Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-009.14
Policy Title: Institutional Review Board - Human Subject Research Determinations

Purpose

The purpose of this policy is to describe the authority and role of the HSPP / IRB as related projects that do not involve human subjects and / or that do not involve research.

Definitions

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

Clinical Investigation (FDA)	Human Subject Research	IRB Approval
Non-compliance, Serious		

Policy

The authority of the HSPP and IRB does not extend to projects that do not involve human subjects or to projects that involve humans but do not constitute research.

If a UConn Health faculty member, employee or student is considering a project that involves human interactions, human materials and / or human data that s/he does not believe constitutes research involving human subjects, s/he is **strongly** encouraged to complete the Human Subject Research Determination Form. If a formal determination is sought from the IRB, a representative of the IRB (i.e. Regulatory Specialist (RS)* or member of the IRB) will review the information and will make an official determination.

Any project determined to be human subject research, including exempt research, must be reviewed and approved by the IRB prior to implementation. If such projects are undertaken without IRB review because the investigator believed the project did not constitute human subject research, but it is later deemed as such, the convened IRB will review the scenario and may determine that conducting the project without IRB approval constitutes serious non-compliance.

Example scenarios of when it is strongly encouraged that an individual complete the determination form prior to starting a project include, but are not limited to quality improvement projects, classroom projects, program evaluations and surveillance activities, case reports, research on decedents.

If a project does not constitute research involving human subjects, individuals may still be obligated to comply with other relevant regulations. For example, for research on decedents, investigators must comply with HIPAA (Refer to policy 2011-014.0).

*The RS may be a member of the IRB, but does not have to be in order to make such determinations.

Procedure

The IRB Administrator will log receipt of such forms and forward them to the RS for review and official determination. While it is expected that the RS will make the majority of such determinations, having the authority to do so does not preclude the RS from consulting with another member of the IRB or assigning the review to an IRB member.

The assigned reviewer will review the applicable form and document his/her final determination as to whether a project constitutes human subject research.

- The reviewer may request additional information if necessary
- If the reviewer determines the project does not constitute human subject research the HSPP / IRB will have no further involvement.
- If the reviewer determines the project does constitute human subject research, the investigator will be instructed that a complete IRB application will be required.

In all cases, the reviewer will return the reviewed form back to the IRB Administrator who in turn will email the outcome of the review to the individual who filed the form.

The review and determination process should be completed within approximately 10 days of receipt.

Related Content

2011-007.0 – Definitions Applied to Policy
2011-014.0 - HIPAA

Basis

Office For Human Research Protections (OHRP) Frequently Asked Questions on Quality Improvement
http://answers.hhs.gov/ohrp/categories/1569

OHRP Decision Chart - http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1

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