**Investigators Guide to the**

**UConn Health HSPP/IRB**

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# Section 1: General Tips

* Know where to find HSPP policies: [HSPP Website](https://ovpr.uchc.edu/services/rics/hspp/policies/)
* Know how to report noncompliance and adverse events
* Understand which activities are overseen by the HSPP and what must be submitted to the IRB
* Know the regulatory standards that apply to your research
* Read IRB application questions carefully and respond accurately
* Understand what constitutes conflict of interest, how a potential conflict of interest is disclosed and reviewed at UConn Health
* Complete and maintain human subjects training (e.g. CITI)
* Recruit subjects ethically and in an equitable manner while adhering to inclusion/exclusion criteria
* Understand the concept of respect for persons and the obligation to obtain the consent of participants or their legally authorized representatives
* Know your role and your responsibilities that go along with conducting human subjects research
* Know how to contact your IRB Coordinator for additional assistance or guidance.

# Section 2: Introduction to the HSPP

In the late 1990’s through early 2000’s several well-known universities and academic medical centers were publicly criticized for failings in the IRB review and institutional oversight of human subjects research. These shortcomings were believed to have contributed to the serious injury or death of study subjects, the most well-known case being that of [Jesse Gelsinger](http://www.circare.org/submit/jintent.pdf). Several programs, including Duke and Hopkins, underwent investigations by federal oversight agencies and subsequently were penalized including the temporary restriction or suspension of their ability to conduct federally funded research. The Institute of Medicine (IOM) was charged with the task of reviewing the national system for oversight of human subjects research and produced two reports, the first in [2001](https://www.nap.edu/catalog/10085/preserving-public-trust-accreditation-and-human-research-participant-protection-programs) and the second in [2002](https://www.nap.edu/catalog/10508/responsible-research-a-systems-approach-to-protecting-research-participants#:~:text=Responsible%20Research%20outlines%20a%20three,The%20approach%20includes%3A&text=Recognition%20and%20integration%20of%20research%20participants'%20contributions%20to%20the%20system%2C%20and). It was the IOM who first introduced the concept of human research protection programs (HRPPs) and accreditation. Since competing interests, such as the business interests of the organization and the financial interests of investigators, were felt to have contributed to the shortcomings of the IRB oversight system, the IOM also made recommendations regarding the identification and management of conflicts and mechanisms to ensure the independence of the IRB.

Subsequent to the IOM reports, accrediting organizations emerged. [AAHRPP](http://www.aahrpp.org/) (Association for the Accreditation of Human Research Protection Programs) quickly became the leader in the field and uses a voluntary, peer-driven and educational model to ensure that a Human Research Protections Program (HRPP) meets rigorous standards for quality and protection. The goals of accreditation are to improve the systems that protect the rights and welfare of individuals who participate in research, and to communicate to the public the strength of an organizations commitment to the protection of human research participants. UConn Health achieved and has maintained full AAHRPP (Association for the Accreditation of Human Research Protection Programs) accreditation since 2006.

The core concept of a Human Research Protection Program (HRPP) is to engage all stakeholders in the oversight and protection of human subjects. This involves (1) institutional commitment in the form of policies establishing authority of the HRPP and IRB and allocation of sufficient resources to ensure adequate oversight and training, (2) core functions including IRB, research training and education, and quality assurance activities, and (3) engagement of the research community including investigators and subjects. A functional HRPP includes coordination of key functions, communication among components, and feedback loops to facilitate effective oversight and best practices in research.

The vision of the University of Connecticut Health Center (UConn Health) is to be nationally recognized for improving the health of the citizens of Connecticut through innovative integration of research, education, clinical care and wellness promotion. In helping UConn Health attain its vision, the goal of the Human Subjects Protection Program (HSPP) is to provide protection to those who participate in research studies and to have that protection be an integral part of a fluid process that responds to the needs of the subject, the researcher, and the institution. Research is brought from the bench to the clinical arena through the review and approval process of the Institutional Review Board panels that are a part of the HSPP.

The primary mission of the HSPP is to ensure that the rights and welfare of those who participate in research studies are protected. This mission is carried out by first ensuring that all research involving human subjects is scientifically sound and has been reviewed and approved by the Institutional Review Board prior to initiation, by continuing review as applicable and monitoring subsequent to approval. These functions ensure that studies are being conducted in accordance with the ethical principles of autonomy, beneficence and justice as set forth in the Belmont Report, and in compliance with internal policies, State law and Federal regulation.

The four primary functions of UConn Health are to provide professional education, to offer patient care, to promote wellness, and to conduct research. The Director of the HSPP has the authority and responsibility to oversee research involving human subjects and reports to the Associate Vice President for Research Integrity and Compliance.

UConn Health holds a **Federalwide Assurance** **(FWA)** which is an agreement between this institution and the government, in particular the Office for Human Research Protections within the Department of Health and Human Services, that assures that whenever UConn Health engages in non-exempt human subjects research conducted or supported by any federal department or agency that has adopted the Common Rule, UConn Health will comply with the terms of the assurance. While the assurance is applicable to federally funded research, UConn Health applies equivalent protection standards to all human subject research, regardless of the funding source. Michael Centola is the **Institutional Official (IO)** designated on UConn Health’s FWA and the HSPP Director is designated as the administrator. The administrator is responsible for ensuring that the HSPP has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. Our FWA number is 00006064 and its expiration date is April 23, 2029.

The Human Subjects Protection Program (HSPP) is comprised of all the units and people at UConn Health that work together to protect the participants that volunteer for research. The IRB is only one component of the HSPP but has a large responsibility in helping protect participants in research. Both the HSPP and the IRB communicate with, and rely on, other components of UConn Health’s integrated program to ensure the rights of research participants are upheld.

The centralized components of the UConn Health HSPP under the direct authority of the Director of the HSPP include the Institutional Review Board, the Compliance Monitor, the Education Specialist and the Scientific Review Committee. Other important entities in the Office of the Vice President for Research contribute to the operation of the HSPP, such as the Associate Vice President for Research Integrity and Compliance, Sponsored Program Services, Office of Clinical and Translational Research, Environmental Health & Safety, and Conflict of Interest Committee. The Organizational Official reports to the Associate Vice President for Research Integrity and Compliance. Entities at the organizational level which support the HSPP operations include the Office of General Counsel, the Office of Healthcare Compliance and Privacy, the Medical and Dental School Research Deans, the Clinical Research Center, investigators and research personnel. All entities help to ensure high quality, ethical and safe research at UConn Health.

As outlined in the [organizational chart.pdf](https://ovpr-uchc.media.uconn.edu/wp-content/uploads/sites/2568/2019/10/OVPR-org-chart.pdf) (PDF), the HSPP Director reports to the Associate Vice President for Research Integrity and Compliance, who in turn reports to the Vice President for Research, Innovation and Entrepreneurship.

The vision of the UConn Health HSPP is to provide complete protection to all volunteer subjects enrolled in research studies and to have that protection be an integral part of a fluid process that responds to the needs of the subject, the researcher, and the institution.

[**HSPP Full Description**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/09/HSPO-Description.docx)

**Which Federal regulations apply to human subjects research at UConn Health?**

UConn Health currently conducts research that is subject to the revised Common Rule, the FDA, HIPAA, the Department of Defense, and the Department of Education. When research is not technically subject to federal human subjects regulations (e.g., because it is not funded), UConn Health applies the principles and standards of the Belmont Report by policy to the review and conduct of the research to ensure equivalent protections for all human subjects. Minor deviations from the Belmont Report that do not diminish subject protections are outlined in HRPP/IRB policies and procedures for non-federally funded or regulated research. Revisions to the Common Rule went into effect in January of 2019. Non-exempt research IRB approved prior to the effective date of the rule were transitioned to the revised rule at the next continuing review.

**Are there categories or types of research that UConn Health does not participate in?**

UConn Health does not currently engage in planned emergency research (research in which an intervention must be administered before consent from subjects or permission from their representatives can be obtained) or VA research.

In the event that an investigator wanted to pursue research within one of these categories, additional policies and processes would need to be put into place in order to ensure that the research was conducted and reviewed in accordance with ethical standards and regulations governing such research. The decision on whether to apply the resources necessary to move forward with such research would be made by the Institutional Official (IO).

# Section 3: Research requiring IRB review

**What does an IRB do?**

The main mission of the Institutional Review Board is to protect the rights, safety and welfare of research subjects. The IRB is formally designated by the institution and given authority through federal regulations and institutional policy to:

* approve, modify or disapprove research,
* conduct continuing review of already approved research,
* suspend or terminate approval of research,
* to observe or have a third part party observe the consent process and the research.

The IRB reviews and approves research in accordance with the rules and regulations described in section 4 of this document.

Determining whether or not a project requires IRB review can be challenging. For that reason, the HSPP has a [Human Subject Research Determination form](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-HumanSubjectResearchDeterminationForm.doc) to assist investigators in determining whether or not a research project meets the definition of human subjects research, andprovides a list of activities that may or may not require IRB as a general guide.

 Any investigator who is unsure of whether a proposal constitutes “human subjects research” must submit a human subjects research determination (HSRD) form to the IRB at irb@uchc.edu*.* If a HSRD form does not qualify as human subjects research, the HSPP will return the form indicating that the project does not require further IRB review or approval. If the project is determined to meet the regulatory definition of human subjects research, the researcher will be advised to submit a new project application for IRB review through the electronic submission system. The HSPP/IRB office makes the final determination on whether or not your project requires IRB review.

The Institutional Review Board (IRB) must review all research involving human subjects conducted by UConn Health faculty, staff, and students prior to implementation. IRB approval is required regardless of funding source (or lack thereof) and/or location at which the research will be conducted. Also, any research reviewed by an external IRB must also be submitted to the UConn Health IRB via a Facilitated IRB application prior to the involvement of any UConn Health agents.

Under the Common Rule, research with human subjects is defined as follows:

* *Research*: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
* *Human Subject*: A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The federal regulations (45 CFR 46.102) further define:

**Intervention** includes both physical procedures by which information or biospecimens are gathered (e.g. venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes

**Interaction** includes communication or interpersonal contact between investigator and subject.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. medical record) **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

**Who determines whether or not a human subjects research project is exempt from the requirement for IRB oversight?**

Determinations of exemption should be made by persons well-versed in the regulations but not personally involved in the investigation or otherwise conflicted. At UConn Health, this responsibility has been delegated to representatives of the HSPP (IRB Regulatory Specialist, IRB member, Research Compliance Monitor, Education Specialist). When action must be taken on a request for waiver or alteration of the requirement for HIPAA authorization, and when limited IRB review is required as a condition of the exemption, the review will be conducted by an IRB Chair or designated IRB reviewers. Like HSR determination requests, requests for an exempt determination are submitted via IRIS and the determinations are documented in a letter provided to the investigator. The federal regulatory agencies have provided a list of categories of research activities that do not require IRB oversight under federal regulation. The proposed research activities must fall completely within one or more of the designated exempt categories. Exempt research is still expected to be conducted in accordance with the ethical principles described in the Belmont report and the reviewer will consider issues such as the recruitment plan, consent, and protections to ensure privacy and confidentiality in their review.

**Who has the authority to approve human subjects research at UConn Health?**

UConn Health’s two IRBs have the authority to approve, require modifications in, or disapprove human subjects research at UConn Health. Other organizational officials may disallow a research study, but they cannot overturn a disapproval by the IRB or approve research that the IRB has not approved. UConn Health may cede IRB review and oversight in full or in part to another IRB through a formal arrangement such as we currently have with UConn-Storrs IRB, WCG and Advarra WIRB. UConn Health may elect to cede review for other research on a case by case basis by the HSPP Director and the IO. Requests for reliance on an external IRB may be submitted via the IRB’s electronic platform (request Facilitated Review on the Application form). When review by a single IRB (sIRB) is required by regulation or funding agency policy, investigators must initiate the reliance request or request for UConn Health IRB to serve as the sIRB prior to grant submission. UConn Health IRB does not intend to be the IRB of Record for NIH-funded multi-site trials. Additional information about IRB reliance and sIRB requirements is available on the HSPP website.

**What does the term “expedited review” mean and how is it conducted at UConn Health?**

Certain minimal risk research may be eligible for expedited review if all of the proposed research activities fall into one or more of the categories designated by the federal regulatory agencies as eligible for expedited review. Expedited review is conducted by the IRB Chair or experienced IRB members designated by the IRB Chair. Research reviewed via expedited review must still satisfy the same criteria for approval as research reviewed by the convened board and all of the requirements for ongoing reporting to the IRB and obtaining IRB approval for any proposed changes to the research apply. Continuing review by the IRB may or may not be required when research qualifies for expedited review. The IRB determination letter will inform research teams whether submission of a continuing review report or annual status report is required.

Researchers may request expedited review of submissions to the IRB and include within their submission the expedited review request form that assists the IRB in determining eligibility. IRB staff review requests for expedited review, and if the request appears appropriate, forward the research to a Chair or designated reviewer for final determination of eligibility and review. An expedited reviewer may approve, solicit additional information, or require modifications to research but cannot disapprove research, only the convened board has the authority to disapprove research. Even if a project technically qualifies for expedited review, the reviewer has the discretion to refer the project to the convened board for review. The outcomes of expedited reviews are provided to investigators via a letter sent within IRIS.

**May an investigator make changes to IRB-approved research without seeking IRB approval for the changes?**

No, investigators must submit amendments to the IRB requesting changes to any aspect of the research activity unless the change is necessary to eliminate apparent immediate hazards to the subject. In the event that the researcher has to make such a change, they must report the event and action to the IRB within 5 business days.

**What types of things are researchers expected to submit to IRBs in between initial and continuing review?**

In addition to proposed modifications to the research, investigators need to report any information that arises that is relevant to the protection of subjects, the criteria for IRB approval, or the safety, welfare, or willingness of subjects to continue participation. This includes, but is not limited to, unanticipated problems, protocol violations or potential noncompliance with regulations or policies within the control of the research team, complaints, external monitoring reports (with any deviations within the control of the research team or corrective actions), or any investigator or sponsor-initiated suspensions or terminations of the research. In addition, investigators must submit requests for changes in personnel through a modification request in IRIS.

**Leadership and composition of the IRBs**

Each IRB has a designated Chair and Vice-Chair, or Co-Chairs. The Chair of IRB Panel 1 is Dr. Julian Ford, clinical psychologist and professor in Psychiatry, and the Vice-Chair is Dr. Ruchir Trivedi, a nephrologist and associate professor in Medicine. IRB Panel 2 is co-Chaired by Dr. Ford and Dr. Upendra Hegde, hematologist, professor of medicine and Director of Oncology Inpatient Unit. The IRBs are composed of physicians, nurses, pharmacists, and other disciplines with a breadth of specialty expertise and knowledge of vulnerable populations. The IRBs are composed of both scientific and non-scientific members and members affiliated and unaffiliated (commonly referred to as Community Representatives) with UConn Health. When the IRB requires expertise beyond its membership, it seeks consultation from others within or external to the organization. Each IRB meets monthly, the meeting schedule is available on the [HSPP Website](https://ovpr.uchc.edu/services/rics/hspp/irb/meeting_dates/). Studies involving prisoners are reviewed by IRB Panel 2 which has a Prisoner Representative.

**May an investigator appeal a decision made by the IRB?**

Yes, investigators are welcome to submit a written appeal to the IRB for reconsideration and to personally present their case, per the [HSPP Appeals Process Policy](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Pol-2011-009.8.pdf) to the IRB Chair, providing information to support the PI’s position. If the original determination was made by the convened board, the investigator’s request will be considered at the next available meeting of the IRB. If the original determination was made by a reviewer under the expedited review process, the request for reconsideration will be considered by the IRB Chair who will determine whether to uphold, reverse or modify its decision. The IRB notifies the investigator of the final outcome via a letter produced within IRIS. For appeals related to determinations of non‐compliance, unanticipated problems, or suspensions or terminations, the IO, Department Chair or Supervisor, and other parties will be notified of the final outcome as appropriate.

**What should an investigator do if they have a concern about how the HSPP or IRB is functioning?**

Investigators who have concerns or suggestions regarding the HSPP or IRB should convey them to the Director, the Institutional Official, or other responsible parties (e.g. IRB Chair, Department Chair), who will in turn inform the Institutional Official. While individuals are encouraged to contact the Director or IO directly in order to facilitate their ability to thoroughly investigate issues, reports may be made via email to the IRB at irb@uchc.edu or anonymously by calling the UConn Reportline via 1-888-685-2637 or through an online report https://compliance.uconn.edu/reporting-concerns/. The issues will be reviewed, and when deemed necessary, the Institutional Official will convene the appropriate parties to form a response for the investigator, make necessary procedural or policy modifications, or take other steps, as warranted.

**In general, how long does it take to achieve IRB approval?**

The HSPP tracks IRB approval timelines as part of ongoing QA activities. The following data are from new project submissions received between Jan and Dec 2023.

|  |  |  |
| --- | --- | --- |
| **Type of Review** | **Mean number of days from receipt of a complete submission to Review** | **Mean number of days from receipt of a complete submission to Exempt Determination or Approval** |
| Exempt (n=103) | 1 | 35 (median 15) |
| Expedited (n=38) | 4 | 43 (median 21) |
| Full Board (n=4) | 17 | 77  |

Although not an apples-to-apples comparison, this data compares favorably to benchmarking data

currently available from AAHRPP:

|  |  |  |
| --- | --- | --- |
| **Type of Review** | **Mean number of days from receipt of a submission to Review** | **Mean number of days from receipt of a submission to Exempt Determination or Approval** |
| Exempt |  | 10 |
| Expedited | 6 | 18 |
| Full Board  | 14 | 42 |

**How long may an IRB approve research for?**

An IRB may grant approval for research subject to convened board review for no longer than a 12-month period. At the time of continuing review, the IRB is expected to review the progress of the research, determine whether or not the research still satisfies the criteria for approval, and whether the consent, if applicable, remains appropriate. Shorter periods of approval may be put in place by the IRB for early phase research, research with known serious risks to participants, research involving particularly vulnerable populations or sensitive topic matter, or for other reasons.

Investigators are expected to submit continuing review applications with sufficient time for the IRB to conduct the continuing review and for the investigator to make modifications if necessary, before approval expires. For research subject to convened board review, submission of continuing review materials at least 28 days prior to expiration is strongly encouraged. IRIS sends automated timed reminders to investigators to remind them to submit continuing reviews (90, 60, 30 day notices). If IRB approval lapses, an expiration notice is sent, and all research activities must cease. If the investigator believes that certain aspects of the research must continue in order to protect subjects (such as continuation of study medication or medical monitoring), they need to contact the IRB Chair to describe the need and seek permission.

Certain minimal risk research and research that has progressed to the point that the remaining activities involve no more than minimal risk (e.g., data analysis) may not require continuing review by the IRB. This depends on the regulations that apply to the research (e.g., the Revised Common Rule or FDA) and the determinations of the IRB. When continuing review by the IRB is not required, investigators are instead required to submit a brief annual status report which is reviewed administratively by the HSPP/IRB office to update the IRB’s records and to determine whether any additional action is needed.

# Section 4: Roles and Responsibilities of Investigators and Research Staff

Although, the IRB looks for procedures that minimize the risks to subjects, it is the investigators that have the primary responsibility for protecting the rights and welfare of human subjects. Safeguarding human subjects takes precedence over the goals and requirements of any research endeavor. The principal investigator (PI), and other members of the research team are expected to be knowledgeable about and adhere to ethical guidelines when conducting any type of research regardless of the level of risk or review category (exempt, expedited, full board):

* The **Belmont Report** identifies and summarizes three main ethical principles that govern human research:
	+ **Respects for persons** (autonomy/voluntary participation/adequate information)
	+ **Beneficence** (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)
	+ **Justice** (selection of subjects is equitable and is representative)

The UConn Health IRB uses the Common Rule as a guide for approving all research regardless of federal support.

* The **Common Rule** [(**45 CFR part 46**)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) is the federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report. The UConn Health IRB uses the Common Rule as a guide for approving all research regardless of federal support.
	+ **Pre-2018 Requirements**: The Federal Policy for the Protection of Human Subjects or the “Common Rule” was published in 1991 and includes four subparts: subpart A, also known as the Federal Policy or the “Common Rule”; subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children. The Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.
	+ **Revised Common Rule:** The Common Rule was revised in January 2019 to strengthen protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research by no longer requiring continuing review for non-exempt minimal risk research. Furthermore, the consent document was amended to include a concise introductory explanation of **key information** that would be most important to individuals contemplating participation in a study. Revisions to the Common Rule took effect on January 21, 2019, and all research approved after this date are subject to the Revised Common Rule.
* The **Office for Human Research Protections (OHRP)** oversees operation of the IRB and provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP is the office to which any serious/continuing noncompliance or unanticipated problems are reported.
* The **Food and Drug Administration (FDA)** is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. When submissions include FDA regulated drugs, devices or biologics, UConn Health follows the FDA regulations for research, 21 CFR Parts 50 and 56. Specific FDA regulations (Parts 312 and 812) are used as when investigators are conducting research with investigational drugs or devices.
* **UConn Health Policies and Procedures:** These include UConn Health specific policies as well as federal regulations. Policies and Procedures for the Human Subjects Protection Program are available here: [UConn Health HSPP Policies and Procedures](https://ovpr.uchc.edu/services/rics/hspp/policies/)
* The **Human Subjects Protection Program (HSPP)** is entrusted to provide support, guidance, and education to UConn Health in support of the mission to protect the rights and welfare of research volunteers. The HSPP has an expansive [**plan**](https://ovpr.uchc.edu/services/rics/hspp/)to ensure that the rights and welfare of participants in Human Research are protected.
* Other federal and state laws and regulations that apply to research, i.e. Family Educational Rights and Privacy Act [[**FERPA**]](https://www.ecfr.gov/current/title-34/subtitle-A/part-99?toc=1), Health Insurance Portability and Accountability Act [[**HIPAA**]](https://www.hhs.gov/hipaa/index.html), General Data Protection Regulation [[**GDPR**]](https://gdpr.eu/) .

# Section 5: Minimizing Risks and Protecting Participants’ Rights and Welfare

A risk is a potential harm or injury associated with the research that a reasonable person in the subject's position would likely consider injurious. Risks can be categorized as physical, psychological, sociological, economic, and legal. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects; and to the importance of knowledge that may reasonably be expected to result from the research.

**Minimal Risk**: the risks of harm anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These are risks that reflect background risks that are familiar and part of the routine experience of life for an average person in the general population.

**Greater than Minimal Risk**: The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Research that is greater than minimal risk is reviewed at full board meetings.

Minimizing risks to participants and ensuring participants rights and welfare are key components of human research protections. Below are some strategies through which these goals can be accomplished.

* Design and implement protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report.
* Verify procedures are consistent with sound research design by ensuring that the research is reasonably expected to answer the proposed question and that the resulting knowledge is expected to be sufficiently important to justify the research. Ensure the proposed research has scientific merit.
* Ensure that recruitment procedures foster the equitable selection of participants and is not just based on convenience. The chosen study population should be justified by the purpose/nature of the research, the research setting and the potential benefits to that population. In addition, the recruitment process should be free of coercion or present no undue influence. Special attention should be given to populations that are more susceptible to coercion or undue influence, such as children, prisoners, cognitively disabled individuals, students, economically or educationally disadvantaged participants. Extra measures of protection should be included in the study protocol when vulnerable populations are included in the research (additional information may be found in Section 6: Enhanced Protections for Vulnerable Populations).
	+ [**HSPP Policy Recruitment and Payment**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-015.0.pdf)
* When applicable, utilize procedures already being performed for diagnostic or treatment purposes.
* Ensure that you have the appropriate resources available to conduct the research (e.g., qualified personnel, facilities, equipment, funding, etc.).
* Establish adequate provisions for monitoring participants to identify adverse events or trends that need to be examined. Review the data collected to ensure participant safety, when appropriate.
* Develop plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:
	+ Privacy – Relates to an individual having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others.
	+ Confidentiality – Relates to the protection of a participant’s data that has been shared with the researcher with the expectation that it will be protected and not disclosed.
* Put in place enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, cognitively impaired individuals, etc.).

# Section 6: Enhanced Protections for Vulnerable Populations

**What categories of subjects are considered vulnerable and what does this mean?**

Federal regulations specifically designate three categories of research participants that are considered so vulnerable that additional requirements apply in order to approve research expected to enroll these types of subjects. These categories are (1) Pregnant women, fetuses, and neonates; (2) Prisoners; and (3) Children. In addition, most institutions and AAHRPP specify special requirements and protections for research enrolling Adults with Impaired Decision-Making Capacity. Most institutions, including UConn Health, also designate employees and students as vulnerable. The following is a high-level summary of this topic; detail can be obtained in the HRPP/IRB policy manual.

The IRB application solicits additional information from investigators who intend to enroll subjects from vulnerable categories for the IRB to consider in its review. The IRB considers this information and other information available within the protocol and application in order to ensure adequate protections are in place and to make the additional determinations that are required by regulation or policy.

When an IRB reviews research involving pregnant women, fetuses, or neonates, among other things, the IRB must identify the specific category that makes the research permissible (categories are based on the prospect of benefits and level of anticipated risks to the pregnant women and the fetus or neonate), ensure that protections are in place to separate the researcher from decisions to terminate a pregnancy or determine the viability of the neonate, and determine when the permission of the father of the fetus or neonate must also be sought in addition to consent from the pregnant woman.

When an IRB reviews biomedical or behavioral research that intends to enroll prisoners, a member who is either a prisoner or who has expertise relevant to prisoners, is expected to be in attendance and to participate in the review. As with other vulnerable populations, there are specific categories that the research must fit within for the research to be approvable. Protections must be in place to avoid issues of coercion or other factors which may influence the prisoner to participate in an activity that they might otherwise find unacceptable. Federally funded research involving prisoners is subject to additional approval or certification by OHRP. If a participant in a research project that did not intend to enroll prisoners becomes a prisoner, they must either be removed from participation (if safe and appropriate) or the IRB must convene and review the research in accordance with the special provisions provided for such research.

When an IRB reviews research that intends to enroll children, the research must be categorized into one (or more) of four categories of research that are considered approvable under the regulations. The categories are based on the level of risk and prospect of direct benefit to the children among other things. The IRB must determine whether assent of children is required in addition to parental permission and how that assent will be obtained and documented. If the research includes children who are under the custody or care of the state, additional requirements and protections apply.

When an IRB reviews research that intends to enroll Adults with Impaired Decision-Making Capacity, it must consider whether the research offers the prospect of direct benefit and whether or not the research could be conducted utilizing a population that does have the capacity to provide consent. The IRB considers whether assent is possible, whether consent for ongoing participation at the time an individual regains capacity is in order, and whether provisions for ongoing consent when capacity is expected to fluctuate are necessary. The HSPP policies refer investigators to the UConn Health institutional policy for guidance on determining capacity and who may serve as a legally authorized representative.

When an IRB reviews research that intends to enroll employees or students, it pays special attention to issues of recruitment and consent to minimize the potential that a person may enroll in the research because they feel obligated or pressured to do so. Additionally, the IRB considers whether or not agreement to participate in the research, or information obtained about the employees or students obtained in the research, will be made available to those in a position of authority over the employees or students.

Some populations are inherently vulnerable to coercion or undue influence due to a lack of autonomy or ability to understand research procedures. Federal regulations outline specific requirements for conducting human research with children, prisoners, pregnant women, and cognitively impaired adults. Pregnant women need special protections in that research participation may affect their unborn child. Additional groups of participants may also be susceptible to coercion and undue influence such as students, economically or educationally disadvantaged participants. It is important to remember that inability to consent does not limit participation in a study but instead requires that additional safeguards and consent procedures are followed. In certain cases, it may be necessary to consult with experts in specialized areas on protecting vulnerable populations.

Investigators must consider whether subjects to be enrolled in their research might be vulnerable, and if so, what additional measures might be appropriate to provide additional protections. In making the latter determination, investigators should consider:

* Is inclusion of the vulnerable person or population necessary? That is, could the aims of the research be accomplished by enrolling persons or a population that is not (or less) vulnerable?
* Do prospective subjects have difficulty providing voluntary, informed consent? Are condition for informed consent satisfied? (Is information presented in an understandable manner? Do subjects comprehend the details of the research and their rights as research subjects? Is the process of consent conducive to true voluntariness?)
* The extent to which proposed participants are already burdened by poverty, illness, poor education, or chronic disabilities.
* Inconvenience to participants (i.e., the time required, travel involved, restrictions on diet, or other activities), and any discomfort, or potential embarrassment in addition to the risks associated with the research procedures.
* Whether the convenience of the researcher, or possible improvement in the quality of the research, justifies the involvement of participants who may be susceptible to pressure or who are already burdened.
* Whether it is possible to reduce pressure on certain groups of participants to participate in research (such as by consulting with a representative of the group beforehand)
* Whether the selection process overprotects vulnerable participants, such that they would be denied opportunities to participate in research.
* Whether recruitment materials and consent documents are appropriate for the population, and do not include exculpatory language

Additional resources include:

* [**2011-006.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-Pol-2011-006.0.pdf)**– Additional Protections – General (2/5/2018)**
* [**2011-006.1.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-006.1.pdf)**– Additional Protections – Pregnant Women, Fetuses or Neonates (6/9/2023)**
* [**2011-006.2.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-Pol-2011-006.2.pdf)**– Additional Protections – Prisoners (3/16/2023)**
* [**2011-006.3.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-006.3.pdf)**– Additional Protections – Children (6/15/2017)**
* [**2011-006.4.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-006.4.pdf)**– Additional Protections – Other Vulnerable Groups (6/5/2023)**
* [Form B204.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-B204PregnantWomenOrFetuses.doc) – Research Involving Pregnant Women, or Fetuses
* [Form B205.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-B205Neonates.doc) – Research Involving Neonates
* [Form B206.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-B206AfterDelivery.doc) – Research Involving Placenta or Fetal Material
* [Form B207.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-B207NotOtherwiseApprovalble.doc) – Research Involving Pregnant Women, Fetuses or Neonates not Otherwise Approvable
* [Form C.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-C-ProtectionsForPrisoners.doc) – Protections for Prisoners
* [Form D.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-D-Children-In-Research.doc)– Additional Protections for Children Involved as Subjects in Research
* [Form S.doc](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Form-VP-S-ProtectionsForSpecialClassesOfSubjects.doc)– Protections for Other Vulnerable Groups

# Section 7: Compliance with HSPP policies

The protection of human subjects participating in research is a shared responsibility between the research community and the institution. The policies and procedures of the HSPP ensure that UConn Health acts responsibly, ethically, and in compliance with federal, state, and local regulations. Below are some requirements that you should be aware of related to this responsibility.

* All research with human subjects must obtain IRB review and approval or a determination of exemption before work can begin (typically, research may be granted exempt status by the HSPP if all research activities involve procedures listed in one or more of the specific categories under 45 CFR 46.101(b): [**Exemptions (2018 Requirements) | HHS.gov**)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html). **HSPP staff or IRB members determine whether research is exempt from IRB review; investigators may not make their own exemption determinations.**
* IRB disapproval decisions may be appealed to the IRB but cannot be overruled by any other institutional official or organization. There is an appeal process when an investigator disagrees with an IRB decision. See [HSPP Appeals Process Policy](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Pol-2011-009.8.pdf)
* The requirements of the IRB (i.e., initial review, continuing review, modifications, and reporting of serious adverse events and unanticipated problems) must be followed and the investigator must follow the protocol approved by the IRB.
* The UConn Health HSPP requires all **investigators to submit an annual administrative check-in report on all non-exempt research that does not require continuing review**.
* All proposed changes to the research, no matter how minor, must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazard to participants.
* Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, continuing review applications, etc.).
* Report Noncompliance to the IRB within 5 working days (this topic will be discussed in greater detail in Section 8: Reporting to the IRB)
* Maintain research records in review-ready state at all times for [HSPP Monitoring Program](https://ovpr.uchc.edu/services/rics/hspp/monitoring/) (Quality Assurance): [HSPP Policy Monitoring of IRB Approved Studies](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Pol-2009-005.0.pdf)

When policy changes or updates occur, the HSPP disseminates the information to the research community through Broadcast Messages, listserv messages, IRIS notifications, Brown Bag training sessions and HSPP newsletters.

# Section 8: Reporting to the IRB

Investigators are required to report certain events that occur during the conduct of a study to the IRB. Report any of the events listed below to the IRB within five (5) working days of the research staff having knowledge of the event through a Problem Report Form submitted via the electronic system (IRIS).

If you are unsure whether an event needs to be reported to the IRB or not, please contact your IRB Coordinator (Patty Gneiting or Steve MacKinnon) for a consultation.

1. **Harm**: Any harm experienced by a subject or other individual, which in the opinion of the investigator is unexpected and probably related to the research procedures. Example: Serious adverse event or **unanticipated problem**
2. **Risk**: Information that indicates a new or increased risk or a new safety issue. For example: safety monitoring report, drug or device changes, interim analysis, or investigator finding.
3. **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
4. **Audit**: Audit, inspection, or inquiry by a **federal agency or government agency**. (Report within 15 days if includes findings or corrective actions)
5. **Report**: Written reports of study monitors or DSMB Reports (within 15 days if includes findings or corrective actions).
6. **Deviation (researcher error):** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
7. **Confidentiality:** Breach of confidentiality.
8. **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
9. **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
10. **Complaint:** Complaint of a subject that cannot be resolved by the research team.
11. **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
12. **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by or associated with a device.

**What is an Unanticipated Problem?**

At a high-level, the term “**unanticipated problems involving risks to subjects or others**” or UAPs refers to any incident, experience, outcome, or new information that:

* Is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol‐related documents, such as the IRB‐approved research protocol and consent documents; and the characteristics of the subject population being studied,
* Is related or possibly related to participation in the research, and
* Indicates that subjects or others are at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

UAPs may be individual events or a series or trend in events. Due to the newly recognized increased risk of harm, UAPs almost always result in a change to the protocol and/or consent form that must be submitted as a modification to the IRB.

PIs are to report to the IRB any occurrence that may be an unanticipated problem within 5 business days

of becoming aware of the event. An occurrence that may constitute an unanticipated problem is to be

reported even if detected after a subject withdraws from a study, after a subject has completed the study

intervention, or for up to 30 days after study completion.

In contrast, **adverse events (AEs)** are defined as any untoward physical or psychological occurrence in a human subject participating in research. An AE can be any unfavorable or unintended event including abnormal laboratory finding, symptom or disease associated in time with the research or the use of an investigational test article.

The IRB will not review external adverse events (e.g. individual adverse event reports, IND safety

reports, MedWatch reports, line listings of suspected unexpected serious adverse reactions (SUSARS)

etc.) unless:

* 1. the sponsor has deemed the event(s) to be an unanticipated problem that:
		1. has been reported to the FDA **and**
		2. that requires that corrective measures be taken; or
	2. unless the UConn Health PI disagrees with the sponsor and believes the event is an unanticipated problem and recommends corrective actions.

The IRB will not review internal expected adverse events that are already disclosed in the informed

consent form unless the PI states that the severity or frequency of the event(s) has been greater than anticipated.

The PI is to complete the Problem Report Form (PRF) found within the electronic IRB submission

system for reporting to the IRB. The PRF addresses all information that is required for submission. If

the PI proposes a corrective action that will require a change to the protocol or study related documents,

the PI must submit a request for modification form.

* [**2009-001.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2009-001.0.pdf)**– Reporting Unanticipated Problems to the Institutional Review Board**
* [**2009-002.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2009-002.0.pdf)**– Reporting Non-Compliance to the Institutional Review Board**uestions about Reporting to the IRB

## Section 9: Obtaining and Documenting Informed Consent

Informed consent is one of the primary ethical requirements underpinning research involving humans; it reflects the basic principle of respect for persons. It should always be remembered that informed consent is **not simply providing a document** to a potential participant. Informed consent is an **ongoing process, not a single event**, designed to provide potential research subjects with all of the relevant information they need to make a fully informed, autonomous decision as to whether they wish to participate in a research study. Informed consent requires full disclosure of the nature of the research, the participant’s role in that research, an understanding of that role by the potential participant, and the participant’s voluntary choice to join the study. In general, at UConn Health, informed consent is to be documented by the use of a written consent document, approved by the IRB, and signed (including in an electronic format) by the subject or the subject’s legally authorized representative **and** the person obtaining consent. A copy of the consent form should be given to the person signing the informed consent document. For more information on obtaining and documenting informed consent, please review [**Informed Consent FAQs | HHS.gov**](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#:%7E:text=Informed%20Consent%20FAQs%20What%20is%20informed%20consent%20and,What%20are%20the%20basic%20elements%20of%20informed%20consent%3F)

* Investigators are responsible for obtaining and documenting informed consent before the research begins unless the IRB waives this requirement.
* Informed consent must be conveyed in language that is understandable to participants or their legally authorized representative.
* Subjects must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate
* Consent must be sought under circumstances that minimize potential for coercion or undue influence.
* Time for questioning between the initial request for participation and the final decision of the participant should be allowed.
* It must be made clear to participants that their participation is voluntary and that they may withdraw at any time with no penalty.
* Consent is documented by use of a consent form approved by an IRB unless a [**waiver of informed consent**](https://vpr.tamu.edu/wp-content/uploads/2021/10/HRP-410-CHECKLIST-Waiver-or-Alteration-of-Consent-Process_2018.pdf) or a [**waiver of documentation of informed consent**](https://vpr.tamu.edu/wp-content/uploads/2021/10/HRP-411-CHECKLIST-Waiver-of-Written-Documentation-of-Consent.pdf) is granted.
* The Common Rule (45 CFR 46.116 (a)) requires that the informed consent document include the following basic elements:
	+ A statement that the study involves research;
	+ Information on the purpose of the research;
	+ The expected duration of subject participation;
	+ A description of the procedures (identification of experimental procedures);
	+ A description of reasonably foreseeable risks or discomforts;
	+ A description of any benefits to subjects or others;
	+ Disclosure of appropriate alternative treatments/procedures, if the research involves clinical treatment;
	+ A description of procedures related to compensation for injury, if the research is more than minimal risk;
	+ Contact information for the PI and IRB;
	+ A statement that participation is voluntary and that the subject may withdraw at any time with no penalty or loss of benefits;
	+ A description of how the confidentiality of records will be maintained; and
	+ Either:
		- A statement that identifiers may be removed from identifiable private information/biospecimens and that, after removal, the information/biospecimens could be used for future research studies or distributed to another investigator without additional informed consent (if this is a possibility); or
		- A statement that the information/biospecimens collected as part of the research, even if identifiers are removed, will not be used/distributed for future research.
* The participant (or their legally authorized representative) must be provided with a copy of the consent document at the time of consent unless this requirement is waived by the IRB. (\*UConn Health requires the subject/LAR receive a signed copy of the consent.)
* Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (six years if an authorization to use or disclose protected health information is involved) or longer if required by the institution or research sponsor.
* [**2011-008.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-CR-Pol-2011-008.0.pdf)**– Informed Consent – Forms (3/16/2023)**
* [**2011-008.1.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-CR-Pol-2011-008.1.pdf)**– Informed Consent – Process (6/9/2023)**
* [**2011-008.2.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-CR-Pol-2011-008.2.pdf)**– Informed Consent – Waivers and Alterations (1/22/2024)**
* [**2011-008.3 .pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-008.3.pdf)**– Informed Consent – Assent (5/1/2017)**
* [**2011-008.4 .pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-CR-Pol-2011-008.4.pdf)**– Informed Consent – Short Form (11/20/2023)**
* [**2011-008.5.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2018/02/HSPP-CR-Pol-2011-008.5.pdf)**– Informed Consent – Providing and Obtaining Informed Consent (6/5/2023)**

## Section 10: Conflict of Interest Disclosure

A **conflict of interest (COI)** occurs when an individual’s private interests compete with his/her professional obligations to the system to a degree that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. Investigators and IRB members have a responsibility to identify and manage, reduce or eliminate conflicts of interest that may arise due to financial or other personal interests.

**What is the COI review process at UConn Health?**

The Principal Investigator and each member of the research team complete Significant Financial Interest disclosure statements at the time of initial and continuing review. Any SFIs will be recorded on the IRB Project-Specific Disclosure of SFI Form and submitted to the Financial COI Committee and identified on the submission form to the IRB.

The Financial COI Committee will review the disclosure, the research protocol and the roles and responsibilities of the individual with the disclosed interest in the performance of the research. The Financial COI Committee will determine whether the interest does represent a COI, whether the COI requires management and disclosure, and, when applicable, will determine the Conflict Management Plan. The Financial COI Committee will return the signed form, and if applicable, the management plan to the PI who will include the documents in the IRB submission.

The IRB reviews the report and may accept the management plan as written or require additional steps to manage or resolve the conflict in order to ensure the protection of human subjects. The IRB may not lessen or weaken the CMP but may add on to it or disapprove the research or the participation of the individual with the COI if the IRB determines that the COI may not be sufficiently managed. If disclosure to potential subjects is required, the IRB will determine the form, detail, and extent of the required disclosure. If a COI exists, final IRB approval cannot be given until an approved management plan is in place or determined to be unnecessary.

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate an investigator’s FCOI include, but are not limited to:

1. For research projects involving human subjects, disclosure of the FCOI to the participants;
2. Appointment of an independent monitor capable of taking measures to protect the design, conduct and reporting of research against bias resulting from the FCOI;
3. Modification of the research plan or research activities;
4. Requiring a change in personnel and/or responsibilities for all or a portion of the research activities;
5. Disqualification of personnel from participation in that portion of the research activities that would be affected by the FCOI;
6. Reduction or elimination of the financial interest (e.g., sale of an equity interest); and
7. Severance of relationships that create an FCOI.
* [**2011-012.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-012.0.pdf)**– Conflict of Interest – Research Personnel**

## Section 11: Principal Investigator Responsibilities

The Principal Investigator (PI) plays a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. The PI has the ultimate responsibility for the conduct of the research study. This includes following the study protocol, keeping the study up-to-date with modifications and continuing reviews and ensuring that the research team has adequate training and resources to conduct the study safely and properly. The PI also holds the responsibility for the following aspects:

* Obtain IRB approval prior to initiating Human Research activities.
* Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
* Ensure that Research Staff are qualified (e.g., including but not limited to appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.
* The Principal Investigator is always held accountable for the actions of the study staff. This responsibility cannot be delegated or explained away. The PI must personally conduct or supervise the Human Research.
	1. Conduct the Human Research in accordance with the relevant current protocol as approved by the IRB, and in accordance with applicable federal regulations and local laws.
	2. When required by the IRB ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
	3. Do not deviate or modify the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
	4. Protect the rights, safety, and welfare of subjects involved in the research. e. Submit to the IRB:
* Submit all **Problem Report Form** the IRB within five (5) working days of the research staff having knowledge of the event being reported.
* Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

For a list of additional investigator obligations, please visit the policy

 [**2011-011.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPP-CR-Pol-2011-011.0ResearchPersonnell.pdf)**– Research Personnel**

## Section 12: Education

All members of the research team involved in the design, conduct or reporting of the research must complete human research protections training. At a minimum, all researchers and staff must complete courses from the Collaborative Institutional Training Institute (CITI), a web-based ethics training program for those conducting or reviewing research with human subjects. Other courses may be required depending on the type of research being conducted. For instance, investigators using FDA regulated test articles are required to complete Good Clinical Practice. UConn Health requires employees complete COI and HIPAA training at regular intervals via the SABA training platform. Investigators and staff performing clinical trials are required to have current (within 3 years) training in Good Clinical Practices (GCP), this requirement can be fulfilled through modules available on CITI or through training provided by sponsors or others that results in a certificate.

**What training or basic educational requirements are required of investigators and IRB members?**

Researchers and their staff complete UConn Health - specified CITI training modules every three years. Alternative trainings may be accepted on a case by case basis by the Director. Completion of human research protections training by key study personnel is checked by the IRB at the time of initial review and when new key personnel are added to the study team. Members of the research team who have not completed human research protections training may not take part in research that involves human subjects.

UConn Health requires investigators acting as a PI at UConn Health for the first time to complete First Time PI Training with the Education Specialist to ensure the PI is familiar with HSPP policies. New IRB members have an orientation session with the HSPP Education Specialist, are required to complete web-based training in IRB review through CITI, observe a minimum of six IRB meetings before conducting a review. Existing members and HSPP/IRB staff are expected to maintain current CITI training (every 3 years) or fulfill their ongoing training requirements through attendance at conferences (e.g., PRIM&R, OHRP) or other approved educational sessions.

The UConn Health HSPP also offers in-person educational sessions for researchers, students, and staff. Investigators may request an individual or group meeting, or schedule a class lecture, to receive additional education and training in research ethics and issues related to human research protections. Monthly Brown Bag sessions are open to the UConn Health community.

The HSPP Educator participates in an annual lecture series for the medical school students regarding IRB basics. In addition, hosts monthly seminars with research community on a wide range of research topics as well as updates on policy and process changes. The HSPP Educator conducts regular training sessions on other topics for departments and for the residents, and provides individual education on the use of IRIS, the development of submissions to the IRBs, and on regulatory and UConn Health requirements.

The HSPP Educator may also attend IRB meetings to provide education on topics relevant to research on the agenda for review, IRB review & documentation, federal regulations and guidance or policy updates.

The HSPP provides funds for HSPP/IRB staff to attend annual conferences on human research protections, such as those hosted by PRIM&R, OHRP, SoCRA, or ACRP.

## Section 13: Quality Assurance / Monitoring Program

The purpose of the Monitoring Program for Human Subjects Research is to provide a systematic, internal process that will increase compliance with federal, state and institutional requirements, and promote human subjects protections through the ethical conduct of research. The objectives of the program is to provide UConn Health Investigators and the IRB with:

1. an internal mechanism for quality assurance, quality improvement and education in human subjects research.
2. practical support in the conduct of human subjects research which optimizes compliance with Federal regulations, institutional policies, and the provisions of IRB-approved protocols.

All studies, including those determined to qualify for exempt status and those for which IRB oversight has been deferred, are subject to audit by the Research Compliance Monitor. The majority of studies will be randomly selected however, consideration may also be given to:

* higher risk studies
* investigator-initiated protocols
* vulnerable populations, including studies with subjects who include: UCHC employees and students, terminally-ill and decisionally-impaired, or identified in 45CFR46 subparts C and D, pregnant women/fetuses/neonates, prisoners, and children.
* potential for conflict of interest
* “for cause” interests of the IRB or HSPP

Investigators are expected to cooperate in all aspects of the audit process, including but not limited to,

scheduling audit visits, providing necessary information and space for the audit to occur, and responding

to audit letters. Cooperation is expected for both internal and external audits.

The functions of the RCM include, but are not limited to, ensuring that

* studies are being conducted in compliance with the approved protocol and supporting documents
* appropriate forms are being used
* consent is being appropriately obtained and documented
* modifications are receiving approval prior to implementation
* financial interests are being appropriately disclosed and when applicable managed
* unanticipated problems and non-compliance are being reported per policy
* data are being recorded accurately
* drug and device inventory is accurate
* study functions have been appropriately delegated
* HIPAA is appropriately addressed, and
* procedures for safety monitoring and to protect privacy and confidentiality are being followed.

The RCM may observe the consent process and the conduct of the research. The RCM also audits the IRB review process to ensure that the IRB has performed its duties in accordance with regulatory requirements and internal policies. The RCM may also provide educational services to study personnel.

The policy and procedures related to the audit program are set forth in policy 2009-005.0.pdf titled [Monitoring of IRB Approved Studies](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2015/08/HSPO-Pol-2009-005.0.pdf).

## Section 14: Single IRB for Multi-Site or Cooperative Research

The Revised Common Rule requires that all sites located in the United States participating in cooperative research conducted or supported by a Federal department or agency must rely upon approval by a **single IRB** for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research, or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

 The following research is not subject to this provision:

1. Cooperative research for which more than single IRB review is required by law

(including tribal law passed by the official governing body of an American Indian or

Alaska Native tribe); or

1. Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.
2. For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another IRB, or make similar arrangements for avoiding duplication of effort.

 The UConn Health HSPP does not intend to be the IRB of Record for federally-funded multisite research.

The HSPP Director or IO signs reliance agreements. Researchers requesting the UConn Health IRB rely on an external IRB are advised to consult the UConn Health HSPP prior to entering into any arrangement with a collaborating institution(s) or any external IRB and must submit a request for Facilitated Review in IRIS.

## Section 15: FDA Regulated Research

The Food and Drug Administration (FDA) regulates research that involves food, dietary supplements, drugs, medical devices as well as electronic products to ensure that the data collected from these investigations was done so in an ethical, compliant, and sound manner before any product developed from the research is marketed and readily available to anyone.

The FDA uses the term “Clinical Investigation” instead of “research”. This is different than the standard human subject regulations, also known as the Common Rule. A Clinical Investigation involves any experiment that involves a test article and one or more human subjects.

* The FDA defines a **tests article** as any drug, food and color additive, biological product, electronic product, and medical device intended for human use.
* The FDA defines a human subject as “*an individual who is or becomes a participant in research, either as a recipient of a test article or control. A subject may be either a healthy human or a patient*.” Notice that there is no mention of intervention or interaction or identifiable data, for that matter. That is because the FDA definition of a human subject is much broader than that found in the Common Rule. For example, if you are using non-identifiable human blood to test a new diagnostic assay or test, that is a human subject according to the FDA.

When an investigator is intending to develop a test article (such as a drug, device, or biologic) to cure, treat, mitigate, diagnose, or prevent disease in humans, it is important that the investigator reach out to the HSPP to obtain additional guidance and instructions on how proceed.

* The FDA defines a **drug**, in part, as “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and any “substance (other than food) intended to affect the structure or any function of the body of man or other animals.”

The FDA defines a **medical device,** in part**,** as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory” “or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

Additional regulations apply to FDA regulated research involving drugs and devices such as:

* [**Investigational New Drug Application (21 CFR Part 312)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=0d59470d8438703d8924ae3e7069dd87&mc=true&node=pt21.5.312&rgn=div5)
* [**Investigational Device Exemptions (21 CFR Part 812)**](https://www.ecfr.gov/cgi-bin/text-idx?SID=2709c96092dbc468b0b3e44d4b6d0f5e&mc=true&node=pt21.8.812&rgn=div5)

When a UConn Health faculty member is also the sponsor of an IND or IDE they must contact the HSPP to arrange an audit prior to submission of an IRB application that proposes to use the IND/IDE as the results of the audit become part of the application. The purpose of this audit is to ensure that the sponsor of the IND is aware of the additional obligations of the sponsor and to ensure that proper procedure will be followed for the manufacture, use, storage, and accountability of the investigational article.

## Section 16: Response Plan for Emergencies-Disaster Impacting the HSPP

The HSPP has an emergency preparedness and response plan that addresses how continuity of operations will be maintained to ensure human participant protections during an emergency. The plan is enacted when an emergency or disaster situation impacting the HSPP has occurred, or in preparation for scenarios where a potential emergency situation is imminent (e.g., natural disaster, man-made disaster, infectious disease pandemic, etc.) and HSPP operations and/or the ability of investigators to conduct Human Research is, or is likely to be, adversely impacted. In such instances, the HSPP leadership will defer to designated institutional leadership and institution-wide disaster and emergency response planning, and limit HSPP-specific disaster and emergency response planning only to those areas of operations or human research protections not otherwise covered by institution-level plans. Investigators will be notified by the HSPP of any additional measures the IRB will take to maximize regulatory flexibility during the emergency/disaster, and issue guidance on developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator’s ability ensure the ongoing safety of research subjects.

**The UConn Health HSPP ran a simulated test of the Emergency Plan and provided education to the research community regarding this plan through a Brown Bag session in January 2024.**

[**2023-035.0.pdf**](https://ovpr.uchc.edu/wp-content/uploads/sites/2568/2023/06/HSPP-CR-Pol-Emergency-Preparedness-2023-035.0.pdf)**–  HSPP Emergency Preparedness Plan (6/12/2023)**

## Section 17: The IRB Submission System - iRIS

[iRIS](https://imedris.uchc.edu/) is the electronic system used by research personnel and the Institutional Review Board (IRB) for the submission and review of research projects that will involve human participants.  Individuals who need to use iRIS are strongly encouraged to review iRIS training materials before using the systemfor the first time.  Individual training may be available; contact the HSPP at irb@uchc.edu  to request a session.

Individuals affiliated with UConn Health can log in with their UConn Health username and password.

Per vendor requirements, training guides may not be posted to the web.  User manuals can be found in the Help section of [iRIS](https://imedris.uchc.edu/%22%20%5Ct%20%22_blank).

Answers to frequently asked questions about iRIS can be found on the [HSPP website](https://ovpr.uchc.edu/services/rics/hspp/iris/)