

**Issuing Department:** Human Subjects Protection Program  
**Policy Number:** 2011-009.16  
**Policy Title:** Institutional Review Board - Undue Influence

### ***Purpose***

The purpose of this policy is to affirm that the Institutional Review Board will operate in an environment free from undue influence.

### ***Definitions***

See Policy 2011-007.0 for the following definitions:

Undue Influence		Suspension		Termination
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### ***Policy***

The IRB must operate in an environment free from undue influence so that it may independently conduct objective and thorough reviews of research protocols.

[Note: The issue of undue influence as related to the protection of research subjects is addressed in the IRB submission and review process. Investigators are required to disclose plans to eliminate / minimize these factors in the IRB application process and the IRB considers this plan in the review process. ]

### ***Procedure***

Any member of the IRB or IRB staff who believes that undue influence is being brought to bear on him/her or any other member of the IRB must report the concern to the Director of the Human Subjects Protection Program (DHSP). If the DHSP is the individual creating the undue influence, the report is to be filed with the individual to whom the DHSP reports.

- Reporting may occur through the Chair of the IRB to the DHSP or directly to the DHSP.
- The person reporting the concern should provide the name(s) of the individual(s) who may be creating the undue influence, the name(s) of who may be being influenced, and a summary of the situation, e.g. junior faculty member being pressured to vote for approval of a senior faculty member's study.
- The person reporting the concern may choose the method of communication.

Once aware of the concern, the DHSP will contact the individual alleged to be creating the undue influence to discuss the issue.

- If after the discussion the issue is not resolved and the DHSP believes it necessary s/he may exercise the authority to conduct an audit of the study that is associated with the issue, suspend or terminate studies previously approved for the individual allegedly creating the influence or coercion, or suspend that individual's involvement in studies for which s/he is not the principal investigator.
- If an allegation is substantiated and the effort to influence was done knowingly and willfully, the DHSP shall report the instance to the immediate supervisor of the individual creating the undue influence and to the Signatory Official. The DHSP may also take other appropriate actions based on the findings, including recommending disciplinary action, including termination of employment.

***Related Policies***

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

2009-005 – Monitoring of IRB Approved Studies

***Basis***

Accreditation Standard Element I.1.C

***Document Attributes***

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**Reviewed and Approved By:**

*Richard H. Simon*

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**Richard Simon, MD**  
**Director Human Subjects Protection Program**

**Date**