INSTITUTIONAL REVIEW BOARD INDEPENDENCE IN HUMAN SUBJECTS RESEARCH

POLICY

The Institutional Review Board (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 have both the right and the obligation to report any undue pressure upon them to make decisions that would favor an individual investigator or the institution over the safety or welfare of research subjects.

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).

RESPONSE TO A REPORT OF UNDUE INFLUENCE

The IO will conduct an official investigation of the reported undue influence of an IRB member in a timely manner. Outcome of the review will be documented, the complainant will be provided with a response (if the complainant is known), the affected IRB member will be informed of the outcome, and a corrective action plan will be instituted if deemed necessary.

Applicable Regulations and Documents:
45CFR46
21CFR56
Human Research Protection
Program Policy

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<tr>
<th>Adoption Date:</th>
<th>Created by:</th>
<th>Date of Revision:</th>
<th>Revised By:</th>
<th>Summary of Revision:</th>
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<td>3/2007</td>
<td>J. Gerlach</td>
<td>8-17-12</td>
<td>C. Norman</td>
<td>Revise wording for clarification and consistency with other HRP policies. Replace VP for Research and Director of ORCRA with IO. Add Applicable Regulations and revision summary table.</td>
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<td>09/2014</td>
<td>A.Braggs-Brown</td>
<td>Revised to reflect AAHRPP recommendations</td>
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<td>3/2015</td>
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<td>3/2015</td>
<td>J. Strasser</td>
<td>Revisions for clarification</td>
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