HARVARD PILGRIM HEALTH CARE IRB GUIDELINES

PRIOR TO SUBMISSION OF A NEW STUDY

CITI training

- Register with Harvard Pilgrim Health Care at www.citiprogram.org
- Complete the training modules: 1) Human Research; 2) Responsible Conduct of Research (RCR)

Register with IRBNet (www.irbnet.org)

- Access training energizers at www.irbnetresources.org, energizers include:
  - New User Registration Instructions
  - Researcher/Study Coordinator Reference Materials (also includes a video)
  - Contact the IRB Administrator for the username and password to access training materials

Complete the Initial Application

- Residents must have a faculty advisor submit as the PI
- Include all recruitment and advertising materials to be used in the study
  - If materials will be sent to HVMA patients, HVMA electronic sign-off in IRBNet is required prior to submission to the IRB
  - If materials are being developed, specify this
- Submit Informed Consent Form or Waiver Request form, if applicable
- Submissions must have all applicable signatures present in IRBNet; Principal Investigator and Grant Manager, and Atrius Health Department of Research and Clinical Program Evaluation as well as RSDC (if applicable)

CRITERIA FOR IRB APPROVAL OF RESEARCH

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Selection of subjects is equitable
- Informed consent will be obtained from each subject or legally authorized representative
- Informed consent will be documented
- Provisions for monitoring data to ensure the safety of subjects are adequate
- Provisions to protect the privacy of subjects and to maintain confidentiality of data are adequate

CATEGORIES OF APPROVAL

Exempt - Minimal Risk and one of the following:

1. Normal educational practices
2. Educational tests, surveys, interviews or observation of public behavior unless identified and sensitive

3. Observation, surveys, or interviews with public officials or candidates
4. Research using existing data, documents, records, pathological specimens or diagnostic specimens, if publicly available or unidentifiable
5. Research/demonstration projects conducted by or subject to the approval of department or agency heads
6. Taste and food quality evaluation and consumer acceptance studies

Expedited - Minimal Risk and one of the following:

1. Clinical studies of drugs and medical devices only when certain conditions are met
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures routinely employed in clinical practice
5. Use of data, documents, records or specimens that have been collected or will be collected for non-research purposes
6. Collection of data from voice, video, digital or image recordings made for research purposes
7. Research on individual or group characteristics or behavior or research using surveys, interviews, oral history or quality assurance methodology

Full Review

- Research that does not meet the criteria of exempt or expedited
- Requires review by the Full Committee at a scheduled meeting
- Submit by the posted IRB deadlines

POST REVIEW POSSIBLE OUTCOMES

Approved

- Requires continuing review according to the degree of risk. For federally funded studies, continuing review must be conducted not less than once per year. Investigators must submit a continuing review form by the designated submission date to ensure review prior to the study expiration date. Automated reminders are sent via IRBNet prior to the expiration date at 90, 60 & 30 days before expiration.
    - ❖ NOTE: Failure to timely submit continuing review materials can result in an expiration of IRB approval. ***The Federal regulations provide no grace period for renewal past the expiration date.***

Approved with Modifications/Conditions

- The study is approved subject to modifications/conditions or clarifications from the PI. The responses are subsequently reviewed through an expedited process and confirmed/approved.
- Submit revisions in IRBNet, submission type 'Response/Follow-up'

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Deferred

- A study is deferred if it requires more than minor modifications to secure approval. The PI will be notified of the decision with suggestions to further develop the study design and/or materials.
- Submit revisions in IRBNet, submission type 'Response/Follow-up'
- A deferred study with revised materials will be placed on the next meeting agenda following submission for review by the Committee.

Not approved

- The investigator will be notified of the decision.

MODIFICATIONS TO APPROVED RESEARCH

Changes to the approved research must be reviewed and approved by the IRB prior to implementation.

- Submit the Amendment via IRBNet
- Significant modifications or new materials require full review unless your study meets an expedited review category.

IRB CONTACTS

For all IRB matters:
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For CITI questions:
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