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Date: May 21, 2025
Title: Understanding the Differences Between Exempt, Expedited, and Greater than Minimal Risk research

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Understanding the Differences Between Exempt, Expedited, and Greater than Minimal Risk research.

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Human Research Protections Program

Institutional Review Board



Baystate Health

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Aims

1. Compare the federal regulations and submission requirements for exempt, expedited, and full board research.

2. Navigate the IRB submission process by distinguishing between package types, locating submission documents, and successfully submitting through IRB Net.

3. Execute follow-on submissions such as amendments, continuing reviews, and study closures according to regulatory requirements.

Human Subjects Research

Institutional Review Boards make sure that research follows Federal Regulation CFR 46. 111 that governs Human Subjects research.

This regulation determines that Human Subjects research is defined as:

- Involving Human subjects
- Generalizable

Three different categories

- Exempt-minimal risk
- Expedited-minimal risk (generally more complex)
- Greater than minimal risk – greater than the risk a person would experience in day-to-day life

What category does my research fall into?

- Go look at the exempt/expedited federal regulations
- Human Subject Regulations Decision Charts: 2018 Requirements | HHS.gov
- https://grants.nih.gov/policy/humansubjects/hs-decision.htm

Exempt-minimal risk

1. Research in schools; educational settings
2. Educational Tests, Surveys, Interviews, observations, focus groups
3. Benign behavioral interventions
4. Secondary research for which consent is not required
5. Research and demonstration projects supported by the federal government
6. Taste and food quality evaluation and consumer acceptance studies
7. Storage or maintenance of secondary research, for which broad consent is required.
8. Secondary research for which broad consent is required

Example of Exempt Projects

1. A retrospective chart review, comparing patient outcomes to interventions. Exempt, Cat. 4, ii (or iii if identifiable)

2. Interviews and focus groups with patients, providers, or community members to determine reaction to a new service or intervention. Exempt, Cat. 2, iii

Baystate Applications

- Exempt Application has the categories for reference
  - https://www.baystatehealth.org/research-at-baystate-health/human-research-protection-program

- Each application also has an application checklist to follow and reference

Exempt application items needed

- Core Data Form (IRB Net Wizard)
- Exempt Application (contains a list of the exempt categories)
- Institutional Scientific Review Committee Letter
- Protocol
- Participant-facing documents (Consent/Recruitment)
- CITI/CVs linked for all study team members/COI forms
- Package signed by PI/submitting staff/Dept Chair

Expedited-minimal risk

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met
   a) Not a new drug
   b) Device exemption not required; or device is already approved for same use
2. Collection of blood samples (finger, heel, ear, venipuncture)—with conditions
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of Data through non-invasive procedures
5. Research involving materials (data, documents, records, specimens) collected for non-research purposes
6. Collection of data from voice, video, digital, or image recordings
7. Research on individual or group characteristics or behavior

Vulnerable Populations

- Children (Subpart D)
- Pregnant Participants/Fetuses/Neonates (Subpart B)
- Prisoners (Subpart C)
  - Supplemental Forms A-D

- Participants with impaired decision making capacity
- People susceptible to coercion

Examples of Expedited Projects

- A repository of data from the electronic health record documenting specific diagnoses within specific populations. Exp, Cat. 5

- A PI wants to take the blood sugar of participants daily after eating a tablespoon of pumpkin seeds. PI is using an FDA approved blood sugar monitor. Exp, Cat.2

Greater than Minimal Risk Research (GTMR)

- Anything that doesn't fit into the exempt or expedited categories!

- Reviewed by a full board of experts, scientists, non-scientists, and community members.

Examples of GTMR studies

- A clinical trial of a new treatment for a specific cancer, utilizing the new drug as compared to prior treatments. (FDA regulated)

- A qualitative interview study exploring children's perceptions of trauma-informed counseling in their residential school

Expedited and GTMR is the same application at Baystate

- Core Data form (IRB Net Wizard)
- Institutional Scientific Review Committee Letter
- Basic App 1 (IRB Net Wizard)
- Basic App2
- Protocol
- Participant-facing documents (Consents/recruitment)
- CITI/CVs linked for all study team members/COI forms
- Package signed by PI/submitting staff/Dept Chair
- Supplemental Forms

Supplemental Materials
Expedited and GTMR

- While filling out Basic App 1 and 2, you may be prompted to include additional supplements for specific items
  - https://www.baystatehealth.org/research-at-baystate-health/human-research-protection-program/forms-templates

- Be sure to include Element of Consent Checklist in your package if you are not using the Baystate Consent form templates OR reference them if requesting a waiver or alteration of a specific element

Protocol Essentials

Key points to include in your Protocol document:

- What is the data being collected?
- How are humans being interacted with (recruitment, chart reviews, surveys, interventions, etc,).
- Specifics about what you are doing with that data? (how storing it, are there identifiers, and what are plans for destroying it once research is complete).
- What are your plans for sharing this data? Publication/presentations/where?
- What does the PI intend to do with the data/how do they intend to use it?

- Be very clear, Ambiguity is your ENEMY!

Full board NS submission timelines

Meeting Schedule & Deadlines for New Projects: Institutional Review Board

New study submissions are divided into two categories: expedited (minimal risk) and full board (more than minimal risk). There are some instances when an expedited study needs to be assigned to the full board. Thus, PIs should consult this calendar for all new study board submission deadlines. Note that new applications that require board review are scheduled based on agenda workload and the availability of appropriate expertise.

Study teams should submit at minimum one week prior to the deadline date listed below. This is because submissions need to be reviewed by an IRB analyst and unlocked for the study team to fix errors. A submission cannot be assigned to an agenda if there are incorrect or missing items.

Once a submission is complete and assigned to a board meeting, a 30-day review process begins. The study is first reviewed by IRB members. Then the research team has the opportunity to respond to the reviewer's initial concerns. Next the revisions go back to the reviewers. Finally, the reviewers present the study to the board and the IRB issues a determination. The principal investigator, or a delegated representative, are invited to attend the convened meeting to answer questions and provide information. All meetings are held virtually via Zoom until further notice.

A well-prepared submission saves time for the study coordinator, investigators, IRB Analysts, and members of the IRB. **Please reach out to the IRB for support with your submission at any point during your application process at irbprotocolsubmissions@baystatehealth.org.**

2025 Meeting Dates

Submission Deadline for Wednesday IRB	Meeting Date for Wednesday IRB	Submission Deadline for Monday IRB	Meeting Date for Monday IRB
December 6, 2024	January 8, 2025	December 24, 2024	January 27, 2025
January 10, 2025	February 12, 2025	January 22, 2025	February 24, 2025
February 7, 2025	March 12, 2025	February 19, 2025	March 24, 2025
March 7, 2025	April 9, 2025	March 26, 2025	April 28, 2025
April 11, 2025	May 14, 2025	April 16, 2025	May 19, 2025*
May 9, 2025	June 11, 2025	May 21, 2025	June 23, 2025
June 6, 2025	July 9, 2025	June 25, 2025	July 28, 2025
July 11, 2025	August 13, 2025	July 23, 2025	August 25, 2025
August 8, 2025	September 10, 2025	August 20, 2025	September 22, 2025
September 5, 2025	October 8, 2025	September 24, 2025	October 27, 2025
October 10, 2025	November 12, 2025	October 22, 2025	November 24, 2025
November 7, 2025	December 10, 2025	November 19, 2025	December 22, 2025

The **Wednesday IRB** (board 2) meets in the 2nd Wednesday of the month from 7:30 AM – 9:00 AM. (* unless otherwise noted)

The **Monday IRB** (board 1) meets the 4th Monday of the month* from 3:00 PM - 5:00 PM. (* unless otherwise noted)

Brain Teaser!

- Tell us what kind of research this is:
  - Reviewing a public database, with de-identified data in order to determine the predictive effect of a particular device, drug, or vaccine on patient mortality or longevity. Data is aggregate, and de-identified.
  - A quasi-experimental study exploring a behavioral intervention to examine the effect of counseling exercises with prisoners to reduce recidivism.
  - Two approved medications for a gastro-intestinal condition exist, both having FDA approval. The study seeks to determine if there is a statistically significant difference between the two, when prescribed for the approved diagnosis.

Continuous monitoring after approval

- Research Status Report-Exempt/Expedited
- Continuing Review-Greater than minimal risk (GTMR)

- Exempt- every three years
- Expedited/GTMR- annually

- GTMR studies may not need to be reviewed to continuing review at the full board if they fall into these expedited categories:

  8 - Continuing review of research previously approved by the convened IRB as follows:

  a) Study is closed, b) No enrollment or no new enrollment, c) Remaining activities limited to data analysis

  9 - Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Documents needed:

- Research Status Report or Continuing Review Report
- COI forms/ CITI training for all current study team members
- Findings/publications
- Signature of submitter/PI

Amendments

- Any changes to the study after the study has been approved need to be submitted to the IRB
- Documents needed:
  - Modification Request (Amendment)
  - Clean and tracked copies of any study documents being changed
  - Copies of any new documents
  - Staffing change: CV/CITI/COI forms of new study team member, revision of Core Data Form/Basic App 2, and their signature on package
  - Signed by submitter and PI

Protocol Deviations/Adverse Events

- Protocol Deviations
- Adverse Events- Unanticipated/Research Related

- Documents Needed:
  - Event reporting form
  - Signatures of PI and Submitter
  - Any documentation to support explanation of Deviation or Event

Administrative Reports

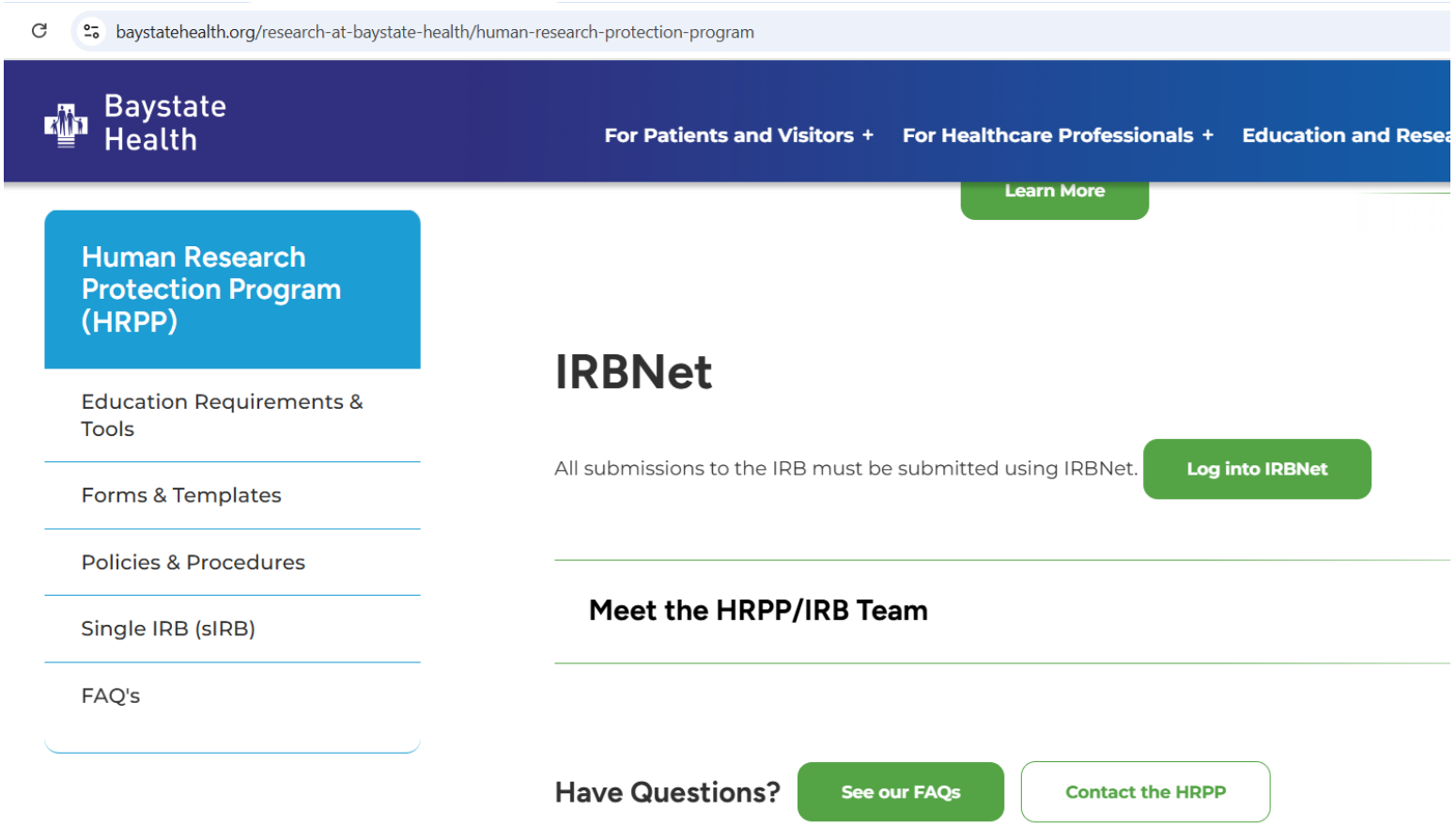
- Administrative Report Form
  - Used to Submit:
    - Audit or Monitor's Report
    - DSMB Report
    - Letter from Sponsor
    - Letter from PI
    - Change in study status
    - Need signature from PI and submitter

Closure

- All research must be formally closed.

- Documents needed:
  - Study Closure Report
  - Publications/Findings
  - Signature of PI/submitter

Create a Profile in IRB Net

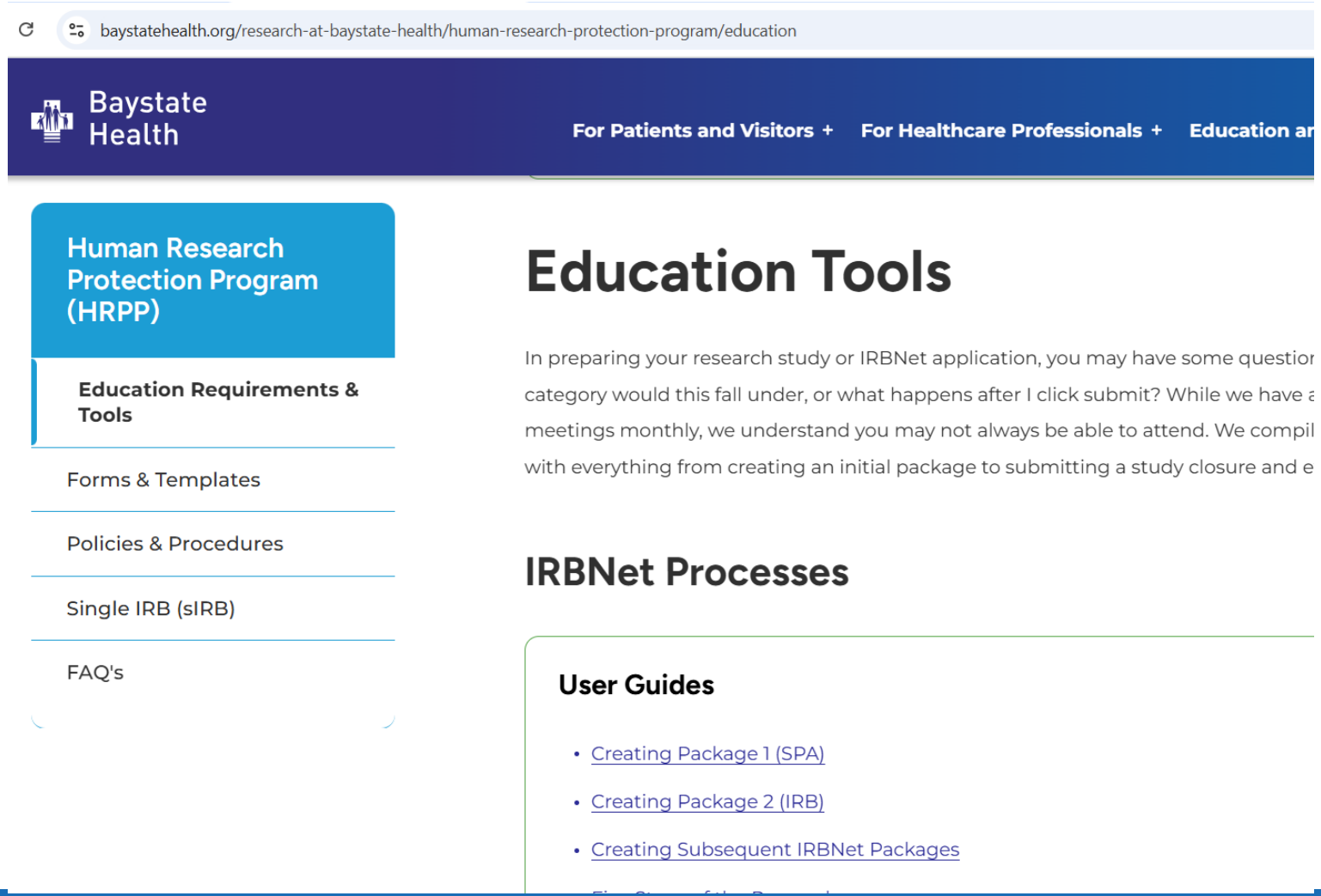


Brief overview for submitting

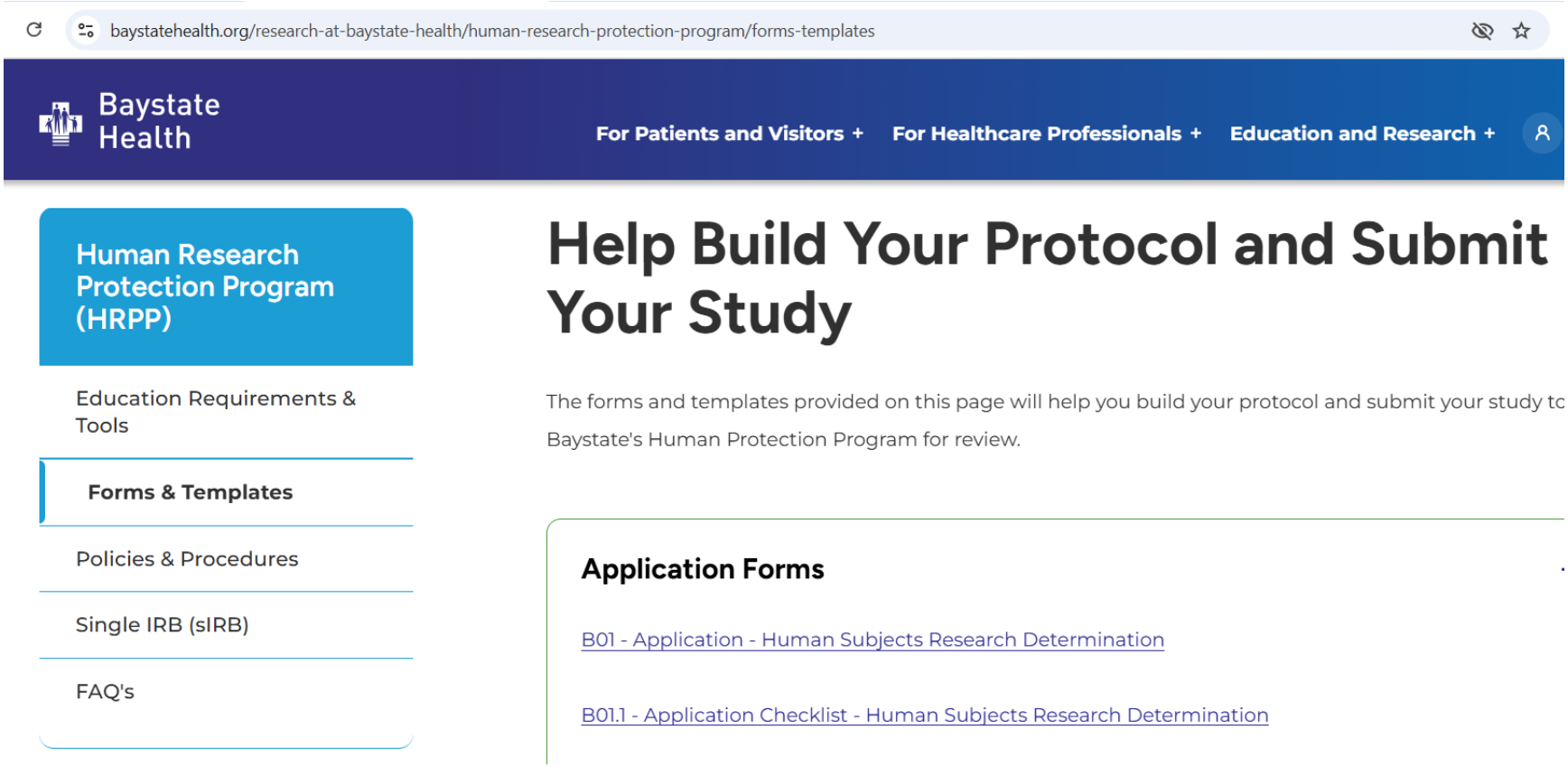
- Create a Package #1 with Core Data Form
  - Submit to SPA (Sponsored Programs Administration)

- Create a Package #2 with Core Data Form, Relevant New Study Application, Protocol, etc.
  - Submit to IRB

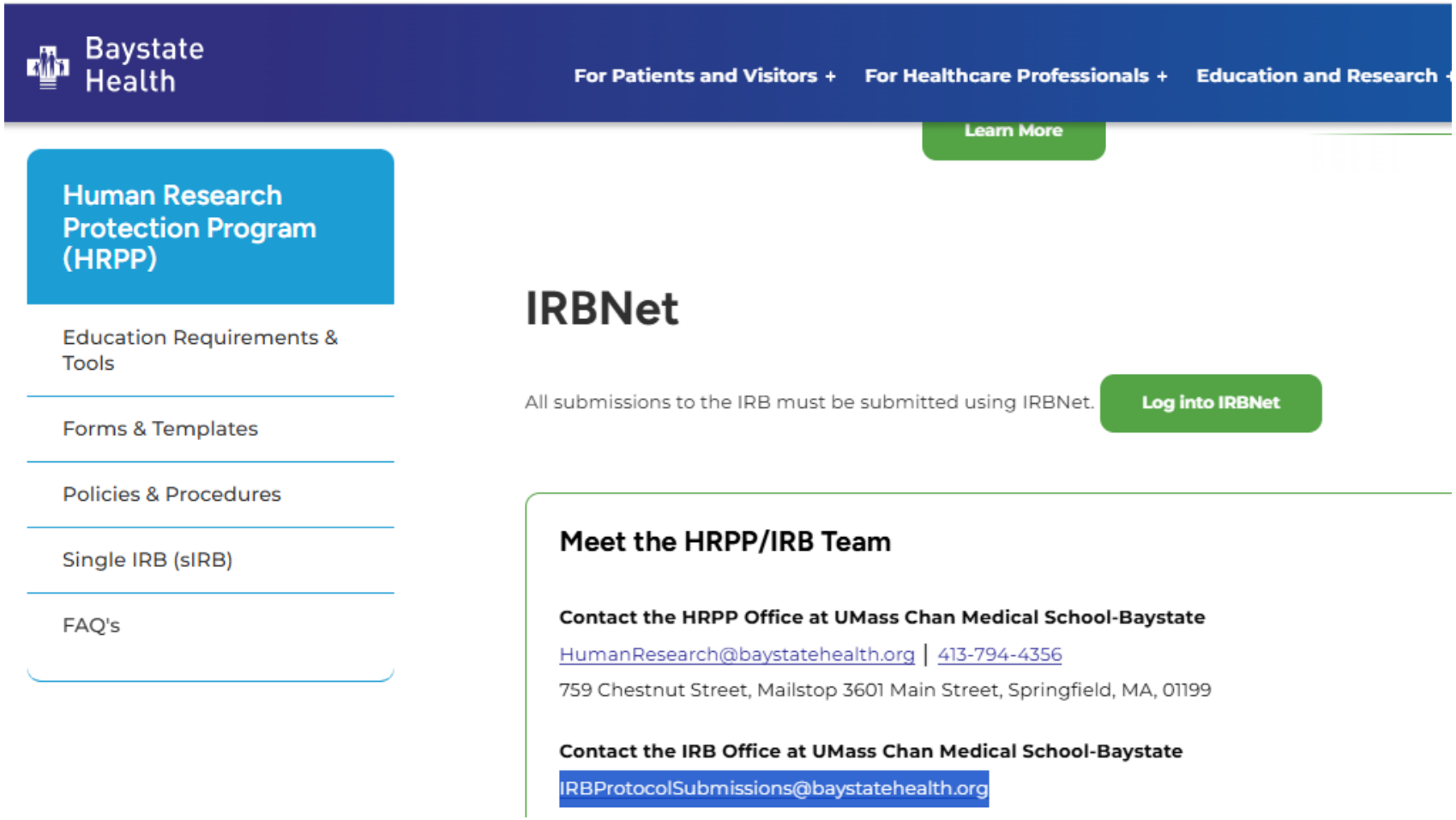
Use the energizers to submit



Forms and Templates



Contact Us!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Human Research Protection Program (HRPP)
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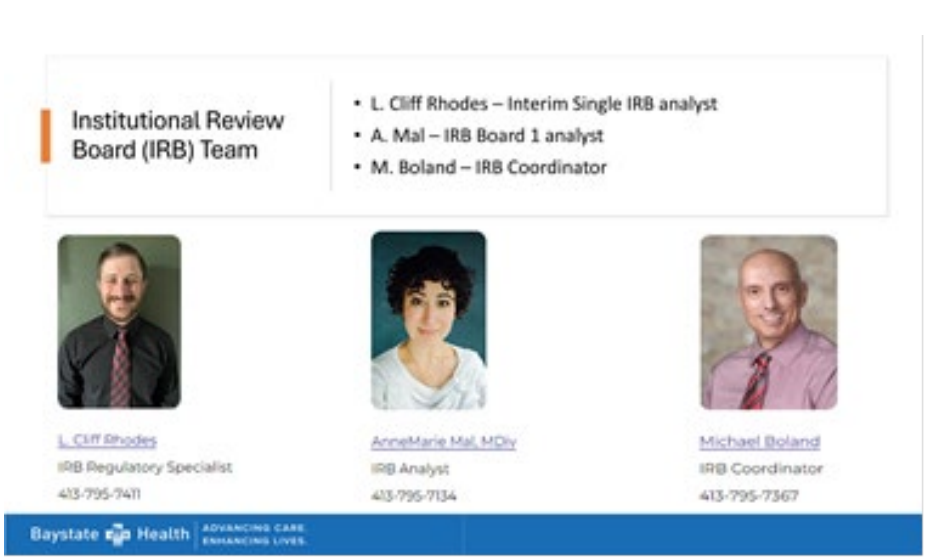
Forms & Templates
Policies & Procedures
Single IRB (sIRB)
FAQ's
IRBNet
All submissions to the IRB must be submitted using IRBNet.
Log into IRBNet
Meet the HRPP/IRB Team
Contact the HRPP Office at UMass Chan Medical School-Baystate
HumanResearch@baystatehealth.org | 413-794-4356
759 Chestnut Street, Mailstop 3601 Main Street, Springfield, MA, 01199
Contact the IRB Office at UMass Chan Medical School-Baystate
IRBProtocolSubmissions@baystatehealth.org

Contact Us!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