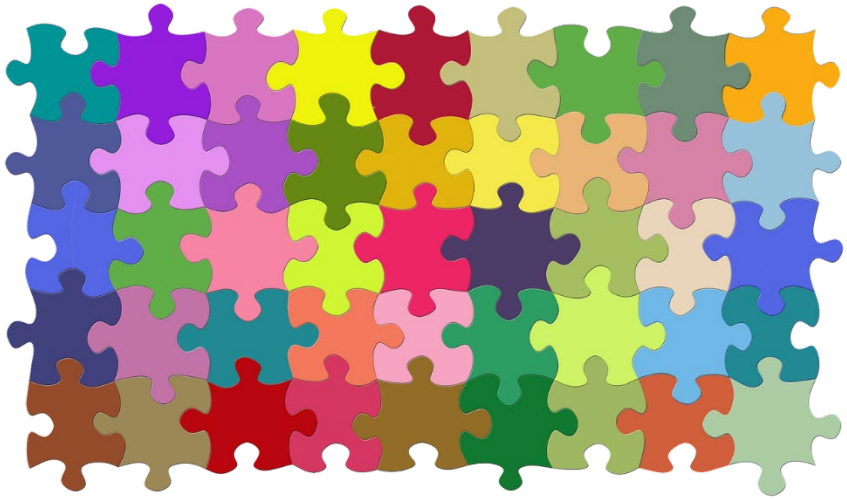
IRB staff will review disclosure forms to identify potential conflict of interests (COI).

Those studies with a potential COI will be forwarded to the Conflict of Interest Committee who will review the disclosures and determine if a management plan is needed.

BC 1.300 Baystate Conflict of Interest Policy

BC 10.400 COI for PHS Funded Research

PREPARING YOUR SUBMISSION



Which Applications Do I Use for a Full Board Clinical Trial?

Wizard Documents

- Core Data Form
- Basic Application Part 1

Attached Applications

- Basic Application Part 2

Attached Documents

- Protocol
- Consent(s)
- Participants materials
- CIS Alert Form
- Supplemental Forms
- Ancillary Services Worksheet
- COI Disclosure Form

Core Data Form

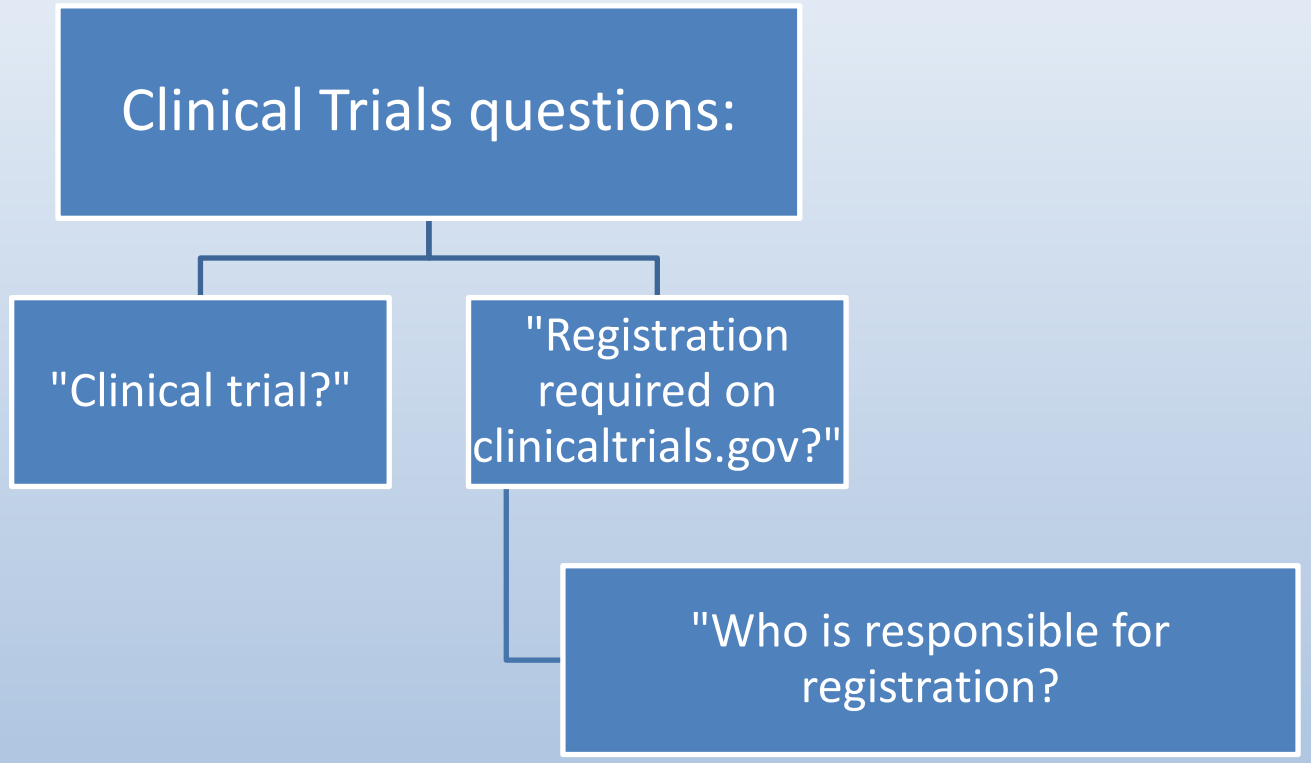
Completion of this form is the first step in seeking the institutional approval that is required for all research and extramurally-funded projects, including community service, educational and any other sponsored projects.

The Core Data Form should be submitted with Package 1 to SPA, Package 2 to the IRB and any subsequent packages that include updates to the information provided (such as staffing changes)



- All study staff should be listed
- Project Start Date should be a future date, the IRB does not retroactively approve submissions

Basic Application Part 1



Required unless you are submitting a study that utilizes a special application form (HSRD, exempt, prep to research, HUD, emergency use)

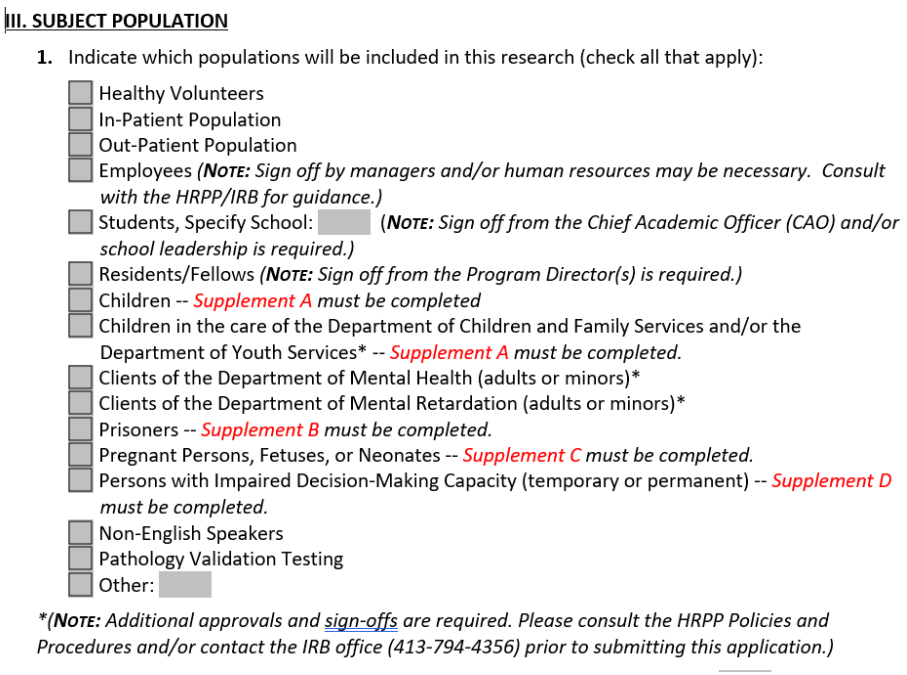
Basic Application Part 2

Basic Application Part 2 is considered your local study implementation plan. Application forms should be consistent with the protocol and consent document if applicable.

When completing make sure to follow instructions for when additional forms or documents might be necessary

All investigators must complete Sections I – XVI.

An energizer for completing Basic application part 2 can be found in the IRBNet library



III. SUBJECT POPULATION

1. Indicate which populations will be included in this research (check all that apply):

- ☐ Healthy Volunteers
- ☐ In-Patient Population
- ☐ Out-Patient Population
- ☐ Employees (***NOTE:*** *Sign off by managers and/or human resources may be necessary. Consult with the HRPP/IRB for guidance.)*
- ☐ Students, Specify School: _____ (***NOTE:*** *Sign off from the Chief Academic Officer (CAO) and/or school leadership is required.)*
- ☐ Residents/Fellows (***NOTE:*** *Sign off from the Program Director(s) is required.)*
- ☐ Children -- *Supplement A must be completed*
- ☐ Children in the care of the Department of Children and Family Services and/or the Department of Youth Services* -- *Supplement A must be completed.*
- ☐ Clients of the Department of Mental Health (adults or minors)*
- ☐ Clients of the Department of Mental Retardation (adults or minors)*
- ☐ Prisoners -- *Supplement B must be completed.*
- ☐ Pregnant Persons, Fetuses, or Neonates -- *Supplement C must be completed.*
- ☐ Persons with Impaired Decision-Making Capacity (temporary or permanent) -- *Supplement D must be completed.*
- ☐ Non-English Speakers
- ☐ Pathology Validation Testing
- ☐ Other: _____

(NOTE: *Additional approvals and sign-offs are required. Please consult the HRPP Policies and Procedures and/or contact the IRB office (413-794-4356) prior to submitting this application.)*

Supplemental Forms

A-D: Vulnerable Populations

E-G: Requests for Waivers

H-I: Data Security, Sharing & Confidentiality

K-O: Repositories, Drug & Device Trials

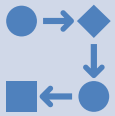
Informed Consent Reminders

- Will you be requesting a waiver of documentation? Or a waiver of consent? Make sure to use the applicable supplemental form
- There are multiple consent templates available including clinical trial and social behavioral specific templates.
- If you require riders for sections of your consent form (such as pediatric, or genomic data) don't forget to include those templates
- Utilize the "Elements of Consent Checklist" to ensure you have all required language (if you are using the sponsor's consent).

Avoid Submission Unlocks and Pre-Review Letters



Answer all the questions fully and provide all applicable documents

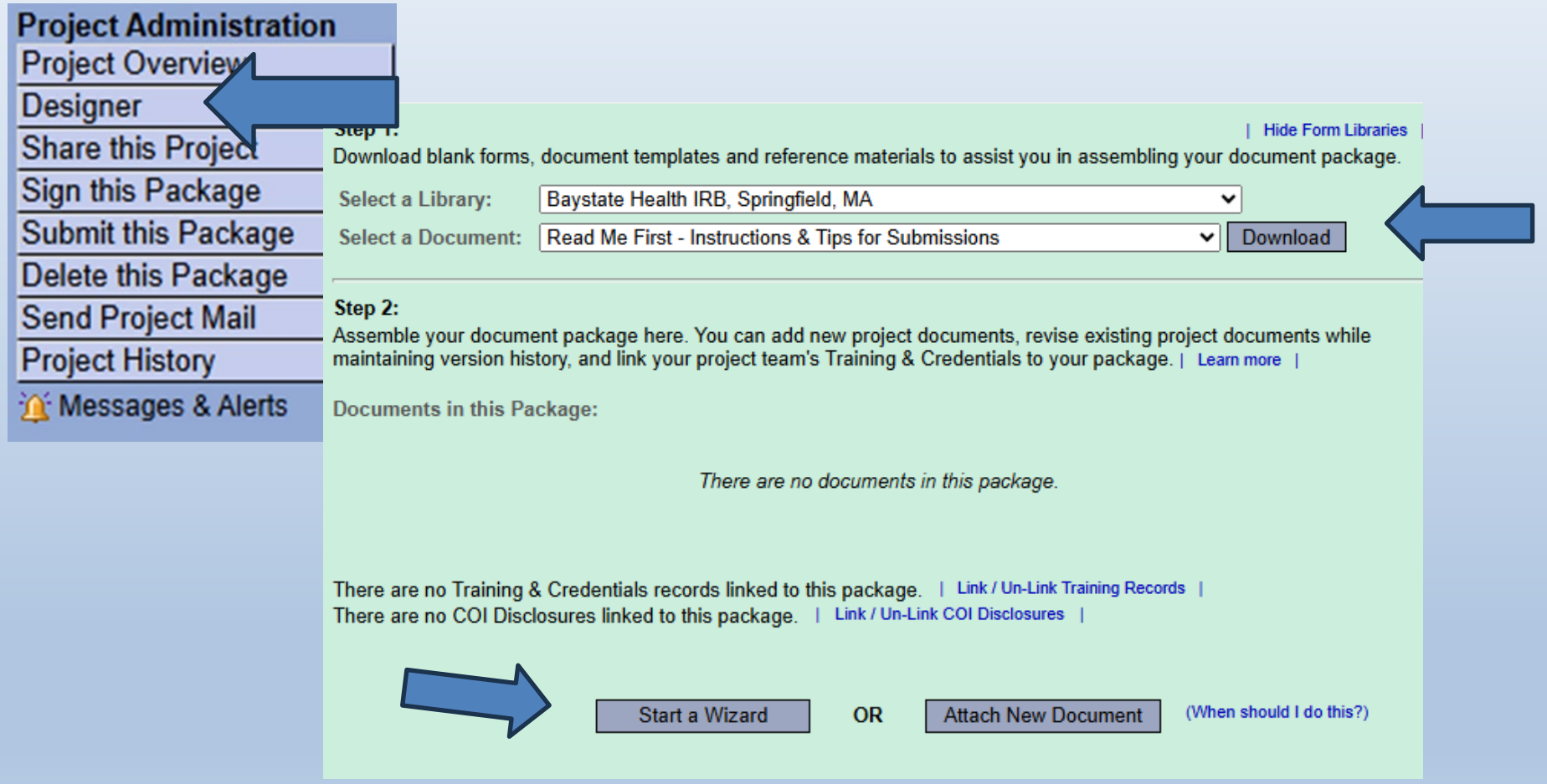


Provide a complete protocol and tell us how you will collect data and from whom; tell us where the data is stored, who has access to it, and when it will be destroyed.



Utilize our templates and checklists to ensure you are providing all required information and documents

How to add documents



Who Should Sign the Package?



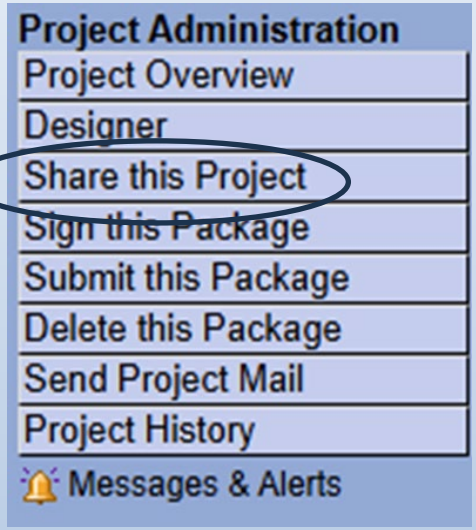
New Study (Package 2)

- PI
- Department Head
- Submitter
- All study team members on the Core Data Form
- Ancillary Services

Amendments/Continuing Reviews/etc.

- PI
- Submitter
- New ancillary services
- New personnel
- New Departments

How to obtain Signatures



Specify the access that you wish to grant to each user at **Baystate Health**. You should grant each user only the minimum level of access necessary to perform their work on this project.

- **Signature Only (Read):** Users whose only role is to sign off on project documentation should be granted "Read" access. Users with Read access can view project documentation, communicate with the project team and add their signature. This would typically include advisors, department heads, and other individuals who are required to sign off on the project documentation prior to submission but do not otherwise have a day-to-day role on the project.
- **Read:** Users that are granted "Read" access can view project documentation, collaborate with other users and add their signature, but may not edit project documents or perform any other administrative functions.
- **Write:** Users that are granted "Write" access can view and edit project documents, collaborate with other users and add their signature, but may not grant access to other users, submit packages for review or perform any other administrative functions.
- **Full:** Users that are granted "Full" access can perform all functions without restriction. This includes editing project documents, sharing the project with other users, submitting document packages for review and deleting document packages. Only Project Owners with day-to-day responsibility for the project should be granted Full access. Users with Full access will receive automatic email copies of all project notifications and alerts that are sent to the Project Owners.

User	Access Type
Admin, Bayibc1	○ Full ○ Write ○ Read ◉ No Access
Admin, Irbc1	○ Full ○ Write ○ Read ◉ No Access
Ainge, Danny	○ Full ○ Write ○ Read ◉ No Access
Andronicus, Titus	○ Full ○ Write ○ Read ◉ No Access
Archibald, Tiny	○ Full ○ Write ○ Read ◉ No Access
Auerbach, Red	○ Full ○ Write ○ Read ◉ No Access
Bird, Larry	○ Full ○ Write ○ Read ◉ No Access
Bunny, Bugs	○ Full ○ Write ○ Read ◉ No Access
C, Karen	○ Full ○ Write ○ Read ◉ No Access
Cousy, Bob	○ Full ○ Write ○ Read ◉ No Access

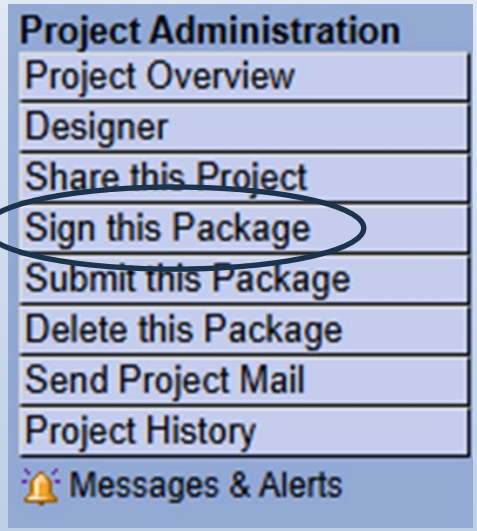
1 - 10 of 25

Each user will be automatically notified that they have been granted access to this project. You may also specify additional comments to be included in this notification:

Your Comments

Save Cancel

How to Sign the Package



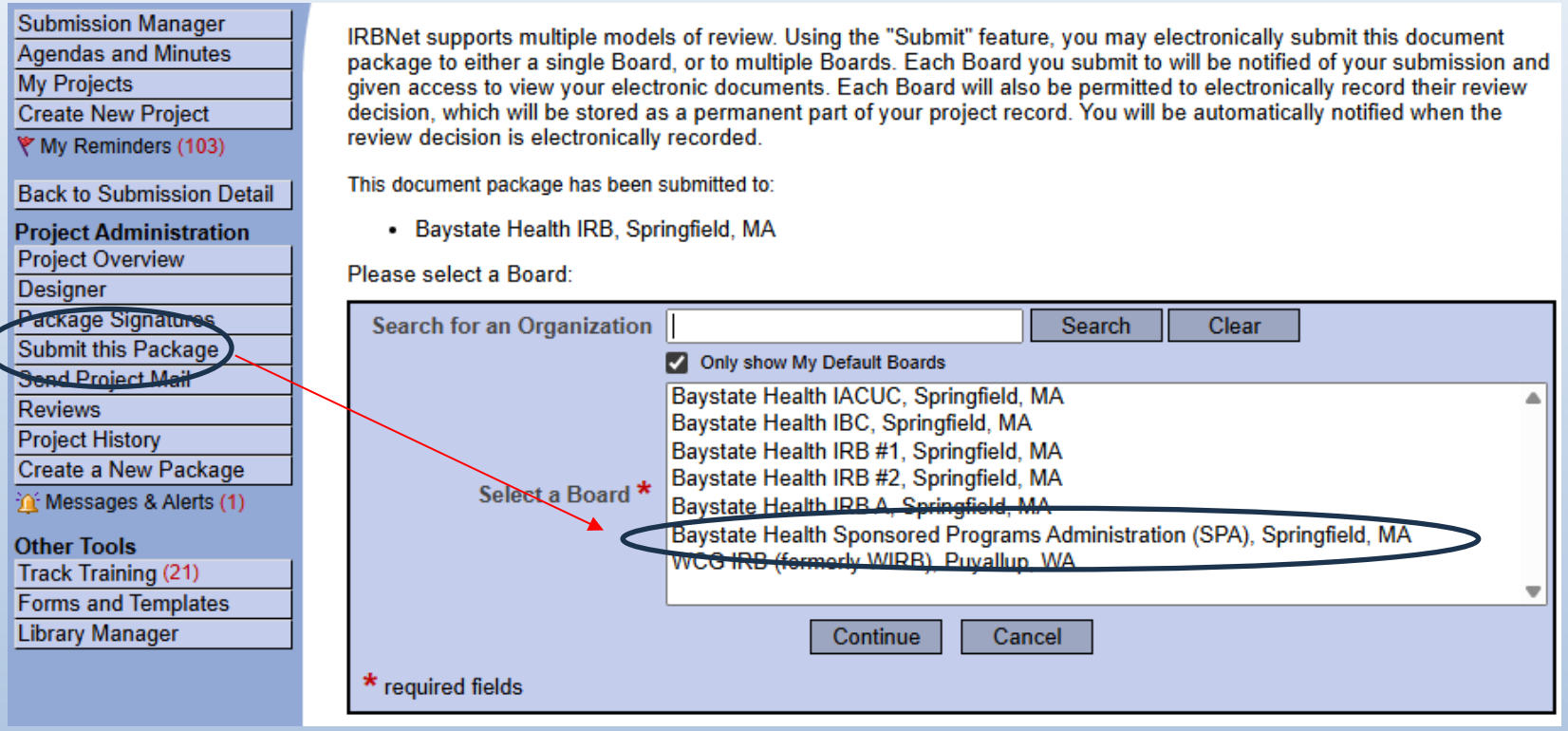
Select the role you will fill for the research study

I Rick Researcher, as [ ], certify that to the best of my knowledge the information contained in this package is accurate and complete, has been prepared in accordance with all applicable institutional requirements and is ready for submission. I further certify that this electronic signature is intended to be the legally binding equivalent of a traditional handwritten signature.

Sign

How to Submit Package 1

RESOURCE: Creating package 1 in IRBNet

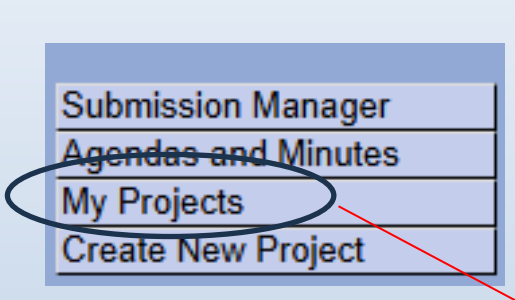


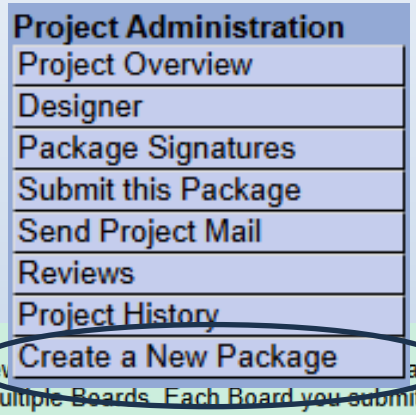
Reminders:

- Package 1 gets submitted to Sponsored Programs Administration (SPA)
- This must be submitted prior to submitting to the IRB
- Package 1 needs to include the Core Data Form

How to Create & Submit Package 2

RESOURCE: Creating package 2 on IRBNet







Help
My Projects
Create New Project
My COI
My Reminders

Project Administration
Project Overview
Designer
Share this Project
Sign this Package
Submit this Package
Delete this Package
Send Project Mail
Reviews
Project History
Messages & Alerts

Other Tools
Forms and Templates

IRBNet supports multiple models of revie ay electronically submit this document package to either a single Board, or to multiple Boards. Each Board you submit to will be notified of your submission and given access to view your electronic documents. Each Board will also be permitted to electronically record their review decision, which will be stored as a permanent part of your project record. You will be automatically notified when the review decision is electronically recorded.

Please select a Board:

Search for an Organization: baystate health — Search — Clear

Only show My Default Boards

Select a Board: *
- Baystate Health Sponsored Programs Administration (SPA), Springfield, MA
- Baystate Health COI Committee, Springfield, MA
- Baystate Health IACUC, Springfield, MA
- Baystate Health IBC, Springfield, MA
- Baystate Health IRB, Springfield, MA

Continue — Cancel

* required fields

Lauryn


ONE DOES NOT SIMPLY
SUBMIT THEIR PROJECT FOR IRB APPROVAL
FIVE WEEKS BEFORE THE DUE DATE
imgflip.com

Reminder: Double check deadline dates

- Study teams should submit at minimum **one week** prior to the deadline date listed below:

New Studies

October 2025 – January 2027 Meeting Dates

Submission Deadline for IRB	Meeting Date for IRB
September 5, 2025	October 8, 2025
October 10, 2025	November 12, 2025
November 7, 2025	December 10, 2025
December 12, 2025	January 14, 2026
January 9, 2026	February 11, 2026
February 6, 2026	March 11, 2026
March 6, 2026	April 8, 2026
April 10, 2026	May 13, 2026
May 8, 2026	June 10, 2026
June 5, 2026	July 8, 2026
July 10, 2026	August 12, 2026
August 7, 2026	September 9, 2026
September 11, 2026	October 14, 2026
October 9, 2026	November 11, 2026
November 6, 2026	December 9, 2026
December 11, 2026	January 13, 2027

The **IRB** meets on the 2nd Wednesday of the month from 7:00 AM – 9:00 AM.

Amendments and Continuing Reviews

October 2025 – January 2027 Meeting Dates

Submission Deadline for IRB	Meeting Date for IRB
September 22, 2025	October 8, 2025
October 27, 2025	November 12, 2025
November 24, 2025	December 10, 2025
December 29, 2025	January 14, 2026
January 26, 2026	February 11, 2026
February 23, 2026	March 11, 2026
March 23, 2026	April 8, 2026
April 27, 2026	May 13, 2026
May 22, 2026	June 10, 2026
June 22, 2026	July 8, 2026
July 27, 2026	August 12, 2026
August 24, 2026	September 9, 2026
September 28, 2026	October 14, 2026
October 26, 2026	November 11, 2026
November 23, 2026	December 9, 2026
December 28, 2026	January 13, 2027

The **IRB** meets on the 2nd Wednesday of the month from 7:00 AM – 9:00 AM.

THEN WHAT? AND OTHER STUFF

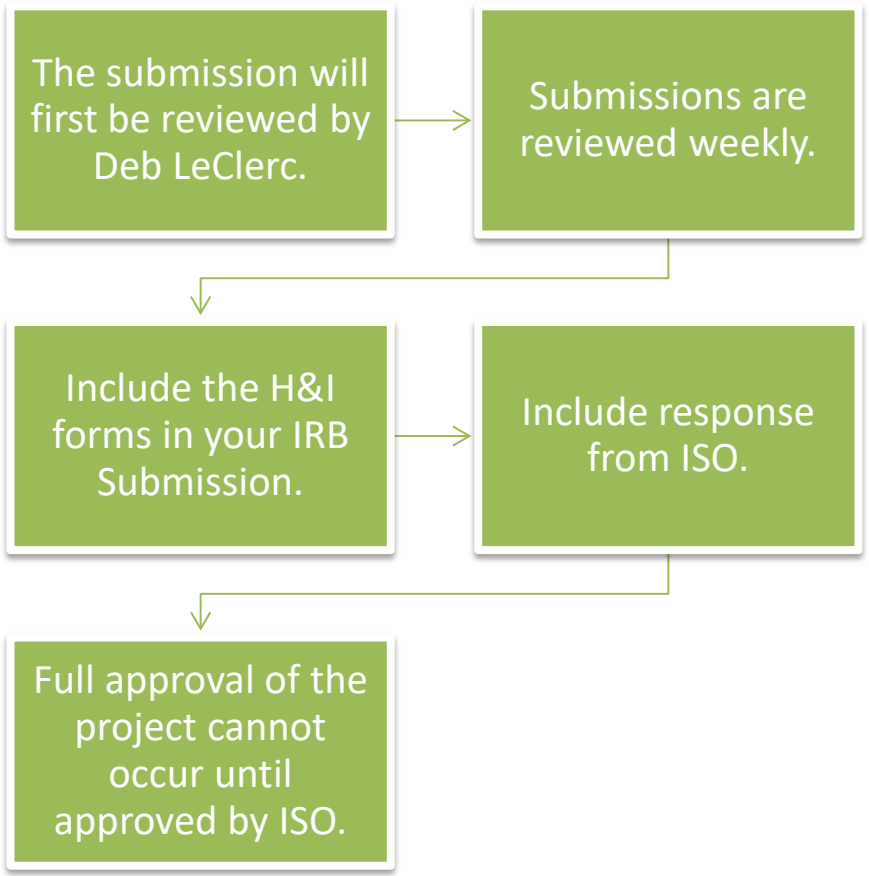


Types of Responses from the IRB

- Unlock
- Pre-review letter
- Modifications required
- Information required
- Acknowledgement
- Approval with Conditions
- Approval
- Disapproval

Information Security Review

- **For any application being used to share data with an external partner:**
- **Complete Supplemental Forms H & I**
- **Submit the Forms H & I to the following email addresses:**
  - **baystatehealth@service-now.com**
  - **cc to: Karen O'Connor, Monica Pokua, and Deb LeClerc**



DUA, UIA, and AIR

All DUA requests are submitted through a **Data Use Agreement Request Form** located on The Hub.



Unaffiliated Investigator Agreement - All individuals who otherwise lack a formal affiliation with BH and desire to participate in research activities at or under the auspices of BH as an Unaffiliated Investigator.

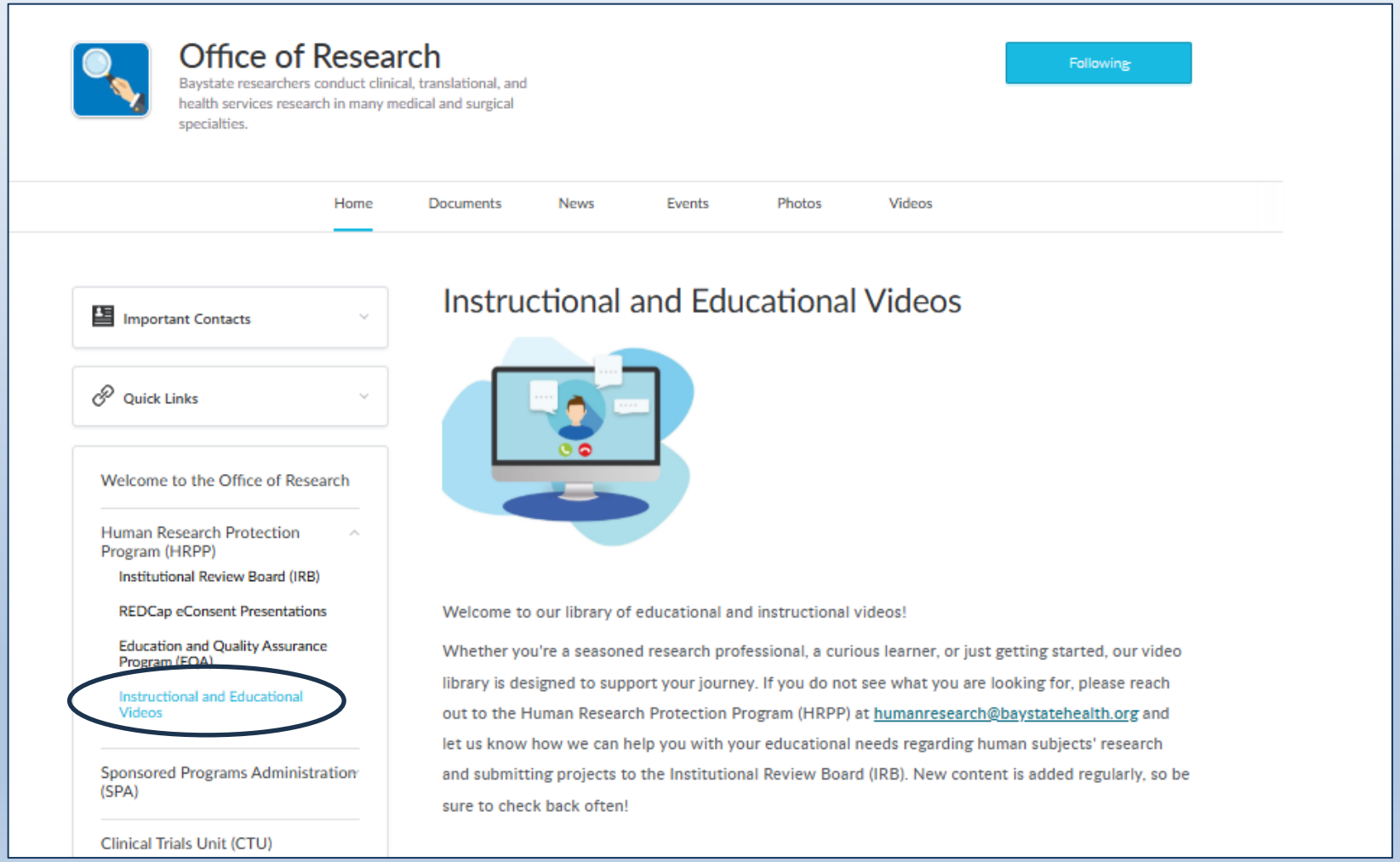
Associate in Research - Any student (outside of UMass Chan – Baystate) who wishes to be a part of a research study at Baystate Health must go through the Associate in Research process.

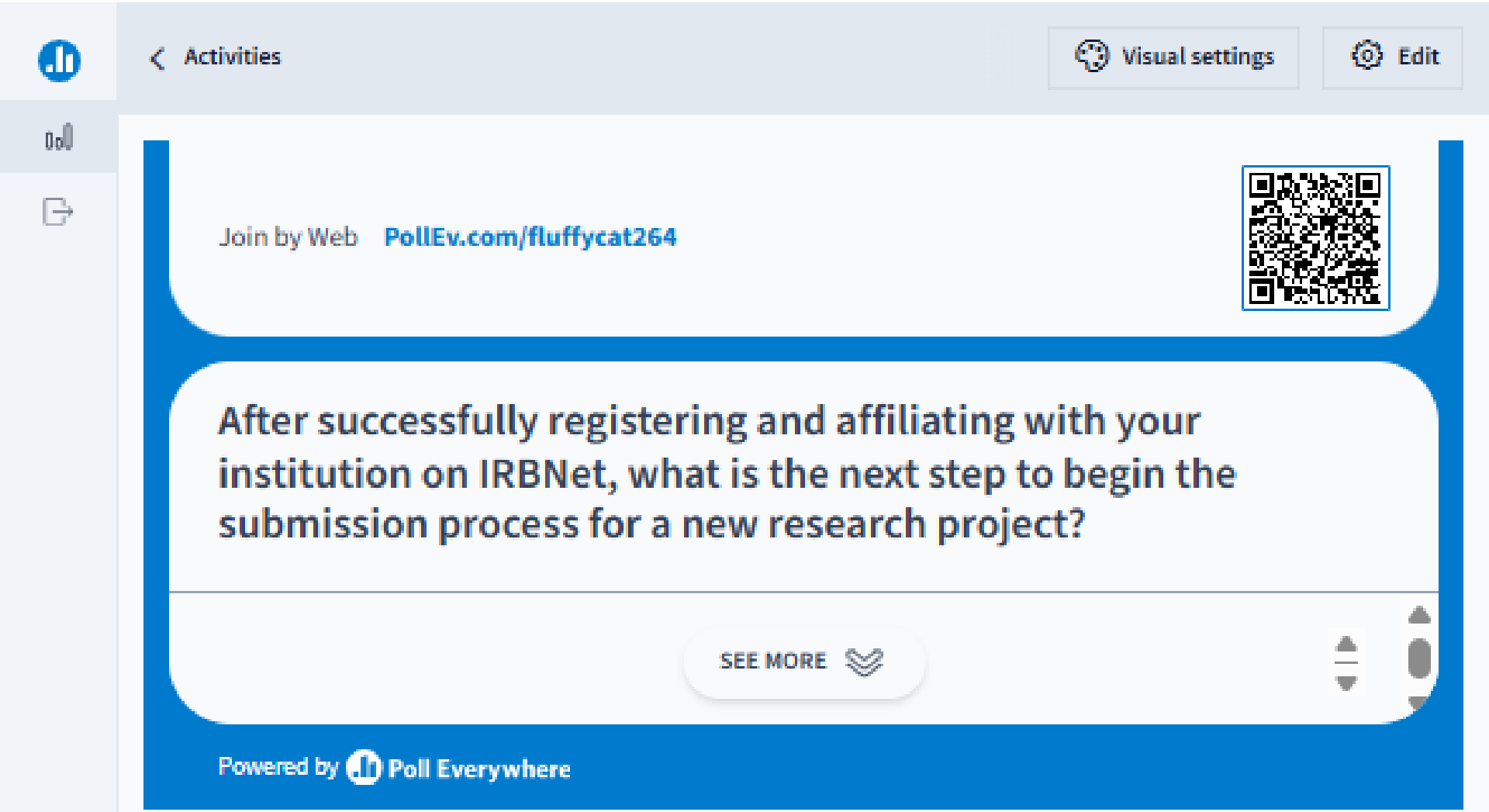
Ancillary Services

Clinical Engineering	Investigational Drug Services	Medical Records
Nursing	Pathology / Laboratory	Radiation Safety
Radiology	Safety	Other

Ancillary Services and Additional Approvals

Instructional and Educational Videos




Activities
Visual settings
Edit
Join by Web PollEv.com/fluffycat264
After successfully registering and affiliating with your institution on IRBNet, what is the next step to begin the submission process for a new research project?
SEE MORE
Powered by Poll Everywhere

Questions

