HUMAN SUBJECTS PROTECTION Program

# mission / purpose

The mission of the Human Subjects Protection Program (HSPP) is to ensure that the rights and welfare of those who participate in research studies are protected. This mission is carried out through the functioning and effective oversight of the Scientific Review Committee, Institutional Review Board Panels and Regulatory Specialists, Research Compliance Monitor, Educational and Development Specialist, and research personnel; and through effective communication with related departments and committees. These functions ensure that studies are being conducted in accordance with the ethical principles of autonomy, beneficence and justice (the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/)), and in compliance with [internal policies](http://research.uchc.edu/rcs/hspp/policies/) and applicable Federal regulation.

**SCOPE AND Definitions**

**Scope:**  
Human subject research is an activity that meets either the DHHS definitions of research and human subject or the FDA definitions of clinical investigation and human subject. The HSPP and the IRB will oversee research (biomedical and/or social and behavioral) involving human subjects when UConn Health is engaged in the research activity; for example when UConn Health employees, students or agents do the following for a research purpose:

1. intervene with living individuals by performing invasive or non-invasive procedures
2. intervene with living individuals by manipulating the environment
3. interact with living individuals
4. obtain individually identifiable private information
5. obtain, receive, or possess private information that is individually identifiable for the purposes of maintaining statistical centers for multi-site collaborative research
6. maintain operations center or coordinating centers for multi-site collaborative research,
7. use human tissue to test the safety or effectiveness of a device;
8. or when UConn Health receive a direct HHS award, or other type of award, to conduct human subject research

**Applicable Regulations:**

Applicable regulations with which the Human Subjects Protection Program will comply include, but are not limited to, the following:

* 45 CFR 46– Protection of Human Subjects (DHHS)
* 21 CFR 50 – Protection of Human Subjects (FDA)
* 21 CFR 56 – Institutional Review Boards (FDA)
* 45 CFR 164 – Health Insurance Portability and Accountability Act

The DHHS regulation noted above is applied to federally-funded or supported research that meets the definitions of human subject and research as defined in 45 CFR 46. When research is not federally funded or supported and meets the definition of research and human subject as defined in 45 CFR 46, the IRB will use subpart A of the regulation as guidance in determining whether to approve the research. However, when the research is not federally funded, and not subject to FDA oversight, the IRB reserves the right to allow for flexibility in the criteria for approval providing the ethical principles of autonomy, beneficence and justice are addressed. The IRB also reserves the right to apply some or all of the additional protections described in Subpart B( pregnant women), Subpart C (prisoners) and/or subpart D (children) described in 45 CFR 46 to non-federally funded research. The FDA regulations apply when the definition of clinical investigation and human subject set forth in 21 CFR 56 are met and the research involves the use of biologics or drugs (except the use of a marketed drug in the course of medical practice), or is conducted to determine the safety or effectiveness of a device or for which data will be submitted to or held for FDA inspection as part of a marketing permit. The HIPAA regulation applies when identifiable protected health information as defined at 45 CFR 164 will be used.

**Definitions**

Definitions related to human subject research are found in HSPP Policy 2011-007.0.

# Goals and Objective

The HSPP will achieve its mission by fulfilling the following goals and objectives:

1. Providing effective oversight of the Scientific Review Committee, Institutional Review Board Panels and Regulatory Specialists, Research Compliance Monitor and the Educational and Development Specialist
   1. ensuring adequate institutional support for the HSPP functions, including support for on-going education of committee members and staff
   2. evaluating the performance of areas and acting to improve when necessary
2. Ensuring effective communication between the HSPP committees and related department and committees;
   1. HSPP Executive Council with various representation
   2. coordinated application process with Clinical Research Center
   3. ancillary approvals incorporated into IRB submission process
3. Ensuring that investigators and study personnel are knowledgeable of internal policies, federal regulations and the ethical principles that govern human subject research;
   1. effective communication between HSPP and investigators
   2. education of investigators and study personnel
4. Ensuring effective communication between the HSPP / IRB and affiliated IRBs with which an IRB Reliance Agreement has been established..
   1. establish IRB Reliance agreements
   2. ensure there is an effective process for sharing of information between IRBs
   3. educate investigators about their responsibilities when utilizing an external IRB

# oversight responsibilities

The mission of the Human Subjects Protection Program is the protection of the rights and welfare of volunteer research subjects. Through oversight of the following areas the Director of the HSPP will ensure the mission is being fulfilled:

* Scientific Review Committee  
  The purpose of the Scientific Review Committee (SRC) is to ensure that the scientific question being asked has societal or individual significance and that the design of a study is appropriate to answer that question, thereby ensuring that subjects will not be exposed to unnecessary risk. The Scientific Review Committee acts in an advisory capacity to the IRB. The specifics of how the SRC operates and interacts with the IRB are found in Policy   
  2011-016.0.
* Institutional Review Boards  
  The purpose of the Institutional Review Board (IRB) is to review protocols to ensure that the ethical principles of the Belmont Report are incorporated into the study design, and that applicable criteria for approval have been met (e.g. that the proposed research activities include no unnecessary risks, that potential risks to subjects are minimized, and that overall potential benefit to the subject, or to society, is reasonable in relation to the risks). The IRB also considers the importance and significance of the scientific knowledge potentially gained against risks to study subjects. Information relating to how the IRB conducts its reviews and the materials that are required for submission are found in the following policies:
  1. Policy 2011-009.1 - Institutional Review Board - Submission of Materials
  2. Policy 2011-009.2 - Institutional Review Board – Exemptions
  3. Policy 2011-009.3 - Institutional Review Board - Expedited Reviews
  4. Policy 2011-009.4 - Institutional Review Board – Convened Meeting Operations
  5. Policy 2011-009.5 - Institutional Review Board – Review by Convened Board
  6. Policy 2011-006.0 – Additional Protections for Certain Populations – General

Additional IRB policies are posted on the HSPP web site.

* Educational and Development Specialist  
  The Educational and Development Specialist is charged with developing educational offerings for research personnel, study participants, and IRB members and also with coordinating sessions to be provided by external speakers. Policy 2011-023.0 discusses how the Educational Specialist interacts with study personnel and IRB members.
* Research Compliance Monitor  
  The Research Compliance Monitor (RCM) is charged with implementing the [Compliance Monitoring Program](http://hspo.uchc.edu/monitoring/index.html). The purpose of this program is to provide a systematic, internal process that will increase compliance with federal, state and institutional requirements, and also ensure that research is conducted in accordance with the approved protocol and the ethical principles set forth in the Belmont Report. Policy 2009-005.0 discusses how the Research Compliance Monitor interacts with the IRB and research personnel.

Institutional policies 2002-42, Review and Approval of Research Involving Human Subjects and 2004-02, Authority of the Human Subjects Protection Office commit the institution to carrying our research in accordance with internal policies, federal regulations and the ethical principles set forth in the Belmont Report. Policy 2004-02 also charges the Director of the Human Subjects Protection Program with the responsibility to ensure the HSPP has adequate resources to operate, conduct reviews, conduct audits, and provide educational opportunities; and to advise the Institutional Official of any resource needs.

The following procedures will be implemented annually to assess the effectiveness of the HSPP.

**Assessment of Resources**

On an annual basis, corresponding with the budget preparation cycles, the HSPP will assess its operations to determine if additional resources are required in terms of supplies, education, staff, and / or equipment. The HSPP will also take into consideration whether there were any activities, supplies or equipment that were previously forgone due to lack of resources.

**Assessment of HSPP Performance**

On an annual basis the HSPP will review a number of criteria in order to assess its overall performance. This assessment will also be used to determine if additional resources are required and when necessary to take action to improve performance. Criteria to be used in the evaluation include the following:

* the number of new full board studies reviewed be each IRB panel within a year in order to assess whether there is an unbalanced distribution of work between the panels that should be addressed, whether an additional panel is needed due to the volume of work; or whether additional expertise is needed in a certain therapeutic area.
* the findings of the audits conducted by the research compliance monitor to determine if there are common areas of non-compliance that could be improved upon with education, clarification of policy or development of new policies
* the performance evaluations of IRB members which consider contribution to discussion, attendance, thoroughness of review, and volume of work reviewed
* the nature, number and outcome of subject complaints to determine if proper action was taken or if improvements can be made
* the nature, number and outcome of investigator complaints to determine if proper action was taken or if improvements can be made
* the educational opportunities which HSPP and IRB members and staff attended throughout the year and whether opportunities were foregone due to lack of funding
* feedback regarding the educational activities conducted or sponsored by the HSPP for IRB staff , IRB members, research personnel and participants
* plans and methods for enhancing the understanding of participants, prospective participants and communities
* evaluation of outreach activities based on feedback provided by participants

# related departments and committees

The Human Subjects Protection Program will ensure that there is effective communication between the components of the HSPP and the following related departments and committees:

1. Institutional Biosafety Committee  
Investigators must obtain approval from the Institutional Biosafety Committee (IBC) prior to seeking IRB approval for research studies that deal with recombinant DNA. The IRB submission checklists requires that proof of approval from the IBC be submitted to the IRB as part of a request for initial approval.

2. Office of Research Safety  
Investigators proposing a research study that will use ionizing radiation, non-ionizing radiation, biological material, or hazardous chemicals must obtain a Risk Assessment Report (RAR) from the Office of Research Safety (ORS) as part of the IRB application process. The IRB application solicits information about the use of such materials and directs the PI to obtain the RAR; and the IRB submission checklists requires that the RAR be submitted with the request for initial review by the IRB.

3. Clinical Trials Office  
Investigators proposing a research study that is sponsored by an external source, typically an industry-sponsor, must have a fully executed contract in place prior to study initiation. If the sponsor is providing for subject injury, the IRB must receive the fully executed contract prior to granting final IRB approval. As applicable, any study generating research charges must also have a budget approved by the CTO prior to submission to the IRB for approval. The IRB submission checklist instructs the PI to include in the submission to the IRB proof of review for budget workbooks and also notes that a fully executed contract must be submitted prior to final approval being granted. If a fully executed contract is not available at the time of initial review and the contract contains subject injury language, approval may be granted contingent upon a fully executed contract with the subject injury language in the contract being consistent with the consent form. The IRB Chair (or designated member), reviews the documents for consistency prior to granting final approval.

4. Office of Research Administration and Finance  
Investigators proposing a study that is grant supported or funded by a private non-profit agency need to route the proposal through the Sponsored Programs. When required by regulation, the IRB must review all funded applications. The IRB submission checklist requires that the PI submit the grant proposal in addition to the routing sheet signed by the Sponsored Programs. Sponsored Programs will then ensure, through receipt of the IRB approval letter, that IRB approval is in place prior to release of funds.

5. Conflict of Interest Committee (CIC)  
On an annual basis all investigators are required to disclose financial interests to appropriate personnel within the Office of the Vice President for Research (OVPR).. Personnel within the OVPR will determine if a significant financial interest exists. If so, the personnel within the OVPR will refer information to the CIC. The CIC will determine whether the interest creates a conflict that must be managed. If so, the management plan may require such actions as the investigator disclosing the financial interests to research subjects, independent monitoring of the data, or restrictions on certain types of involvement (e.g. the consenting of subjects may not be allowed). Personnel within the OVPR who support the CIC will provide the IRB with copies of such plans.

Investigators must also disclose financial, professional and/or personal interests on a study specific basis at the time of initial review, and at continuing review when continuing review is a requirement. Disclosures are captured on the IRB Project Specific Disclosure form. This form is routed to designated personnel within the OVPR to for review and sign-off. When a disclosure is made, if a management plan or determination that a plan is not needed is not already on file, personnel within the OVPR will forward the information for review by the CIC. The outcome of the CIC review (i.e. management plan or determination that one is not required) will then be incorporated into the IRB submission. This ensures 1) that any conflict of interest is being addressed in accordance with the management plan and 2) that any new conflicts that develop during the course of the year are addressed. The IRB retains the right to require management strategies in addition to those imposed by the CIC and makes the final determination as to whether the conflict can be sufficiently managed to allow for approval of the research without affecting subject protections.

6. Pharmacy

The IRB application solicits information regarding the use of drugs in research projects. For all studies that use drugs, the Research Pharmacist (or designee) must review the information to determine the plans for dosage, storage and inventory are sufficient. This review is required prior to the submission to the IRB and proof of the review must be included in the submission packet. Investigators are informed of this requirement on the IRB submission checklist as well as through instructions on the IRB application form.

7. Human Subjects Protection Office Executive Council  
This committee acts as an advisory board to the Director of the Human Subjects Protection Office. The committee discusses policies, regulations and issues related to human subject protections. . Committee membership includes representation from the IRB, the School of Medicine and the School of Dental Medicine. The Director of the HSPP determines when a committee meeting is necessary.

8. Human Resources   
The Search Request form to hire personnel incorporates a question as to whether a new hire will be involved with either the administration or conduct of human subject research. HR generates a bi-weekly report for the HSPP such that HSPP staff can proactively inform employees of training requirements and invite attendance at educational workshops.

9. Information Technology  
Investigators requesting information from the patient data system must do so through information technology through a Patient Data Request form. Such requests are disseminated to a distribution list of areas that may have oversight of/interest in such requests. A designated member(s) of the HSPP/IRB staff receive all such requests and when applicable comment as to whether the request is consistent with the IRB approved protocol such that data can be released. Investigators intending to use mobile apps for collection of protected health information must provide confirmation that I.T. has determined that the app has appropriate security measures in place.

***SCIENTIFIC REVIEW COMMITTEE***

*A Committee of the Human Subjects Protection Program*

*Advisory to the Institutional Review Board Panels*

**Purpose**

The purpose of the Scientific Review Committee (SRC) is to enhance subject protection through thorough review of proposed protocols to ensure the scientific question being asked is relevant and that the study design is appropriate to answer that question.

**Goals and Objectives**

The primary goal and objectives of the SRC are to provide, the Human Subjects Protection Program and the Institutional Review Boards with the following:

1. A thorough scientific review of proposed protocols that considers:

a. the study design

b clarity of the research question

c. appropriateness and efficiency of design

d. rigor and feasibility of methods

e. qualifications and expertise of the research team

f. scholarship and pertinence of background material and rationale

g. adequacy of sample size and relevance of controls

h. validity of the statistical analysis plan

2. A recommendation based on that review as to whether the study warrants approval.

3. The Committee comments on the proposal’s scientific significance, and may desire to comment on compelling ethical or patient safety issues.

**Structure and Operation of Committee**

1. Chaired by individual with clinical research experience

a. appointed by Director of Human Subjects Protection Program

2. Membership

a. at least 3 standing members

b. membership appointed by Director of HSPP with input from SRC Chair

c. appointments open ended

d. may call upon consultant for review if expertise is needed

3. Meeting Format

a. week prior to IRB convened meetings on an as needed basis

b. application, protocol and consent distributed for review, all material available upon request

c. meeting format may be through electronic means or in person

4. Reporting

a. two members assigned as primary reviewers

* exception for use of one reviewer is allowed if two reviewers are not available

b. consensus reached for final report to IRB

c. report provided vi e-mail to IRB staff

d. IRB staff circulate to IRB members via e-mail

5. Consultants

a. may call upon consultant

b. reviewer obtains assurance that consultant has no conflict with the study

**Selection of proposals for Review**

Review by the SRC is required of any study that will be presented to the convened IRB that has not already been reviewed by another scientific review body. The SRC will most often be conducted prior to the IRB meeting. The IRB may accept the scientific review of another body (e.g. NIH, FDA, pharmaceutical industry) or may require additional internal review by the SRC. If an investigator has not requested scientific review by the SRC and the IRB determines it is required, or in the event the SRC did not complete the review prior to the meeting, the study may be approved contingent upon a favorable report from the SRC. If any concerns relating to the criteria for approval are expressed by the SRC, the study will be referred back to the convened board.

**recommendation of scientific review committee:**

The SRC will submit a summary of their evaluation to the IRB and report their final recommendation as:

* recommend approval without revision
* recommend approval pending acceptable revision
* recommend rejection

***INSTITUTIONAL REVIEW BOARDS***

*A Committee of the Human Subjects Protection Program*

**PURPOSE**

The purpose of the UConn Health Institutional Review Board (IRB) is to ensure subject safety by thorough review of protocols to ensure that the ethical principles of the Belmont Report are incorporated into the study design and that applicable criteria for approval have been met (e.g.. that proposed research activities include no unnecessary risks, risks to subjects have been minimized , overall potential benefit to the subject, or to society, is reasonable in relation to the risks). The IRB also considers the importance and significance of the scientific knowledge potentially gained in relation to the risks to study subjects.

**Goals and Objectives**

The primary goals and objectives of the IRB are to provide the Human Subjects Protection Program with the following:

1. A mechanism for providing thorough prospective review of proposed research. Consideration will be given, but not limited, to:

a. criteria for approval as noted in applicable regulations

b. elements of informed consent

c. methods of obtaining informed consent

d. plans for recruitment

e. inclusion / exclusion criteria

f. risks and the procedures in place to minimize them

g. potential benefits

h. scientific merit of a study

2. A mechanism for providing continuing review of previously approved studies. Consideration will also be given, but not limited, to:

a. study enrollment

b. unanticipated problems

c. subjects withdrawals or complaints

d. progress report by the investigator

e. new findings or developments

**Structure and Operation of Committee**

1. Chaired by qualified individual

a. appointed by Director of Human Subjects Protection Program

b. appointment period open ended

c. possessing at least 2 years of IRB experience (at UConn Health or elsewhere)

d. internal to UConn Health

e. demonstrated ability to work in committee

f. familiar with clinical research

2. Membership

a. at least 5 standing members, at least one non-scientific and one non-affiliated

b. membership appointed by Director of HSPP with input from IRB Chairs

c. appointments open ended

d. may call upon consultant for review if expertise is needed

e. appropriate number and expertise to review volume and types of research proposed

3. Reviews

a. primary reviewer system for full board studies with at least one reviewer being scientific

b. reviewer cannot have conflict

c. d. all members informed of expedited/exempt reviews; any member may request additional review

3. Voting

a. majority of members, including non-scientific member, must be present for vote to occur

b. majority vote of those members present will carry motion

b. consultant to review process does not participate in deliberation or vote.

c. no member can vote on a study for which s/he has a vested (conflicted) interested

d. vote of IRB cannot be influenced or overturned by any institutional official

4. Meeting

a. each panel to meet once per month

b. in person preferred, teleconferencing with all parties having two way communication is acceptable

**Selection of proposals for Review**

All research/clinical investigations conducted by UConn Health employees, agents or students that involve human subjects, must be reviewed prospectively by an IRB. Studies may be reviewed under one of three categories those being Exempt, Expedited or Full Board. The IRB Chair, Vice-Chair or authorized designee makes the final determination as to the review category.

**determinations of the irb:**

No institutional official may approve a study that has not been approved by the IRB. Institutional officials may however require additional review or suspend or terminate approval granted by the IRB. The IRB may determine that

* revisions are needed prior to or after initial approval
* approval can be granted
* approval cannot be granted
* approval is to be suspended or terminated
* corrective measures (e.g. additional training) are required to address issues of non-compliance or unanticipated problems

**irb Reliance Agreements:**

Whether UConn Health is acting as the IRB for another institution or relying upon the IRB of another institution, IRB personnel will ensure that an IRB Reliance Agreement has been executed. Such agreements will outline the responsibilities for each institution.

***COMPLIANCE MONITORING PROGRAM***

*A Function of the Human Subjects Protection Program e*

**PURPOSE**

The purpose of the Compliance 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.

# Objective

The objective of the Compliance Monitoring Program for Human Subjects Research is to provide UConn Health Investigators and the HSPP with an internal mechanism for assessing compliance with Federal regulations, institutional policies, and the provisions of IRB-approved protocols.

# selection of studies

The majority of studies will be selected at random for audit. However, consideration may also be given to other factor, for example:

1. higher risk studies
2. investigator-initiated protocols
3. studies involving vulnerable populations
4. potential for conflict of interest
5. for cause interests of the IRB or HSPP

# Types of audits

1. **Random** **Scheduled** audit - This type of review is considered a full audit. The focus of the review includes roles and responsibilities of research team members, regulatory and IRB compliance, consent form elements, recruitment, eligibility and consenting process, case review for protocol adherence, source documentation and data collection, adverse events, file security, pharmacy operations and other aspects of the study.
2. **Random Unscheduled** audit – This type of review is a mini-audit to review study file for regulatory documents, protocol version in use, recent modifications, informed consent documentation, and data confidentiality and file security.
3. **Informed consent** audit - This type of audit is intended to support researchers in assuring that adequate informed consent is obtained from human subjects participating in their trials. This type of audit may include observation (when possible) of the consenting process; verification that the person consenting the subject is qualified and designated by PI; review of the consent form for signatures and dates; and the basic elements of consent according to applicable regulations.
4. **For cause** audits – This type of audit is performed when concerns regarding compliance, protocol adherence, or subject safety are brought to the attention IRB or Director of the HSPP. This type of audit may also be referred to as an IRB Directed Audit or an Emergency Audit.
5. **Web audit -** The RCM may periodically review the content of the UCHC clinical trials listing on the UCHC web site to ensure that the information posted does not exceed that allowed per FDA guidance and HSPP/IRB policy. The RCM may also audit departmental web sites to ensure compliance with recruitment policies. Recruitment audits may be incorporated into another type of audit or done as a stand-alone audit.
6. **IND/IDE Pre-Audit** – This type of audit must be requested by a PI when that PI will also be the sponsor of an IND or IDE. The purpose of the audit is to ensure that the PI is aware of the additional responsibilities of the sponsor and to ensure that manufacture and use of the test article will be in compliance with regulatory requirements. The audit must be conducted prior to submission to the IRB.

Other types of audits may occur as necessary. For example, the RCM may conduct follow-up audits to ensure corrective actions have been implemented, or audits of studies with frequent lapses in approval to ensure no research activity occurred during a lapse.

# Arranging an audit

Written notification of pending audit will be sent from the RCM. It is the responsibility of the Research Compliance Monitor to prepare the correspondence and to schedule the visit after notice has been received.

The following is an estimate of the timeframe for notification depending on the type of audit being employed:

1. **Random audits** will be scheduled in advance; however unscheduled “mini” audits may be performed without notice.
2. **Consent audits** may be scheduled by mutual convenience when it involves the observing the consenting process,.
3. **For cause audits** may be scheduled or may be unannounced. If scheduled, notice may be short (e.g. within 24 hours)

# elements of audit

**Roles and Responsibilities:**

The following items will be reviewed to understand the roles and responsibilities of the research team members:

1. identification of staff authorized by the PI to consent subjects
2. verification of the team members human subjects protection training
3. disclosure and description of gifts / payments / services from the sponsor
4. verification of status of team member as UConn Health-affiliated or other

**Regulatory Compliance**

The following items will be reviewed to assess compliance with regulatory compliance:

1. Review of IRB study related material, type of review, protocol version and IB, consent changes, availability of documents in IRB chart and study chart; and document any deficiencies.
2. Review the IRB meeting attendees (quorum, diversity, conflict of interest), adequacy of review materials, completeness of minutes to assess requirements of IRB review
3. Determine whether IRB study chart contains all correspondence / amendments and adverse reactions the investigator submitted
4. Determine whether continuation review was completed within 365 days (or more often as appropriate)

**Informed Consent Form**

This review will look at the required elements of informed consent according to applicable regulations and institutional policy to determine if the consent form meets all the requirements.

**Informed Consent Process**

This review will look at the process of informed consent including:

* The recruitment and screening process in relation to obtaining informed consent (timing).
* The appropriateness of the research team member(s) obtaining consent
* Identification of vulnerable populations and use of legally authorized representatives
* Identification of special needs of participant in understanding consent (e.g. language barrier, illiteracy, etc.)
* If applicable, review of participant comprehension forms to assess the understanding of the subject

**Subject Case Review**

This review determines protocol adherence, by determining if a study is implemented as approved by the IRB. The review will encompass, but is not limited to, the following items:

1. Participant charts:

* To determine if the approved inclusion / exclusion criteria were met
* To determine if the signed consent was the current, approved version
* To verify that data found in source documents is recorded on case reporting forms
* To determine if the study treatment is being delivered according to protocol (including dose reductions, stopping rules, etc.)
* To determine if study-related procedures / events are scheduled and performed per study calendar
* To determine if charts and data are being stored securely according to informed consent language.
* Determine if data is supported by source documentation.
* Determine if payments were made to subjects as described.

**Pharmacy Operations**

For studies with drug provided under IND or by sponsor; to review the research pharmacy procedures and accountability for ordering, inventory, dispensing, storage, security and return of study drug.

# report of audit findings

Standard Audit Results Letter

1. Prepared and signed by Research Compliance Monitor who conducted the audit with review by the DHSPP before the letter is sent.
2. Copied as indicted in HSPP policy 2009-005.0

Major protocol violations that place subjects at risk or substantive systematic deficiencies will be reported immediately to the Director of the HSPP.

An annual audit summary will be included as part of the HSPP annual evaluation. The summary will address the volume of audits conducted, types of audits conducted and any common areas of deficiencies and corrective actions taken.

***EDUCATIONAL OUTREACH***

*A Function of the Human Subjects Protection Program*

**Purpose**

The Educational and Development Specialist (EDS) is charged with developing, implementing and hosting educational opportunities for research personnel, IRB members and staff, and study participants.

**Goals and Objectives**

The primary goal of the EDS is to improve protections afforded to research participants through education of all interested parties (i.e. the IRB, research team, and participants). This goal is achieved by offering a variety of educational opportunities, including, but not limited to, the following:

1. hosting educational sessions for investigators and study personnel
2. providing instruction for accessing the on-line training program in the protection of human subjects in research (currently CITI);
3. providing information via policy changes on the HSPP website and via broadcast messages and newsletters;
4. providing information and resources for investigators via the HSPP web site;
5. providing an investigators guide to human subjects research
6. informing investigators of their responsibilities via communications from the IRB office;
7. outreach to community groups and continuing education programs

**Types of offerings / Outreach**

**Study Start-up Visits** – This type of session is held close to the time that a study is approved or approved contingent by the IRB. , The EDS will contact all study personnel via e-mail and offer an education session tailored to their specific protocol. The EDS will review with the staff 1) what would be looked for in an audit should that study be selected and 2) the plans for study conduct (e.g. plans for storage of investigational articles, plans for recruitment etc.) to ensure that all planned activity is consistent with the approved protocol, policies and regulatory requirements.

**Brown-Bag Lunch Sessions** – These sessions will be developed based on input from the research community as to their interest and needs and from the IRB staff and RCM based on common errors that are seen. The sessions will be implemented at regular time intervals so that research personnel can plan accordingly to allow for attendance.

**First Time Principal Investigator (PI) at UConn Health Center Orientation Meeting:** The purpose of the orientation meeting is to ensure that individuals acting as a PI for the first time at UConn Health are aware of IRB policies and procedures, educational opportunities, and compliance expectations.

**As Requested** – The EDS provides tailored educational sessions on human subject protections upon request.

**Student Sessions** – The EDS will work with faculty and staff of the various educational programs offered at UConn Health to provided educational sessions to students, residents, and fellows who will be conducting research. This may include sessions developed by the EDS, or the EDS teaching a component of a larger course offering (e.g. teaching one session within the responsible conduct of research course).

**IRB Sessions** – The EDS will coordinate an annual educational sessions offered to IRB members from all panels as well as to other areas related to the HSPP (e.g. members of the scientific review committee, members of the HSPP Executive council). The EDS may also present educational sessions at convened meetings.

**Community Outreach** – the EDS will conduct outreach activities to educate potential participants.

**Teaching in Course Offerings** – The EDS participates in various course offerings sponsored by other areas of the institutions, e.g. the EDS teaches a component of the Responsible Conduct of Research course as well as a session with the Study Coordinators course.

**Departmental Newsletter** – The EDS will prepare a periodic newsletter that will cover topics related to human subject research.

**System Training** - the EDS will offer training on the electronic system used for the submission and review of research protocol.

In addition to the above, the staff of the HSPP and IRB will also be available to answer questions and to provide guidance to investigators and study personnel. The HSPP and IRB may require additional educational activities of investigators who are found to be non-compliant with internal or federal policies.