Guidelines for Students and Non-HHC Collaborating Investigators

This information has been prepared to assist individuals in the following five categories with conducting their research at Hartford HealthCare:

1) Hartford HealthCare employees needing to meet their own educational requirements for attaining a degree
2) Summer Student Fellows
3) Medical Students
4) Outside Students (non-employees) from surrounding colleges/universities
5) Outside Investigators seeking to use HHC as a data collection site

PLEASE BE ADVISED THAT THE COMPLETION OF THE FOLLOWING PROCEDURES DOES NOT GUARANTEE OR IMPLY THAT THE PROJECT IN QUESTION WILL ULTIMATLY RECEIVE APPROVAL TO BE CONDUCTED AT HARTFORD HOSPITAL.

Getting Started:

- Individuals falling into categories 3-5, above, must initiate contact with the clinical area in which they plan to conduct the research. The Department manager/supervisor must be aware of the project. A Hartford Hospital/Hartford HealthCare employee or member of the Medical Staff must agree to serve as the site Principal Investigator (PI) and be responsible for advising and overseeing the conduct of the research.

- Individuals falling into categories 3-5, above, who will have any contact with patients/research participants or access Protected Health Information (PHI) must register through the **Volunteer Services Department**.

  - For Hartford: Contact Susan Peck 860 972-2182 or Erin McCallon-Estremera (860) 972-2079
  - For THOCC or MidState: Contact Diamond Belejack (203)-694-8572

- Complete the CITI training in human subject protection. This web-based training can be accessed at www.citiprogram.org. If this has been done previously at another institution, Hartford Hospital must be added as an "affiliated institution". Training is good for three (3) years and must be completed prior to submission to the IRB for review.

- Individuals are encouraged to check with their institution's Institutional Review Board (IRB) to assess whether they require their own independent review or whether they are willing to invoke the cooperative agreement (this applies to individuals from UCHC, UConn Storrs, and CCMC) and accept the HHC IRB determination.

- If your project involves any funding, contact the Grants & Contracts office at: (860) 972-4592 or gcresearch@hhchealth.org

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- All materials must be submitted to the IRB using iRIS https://iris.hhchealth.org/. Once you are registered through volunteer services you will receive a Novell log in ID that you will need in order to log into iRIS. If you have a problem logging in please select "request new account" (see below) and an account will be created for you.

In addition to standard IRB review procedures, the following requirements and/or procedures must be followed:

- All categories of individuals must follow all applicable Hartford HealthCare Research Institute policies and procedures.

- Student Applicants must **submit documentation of approval for the project from their academic advisor or faculty mentor**.

- The HH/HHC PI/mentor/advisor must be listed as such on the Research Application. In addition, he/she must **personally sign** the **"Agreement to Act as Principal Investigator for a Student Researcher/Outside Collaborator"** form. This form serves as notification to the IRB that the PI has reviewed the proposal and agrees with its submission.

- All proposed studies **must include a statement of Benefit/Significance to Hartford Hospital and its patients**. The significance of the study to the hospital mission and its patients must be explained and any clinical benefit/utility described. These assurances should be included in the protocol document.

- If approved, the individual and HHC PI must ensure that appropriate clinical staff in the area where the research activity is taking place is aware of the timing and schedule of activities (what times of day will subject recruitment occur, over how many months will the data collection be done, etc.) and is provided with a list of any person(s) that will be in the area assisting with the research.

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- All categories of individuals **should provide recognition of Hartford Hospital or other appropriate Hartford HealthCare institution in any publication or work resulting from the research**. Adherence to HHC authorship policy should be maintained (*i.e.*, senior scientists listed as co-authors for significant contributions to analysis and writing).

- Collaborating Investigators from other institutions must **submit a copy of their current Curriculum Vitae (CV) and professional license(s**) [if applicable] with the Research Application.

Helpful Tips for Preparing a Research Application for the IRB:

- **Ask questions early** in the process.

- The **protocol should be well thought out and defined** before beginning the IRB application process. The research question should be well formulated, variables to be collected should be identified, and there should be a clear plan describing how the data will be analyzed.

- There are **3 levels** of IRB review (see "**IRB Review Basics**", below): Full Board, Expedited, and Exempt. Please think about the **level of risk** that your study may impose to human subjects, and be aware that the final determination will be made by the IRB.

- **Submit early** to allow time for clarification of issues or for full board review if necessary.

- **Answer all questions on the IRB Application thoroughly and clearly**. Plans for the conduct of the project, including recruitment strategies, should be well thought out by the time of IRB submission. Any logistical issues related to data collection, subject recruitment, data security and storage, etc. should be planned in advance of the IRB application by consulting with the clinical department.

- **iRIS TIPS**: All iRIS documentation can be found in the iRIS system https://iris.hhchealth.org/, under the help link located on the upper right corner of the screen within iRIS.

  For technical assistance, call TECH SUPPORT at (860) 972-5621.

- **Prepare and submit the informed consent form** using the Hartford HealthCare template found at: https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/forms

- When applicable, **indicate plans and provide documents** to obtain permission of the parent and assent of the child when minors are to be involved in the study.

- **If requesting a waiver of the requirement to obtain consent, provide complete answers on the Research Application.** A waiver of consent is often requested for chart review studies in which identifiable information is being extracted from the chart. In order for the IRB to approve such a waiver you must provide a description of how the following four criteria are met:
  1. The research involves no more than minimal risk
  2. The research could not practicably be done without the waiver

3. Granting the waiver does not adversely affect the rights or welfare of the subjects
4. When possible, pertinent information will be provided to the subjects at a later date

- **Waiver completion instructions with sample answers can be found at:** https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/forms

- **DO NOT** cut-and-paste the sample language if it is not what you intend to do. **What you say must be applicable to your particular study!**

- **If the study meets one of the Exempt categories,** an informed consent or request for waiver is not necessary. When applicable, however, you still must provide the subjects with an information sheet that includes the elements of consent. The information sheet template can be found at https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/forms

- **Prepare and submit the appropriate HIPAA** documents. For studies seeking to waive the requirement to obtain written authorization, complete the waiver section within the Research Application. If obtaining written consent and authorization, prepare the "**Authorization for Use/Disclosure of Protected Health Information"** found at: https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/forms

- **Submit final versions** of surveys, interview tools, recruitment advertisements, etc.

- **For retrospective chart review studies, provide a data collection sheet.** This is a list of the variables that will be extracted from the medical record or queried from an existing database/data system. If you've already prepared this list as a set of field headers (*e.g.*, in the first row of an Excel document), please think about transposing the list into a document that fits onto as few pages as possible.

- **Make sure there is consistency between the IRB documents**. For example, the Research Application, Protocol, Informed Consent Form, and HIPAA Authorization should all be consistent regarding what procedures will be done, what data will be collected, etc.

- Final approval will not be granted until all required documents have been provided to the IRB.

- Once you have received IRB approval, you are **not permitted** to make any changes (*e.g.*, additions of new procedures, collection of new data) to your protocol. If any change is needed, you are required to contact the IRB and get permission for the change(s) before proceeding with the modification(s).

What to expect after submission of the Research Application to the IRB:

- The speed with which a study moves through the review process depends on the level of complexity of the study, how well investigators have addressed the questions

and requirements outlined in the Research Application, and the type of review to be performed by the IRB.

- Please **expect at least a 2-week turnaround time** for studies that can be reviewed by the expedited procedure.
- Turnaround time for studies reviewed by the Full Board varies.
- Research Applications that are not industry sponsored clinical trials will be routed in iRIS for Scientific Review prior to being submitted to the IRB.
- Once the protocol is reviewed for design and methodology by the Proposal Design and Statistical Analysis Group. The Senior Scientist from this review group will contact you directly to request any clarifications, make suggestions, or require additions to the protocol document.
- When the Senior Scientist assigned to the project has signed off on the protocol, it will be routed to the IRB Administrators for review.
- The IRB Administrators will screen the submitted materials for completeness within 5 days of receipt.
- Then, if needed, stipulations will be submitted through iRIS to PI and Primary Contact requesting additional information/clarification.
- Once all stipulations have been addressed, the submitted materials will be forwarded to the IRB reviewer for final review and approval.
- For studies eligible for expedited review, the IRB Chair may approve the project or request additional information or clarification resulting in another e-mail.
- iRIS will send you an e-mail whenever this is a stipulation to address. Quick responses from the study team will ensure timely processing of the study.
- You cannot begin the project until you have IRB approval. Final IRB approval will not be granted until all requirements have been met.

IRB Review Basics

All research involving human subjects must be approved by the IRB **before** it is initiated. Applications may be reviewed under one of the following three review categories. The investigator may request a specific type of review but the IRB makes the final determination.

1) **Full Board Review**: Protocols are reviewed by the full board when the study involves greater than minimal risk to the potential participants. Protocols must continue to be reviewed by the Board at least annually.

2) **Expedited Review**: This typically is granted when there exists no more than a minimal risk to subjects and the research falls into a specified category described in federal guidance. Protocols must continue to be reviewed by the Board at least annually. Categories of research that may qualify for expedited review are listed on the IRB

website. Most student projects will qualify for expedited review or exempt status. The IRB will make that determination. Expedited review means that only one IRB member (generally the Chair or Vice Chair) is required to review the application, it **does not** mean a faster response time.

3) **Exempt Review:** After initial review, the IRB may provide exemption from further review only when the recruitment, enrollment, and data collection do not contain identifying information that link the data to the human subject. This is usually limited to research designed to examine de-identified, existing laboratory/pathological specimens, or anonymous educational tests surveys and questionnaires.