

## Getting Started How to be "Research-Ready"



### Important Website Links:

- Research Home Page: <https://hartfordhealthcare.org/health-professionals/research>
- IRB Templates, Tools, and Instructions (**Elements of a Research Protocol, Informed Consent, HIPAA Authorization**): <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/forms/institutional-review-board-irb-forms-and-instructions>
- IRB Policies: <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/institutional-review-board-irb/policies>
- Research Budget Templates: <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/grants-and-contracts/budgets>

### Required CITI Training:

There are 2 training courses to complete in the CITI Program:  
<http://www.citiprogram.org>

1. **Human Subjects Protection Training in CITI (Basic Course):**
  - Most Physicians should choose "Group 1: Basic Biomedical" as their Learner Group
  - Refresher training is due every 3 years.
2. **Conflicts of Interest (COI) Training in CITI:**
  - Refresher training is due every 4 years.

#### *What if I already did CITI training somewhere else?*

- Add "Hartford HealthCare" as an affiliated institution to your current CITI account and your training will transfer over. There will be several HHC specific modules you may need to do to complete the transfer.
- Do NOT create a new CITI account.

**Please Note:** *Federally-funded research* also requires completion of the **Responsible Conduct of Research (RCR) Course** and the **Good Clinical Practice (GCP) Course**.

### Financial Conflict of Interest (FCOI) Disclosure:

- Request the disclosure form from the Human Research Protection Program by sending an e-mail to [irb@hhchealth.org](mailto:irb@hhchealth.org)
- The form will be provided through a personalized link to a REDCap survey
- This form is due every year.
- For more information: <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/how-to-conduct-research-at-hartford-healthcare/training-coi/financial-conflict-of-interest-fcoi-in-research-disclosure-form>



### Informed Consent Training:

Individuals who are obtaining informed consent and HIPAA authorization from research participants should contact Pamela Johnson, Research Education and QI Program Manager, at [Pamela.Johnson@hhchealth.org](mailto:Pamela.Johnson@hhchealth.org) or (860) 972-0141 to obtain the list of training dates. They can also be viewed on-line at: <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/research-education>

### On-line IRB Submission System "iRIS":

- All materials must be submitted to the IRB through iRIS, no exceptions.
- To log into iRIS - <https://iris.hhchealth.org>
- Use your HHC user name and password to log in.

### Review Timelines:

- Only studies involving greater than minimal risk requiring Full Board review have submission deadlines. Minimal risk research qualifying for Expedited review have no deadlines and are reviewed on an on-going basis. Don't wait to submit your expedited study, just submit it.

Average IRB turnaround time\*† (in calendar days);

- Full Board Project ~ 47 days
- Expedited Project ~ 9 days
- Quality Improvement project determination ~ 5 days
- Average Scientific Review turnaround time ~ 13.5 days (in addition to IRB review time)

\*This includes the amount of time the submission is with both the IRB and the investigator.

†These averages include both experienced investigators and new investigators. It typically takes new investigators a little longer than average due to the learning curve, so please plan accordingly.

### Information for Residents and Investigators Working with Residents:

- Residents cannot serve as Principal Investigator and will need a Hartford HealthCare attending to serve as PI on their studies.
- Studies involving minimal risk, that are eligible for Expedited review (i.e. retrospective chart reviews) have no IRB submission deadline.
- Prospective studies typically require written informed consent and HIPAA authorization (they may also need a partial waiver for screening or waiver of documentation of consent).
- Retrospective studies typically qualify for a full waiver of consent and HIPAA authorization, but it must be justified appropriately.
- Retrospective chart reviews still need a budget form even if they are un-funded (in-kind budget form - <https://hartfordhealthcare.org/health-professionals/research/medical-professionals/grants-and-contracts>)



### Research Involving Collaborators from non-HHC Institutions:

- Residents, Fellows, Students, Volunteers, Interns etc. from external institutions are permitted to work on research studies as long as their involvement is in compliance with the HHC Access Policy: <https://hhc.policytech.com/dotNet/documents/?docid=18416>
- To Register as a volunteer at Hartford HealthCare contact Penny Ross from Volunteer Services at [Penelope.Ross@hhchealth.org](mailto:Penelope.Ross@hhchealth.org).
- If collaborators from external locations (i.e., UConn Health, UConn Storrs, CCMC, Yale, St. Francis, etc.) plan to work on the study, they will need to check with their home institution's IRB to see if their involvement "engages" their institution in the research. HHC IRB has cooperative agreements in place with many local institutions so that we can efficiently rely on only one IRB of Record. The HHC IRB Administrators can help with this process as long as it is made clear on your Research Application that an outside institution is involved.

### Data Security and HIPAA Privacy Rule Compliance:

If you are working with a dataset that contains Protected Health Information (PHI):

- **DO** – password protect and encrypt the file
- **DO** – only use your @hhchealth.org e-mail account to share the file
- **DO** – encrypt the e-mail (i.e. type "Secure" in the subject line)
- **DO** – Use and disclose only the minimum amount of PHI necessary to answer the research question. (Check the protocol and HIPAA authorization to see what info you are approved to collect.)
- **DON'T** – send it using an external e-mail account (gmail, yahoo, hotmail, etc.)
- **DON'T** – share it with anyone not approved by the IRB to work on the research project
- **DON'T** – save a copy to an external computer/laptop
- **DON'T** – hide non-compliance issues, address them with the PI and IRB promptly.

### The 18 HIPAA Identifiers:

If a dataset contains any of these elements, it is considered to be identifiable. In other words, for a dataset to be considered de-identified, **ALL** of the following 18 identifiers must be removed:

- |  |   |  |
|--|---|--|
| 1. Names   | 5. Fax numbers  | 14. Web Universal Resource Locators (URLs)   |
| 2. All geographic subdivisions smaller than a state, including: street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, and their equivalent geographic codes  | 6. Electronic mail addresses  | 15. Internet Protocol (IP) address numbers   |
| 3. All elements of dates (except year) for dates directly related to an individual, including: birth date, admission date, discharge date, date of death; all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older | 7. Social security numbers  | 16. Biometric identifiers, including fingerprints and voiceprints  |
| 4. Telephone numbers   | 8. Medical record numbers   | 17. Full face photographic images and any comparable images  |
|  | 9. Health plan beneficiary numbers  | 18. *Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification; [creation of a unique code not disclosed to the investigator or investigator creation of such a code] |
|  | 10. Account numbers   |  |
|  | 11. Certificate/license numbers   |  |
|  | 12. Vehicle identifiers and serial numbers, including license plate numbers |  |
|  | 13. Device identifiers and serial numbers                                   |  |

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### Lifecycle of a New Research Study Submission:

- 1) A Principal Investigator (PI) has an idea or hypothesis to investigate.
- 2) If the PI's clinical department has an established Research Council, this idea is explored through their established process.
- 3) PI consults with a Senior Scientist in the Research Administration Department. They provide guidance in protocol writing, including proper study design methodology, statistical analysis planning, and sample size estimation.
- 4) The Research Protocol is designed and written. It is recommended to use the "Elements of a Research Protocol" guide as a template.
- 5) All key study personnel completes CITI Human Subjects Training, CITI COI Training, and the Financial Conflict of Interest (FCOI) in Research Disclosure via REDCap.
- 6) If funding has been obtained to conduct the research study, a budget of costs is built in the appropriate template.
- 7) Research Application is completed on-line in iRIS.
- 8) The following documents (referred to as "submission components") are uploaded to the iRIS Research Application (\* = if applicable):
 

<ol style="list-style-type: none"> <li>a. Protocol</li> <li>b. Data Collection Forms/Tools</li> <li>c. Rating scales/questionnaires/surveys*</li> <li>d. Recruitment materials/advertisements*</li> <li>e. Phone screen script*</li> <li>f. Informed Consent Form (ICF)*</li> <li>g. Research HIPAA Authorization*</li> <li>h. Investigator Brochure (for non-FDA approved drugs)*</li> </ol>	<ol style="list-style-type: none"> <li>i. Package Insert (for FDA-approved drugs)*</li> <li>j. Instructions for Use (for device studies)*</li> <li>k. Non-Significant Risk/Significant Risk Determination (for Device studies)*</li> <li>l. Approvals from external IRB (if multi-site study)*</li> <li>m. Budget</li> </ol>
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- 9) PI signs off and submits the completed Research Application in iRIS. The application then hits several checkpoints in the workflow before it reaches the IRB.
  - a. **Research Navigator** - Checks the application for completeness → returns submission to the PI if any required components are missing and provides guidance → advances the application.
  - b. **Scientific Review** - Senior Scientists (SS) review the protocol for sound methodology. If the PI has worked with a SS in advance of the iRIS submission process, this checkpoint will be quick. If the protocol requires revision, the SS will contact and work with the PI to address the issues. Once the protocol is finalized the PI will be asked to upload the final version of their protocol to the iRIS application → advances the application.
  - c. **Grants & Contracts** - Ensures that the appropriate budget template has been uploaded to the application (continues to work on budget and contract in parallel with IRB review) → advances the application forward to the IRB.
- 10) IRB receives the Research Application submission. IRB Administrators pre-review the application, submission components, and ensures all key study personnel meet training and FCOI requirements. Any questions/clarifications are sent to the investigator through iRIS in the form of "stipulations."
- 11) PI responds to pre-review corrections requested ("stipulations") in iRIS.
- 12) IRB Administrators review the PI responses and sends the submission for final review to either the Full Board IRB committee for studies that involve greater than minimal risk or to the IRB Chair or Designated Reviewer for studies that are deemed to be minimal risk and qualify for Expedited review.
- 13) If the IRB requests further clarification, another round of stipulations will be sent via iRIS for the PI to address.
- 14) IRB grants final approval. Approval letter sent through iRIS to the PI.

**\*Approval from BOTH the IRB AND Grants & Contracts must be obtained before work on the research project begins.**

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### Important Contacts:

## Research Administration

Website: <https://hartfordhealthcare.org/health-professionals/research>

<u>RESEARCH ADMINISTRATION</u>	Main Line Liz Roper	(860) 972-2865 (860) 972-1964
<u>IRB &amp; HUMAN RESEARCH PROTECTIONS PROGRAM</u>	Cherie Bilbie <a href="mailto:irb@hhchealth.org">irb@hhchealth.org</a>	(860) 972-2893
<u>RESEARCH NAVIGATOR</u>	Emily Shearier	(860) 972-1255
<u>GRANTS &amp; CONTRACTS</u>	Tammy Weirs <a href="mailto:gcresearch@hhchealth.org">gcresearch@hhchealth.org</a>	(860) 972-4592
<u>GRANT WRITING</u>	Anne Williamson	(860) 972-3183
<u>DATA MANAGEMENT</u>	Jeff Mather	(860) 972-3560
<u>iRIS/REDCap SUPPORT</u>	<a href="mailto:iris@hhchealth.org">iris@hhchealth.org</a>	(860) 972-5621
<u>STATS DESIGN</u>	<a href="mailto:statsdesign@hhchealth.org">statsdesign@hhchealth.org</a>	(860) 972-5065
<u>CLINICAL RESEARCH CENTER</u>	William Roman	(860) 972-1558