

Undue Influence of IRB Members and OPRS Staff

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POLICY:

- I. Undue influence with regards to the IRB refers to any attempt to interfere with the standard procedures of the IRB or to inappropriately place pressure on an IRB member, IRB Chair or OPRS staff member in order to obtain a specific outcome from the IRB or one of its members or staff.
- II. Attempts to unduly influence any member of the IRB or OPRS staff threaten the independence of the IRB and the integrity of the HSPP; and require prompt reporting by individuals who experience or are aware of occurrences of undue influence.

PROCEDURES:

- I. Procedures for reporting allegations of undue influence for all research in which UIC is engaged are as follows:
 - A. IRB members should report this behavior to the Chair of their IRB.
 - B. IRB Chairs should report this behavior to the Director of OPRS and UIC IO.
 - C. OPRS Staff should report this behavior to the Director of OPRS.
 - D. If the IRB member, including the Chair, or OPRS staff believe that the undue influence is coming from either the IRB Chair or Director of OPRS, they should report the allegation directly to the UIC IO.
 - E. If the UIC IO has a conflict due to the perceived source or the nature of the undue influence, the occurrence should be reported directly to the University of Illinois general counsel assigned to OPRS, who will act as a mediator and consult with the University of Illinois Ethics Officer as necessary.
- II. Any allegations of undue influence are initially assessed for merit by the Director of OPRS. Alternate individuals are assigned to fulfill these responsibilities in the event of a conflict of interest with the allegation of undue influence. In the event of a conflict of interest, the individual responsible for review must recuse themselves from the review and the next individual responsible for review takes his or her place in the following order:
 - A. OPRS Director;
 - B. UIC IO;
 - C. University of Illinois general counsel assigned to OPRS.

- III. If the allegation involves non-VA research, and if the allegation appears to have merit, the UIC IO forms an investigative committee of uninvolved investigators and/or IRB members to gather and review information related to the allegation.
- IV. If the allegation involves the JBVAMC/NU/UIC Collaborative IRB, and if the allegation appears to have merit, the EC serves as the investigative committee.
 - A. The JBVAMC or NU representatives of the EC are responsible for investigating complaints of undue influence originating from their respective sites.
 - B. The JBVAMC and NU are responsible as delineated in their respective MOUs for their institutional role in undue influence investigations.
 - C. Any member of the EC having a conflict of interest with the allegation of undue influence is expected to identify the existence of a conflict and recuse themselves from the committee's discussion of the matter.
- V. Determinations resulting from the appropriate committee's review of the allegations may include the following:
 - A. No response necessary, there was no intent for undue influence and there was no resultant influence on an IRB determination, OPRS staff process, or within the HSPP program; or
 - B. Undue influence occurred; the appropriate committee will develop a corrective action plan, which may include possible sanctions.
- VI. The determinations of the appropriate committee are submitted to the UIC IO in a written report prepared by OPRS staff.
- VII. The written report is copied by OPRS staff to:
 - A. The Associate Vice Chancellor for Research;
 - B. The Director of OPRS;
 - C. The appropriate IRB; and
 - D. As appropriate, other Institutional Officials (i.e., Research Standards Officer).
- VIII. If the complaint involves research at the JBVAMC or JBVAMC employee, the report is also copied by OPRS staff in addition to the above individuals:
 - A. The JBVAMC ACOS of Research and Development;
 - B. JBVAMC Chief of Staff;
 - C. JBVAMC Medical Center Director;
 - D. JBVAMC R & D Committee; and
 - E. The EC.
- IX. If the allegation involves research at NU or a NU employee, the following are copied in addition to the individuals listed in VIII of this document:
 - A. NU OPRS;
 - B. OPRS Executive Director;
 - C. NU Vice President of Research; and
 - D. The EC.

- X. The UIC IO determines whether more information from the appropriate committee is necessary and makes a final determination as to the report written by the respective committee. If the UIC IO has a conflict due to the perceived source or the nature of the undue influence, the behavior should be reported directly to the University of Illinois general counsel assigned to OPRS, who will act as a mediator and consult with the University of Illinois Ethics Officer as necessary.
- XI. The IO from the institution at which the undue influence occurred is responsible for providing written notification to the person(s) who the investigation is directed against of the findings and the corrective action plan, if applicable, and ensuring the corrective action plan is carried out. If the undue influence involved JBVAMC research, the IO must provide the EC with a progress report twice a month.
- XII. The corrective action plan will be reviewed by the appropriate IRB. The IRB will evaluate whether the occurrence represents serious and/or continuing non-compliance.

REFERENCES:

[21 CFR 56.109\(a\)](#), [21 CFR 56.109\(e\)](#), [21 CFR 56.112](#), [21 CFR 56.113](#)
[38 CFR 16.109\(a\)](#), [38 CFR 16.109\(c\)](#), [38 CFR 16.112](#), [38 CFR 16.113](#)
[45 CFR 46.109\(a\)](#), [45 CFR 46.109\(e\)](#), [45 CFR 46.11](#), [45 CFR 46.113](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 06/18/09	1.0, 10/15/08	Small correction of reference and clarification of progress report time table in Section XI.