





Standard Operating Procedures		
SOP #208.0 Revision 0	TITLE: Undue Influence of IRB and OIRB Staff	Effective Date: 7/7/2016
Approved By: OIRB Director	Signature 	Date 8/25/2016
Approved By: IRB Chair	Signature 	Date 8/29/16

PURPOSE

To describe the procedure for investigations of attempts to unduly influence any member of the UNM Institutional Review Board (IRB) or Office of the IRB (OIRB) staff.

REVISIONS FROM PREVIOUS VERSION

None

POLICY OBJECTIVE

The IRB is charged with specific regulatory functions by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) with regard to oversight of human subjects research (HSR). To perform those functions well, the IRB review process and the implementation of HSR policies and procedures must be conducted objectively and without undue influence. Individual IRB members and OIRB staff have both the right and the obligation to report any undue pressure upon them to make decisions that would favor an individual researcher or the institution over the safety or welfare of research participants.

RESPONSIBILITIES

Execution of SOP: OIRB Director, OIRB Staff, IRB, IO, OUC.

PROCEDURE

Reporting Undue Influence

Individuals who are responsible for business development (i.e. commercialization of the technology) are prohibited from carrying out the day-to-day operations of the review process. Reports regarding undue pressure of an IRB member can be made orally or in writing, with or without the reporter's identity, to the IRB Chair or Institutional Official (IO). Reports regarding undue pressure of an OIRB staff member can be made to the Director of the OIRB. If the staff member feels that undue influence is coming from the OIRB Director or other IRB administrator, the report can be made directly to the IO. If the IO has a conflict due to the perceived source or the nature of the undue influence, the occurrence should be reported directly to the UNM Office of University Counsel, who will act as mediator.



Response to a Report of Undue Influence

The OIRB Director and/or IO will conduct an official investigation of the reported undue influence of an IRB member or OIRB staff member in a timely manner. Alternate individuals are assigned to fulfill these responsibilities in the event of a conflict of interest with the allegation of undue influence. Outcome of the review will be documented, the complainant (if known) will be provided a response, the affected IRB member or staff will be informed of the outcome, and a corrective action plan will be instituted if deemed necessary.