

Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-025.0
Policy Title: HSPP Authority, Support and Evaluation

Purpose

The purpose of this policy is to recognize the authority granted by the institution to the Director of the HSPP (DHSPP) and also to set forth a mechanism by which the DHSPP will evaluate and if necessary secure additional resources for the department.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Human Subject	IRB Approval	Noncompliance, Continuing
Noncompliance, Serious	Suspension	Termination

Policy

Authority: Institutional policy number 2004-02 charges the DHSPP with the responsibility of protecting human subjects. As such, the DHSPP is empowered to suspend or terminate any study previously approved by the IRB or to require additional reviews. Suspension or termination may be due to serious and / or unexpected increased risks to subjects, or continuing or serious non-compliance of the investigator(s) or other factors that the DHSPP deems warrant suspension or termination. The DHSPP cannot influence the decision of the Institutional Review Board (IRB) or approve a study that has not been approved by the IRB.

The DHSPP has the authority to create, change and implement policy related to human subject protections. New policies or changes to policies may be presented to the IRB panels to solicit input from the committee members. The IRB Chairs or Vice Chairs will bring that feedback to the DHSPP. The DHSPP may elect to bring policies to the Human Subject Protection Program Executive Council (HSPPEC) for addition input. The HSPPEC meets on an ad-hoc basis and is advisory to the DHSPP. The DHSPP has the final authority on departmental policies.

At the discretion of the DHSPP, input may also be sought from those parties that would be affected by the policy.

Institutional level policies related to human subject protections will be presented to the Executive Policy Committee by the DHSPP or a designated staff representative for review, approval, and implementation.

Institutional Support: The institution provides support to the HSPP, the IRB members and the IRB staff in terms of staffing, office space and operating budgets, including educational opportunities. The DHSPP or designee presents the needs of the HSPP to the budget office on an annual basis corresponding with the budget cycle. If necessary the DHSPP may make appeals to the Institutional Official in efforts to secure additional resources.

Procedure

The DHSPP or designee will periodically review all HSPP / IRB policies. Such review will include an assessment of the accuracy and relevancy of the policies, (e.g. a determination as to whether the policies

are in-line with institutional policies, regulations, guidance documents and accreditation standards) and whether there is a need for new policies to be developed. Reviews will occur at least as frequently as accreditation renewal is required.

On an annual basis, corresponding with the budget cycles, the DHSPP or designee will assess the operations of the HSPP to determine if additional resources are required in terms of supplies, education, staff, and / or equipment. Expenditures from the previous year, response time from the IRB to investigators, number of protocols reviewed per meeting, the number of audits conducted and types of findings, may be among the items included in the assessment. Information will also be solicited from IRB members and staff, and HSPP staff.

The DHSPP will also take into consideration whether there were any activities, supplies or equipment that were previously forgone due to lack of resources.

On an annual basis the Deputy Director or designee of the HSPP will prepare for the DHSPP an evaluation of the overall performance of the HSPP. The evaluation will encompass the review of a number of criteria. If applicable the report will also include actions taken to improve the performance. Upon review of the report the DHSPP may require further action to improve performance. Criteria to be used in the evaluation include the following:

- the number of new full board studies reviewed by each IRB panel within a year in order to assess whether there is an unbalance between the panels that should be addressed, whether the number of panels is appropriate in relation 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, volume of work reviewed, and participation in educational activities
- the nature, number and outcome of subject complaints to determine if proper action was taken or if improvements can still be made
- the nature, number and outcome of investigator complaints to determine if proper action was taken or if improvements can still 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
- the educational activities conducted or sponsored by the HSPP for staff and IRB members
- the nature and number of participant outreach activities offered by the HSPP or other units within the UConn Health. Such activities will be logged by a designated HSPP/IRB staff person as they are announced in Broadcast messages or other media venues if applicable.

Related Policies

2004-02 – Authority of the Human Subjects Protection Office (Institutional Policy)

2009-003 – Imposing and Lifting Suspension of IRB Approval or Imposing Terminations of IRB Approval

2011-007.0 – Definitions Applied to Policies

Basis

45 CFR 46.103(a)(2)

Document Attributes

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