1.0 Reason for Policy
This policy describes the process for handling allegations of non-compliance with IBC policies and procedures.

2.0 Scope of Policy
This policy applies to the University research community and its partners.

3.0 Policy Statement
The IBC will review allegations of non-compliance, obtain input from the researcher under review, and take appropriate action to address actions found to constitute non-compliance. An activity is considered to be non-compliant if it varies from the approved IBC protocol, IBC policies and procedures, or relevant state or federal laws.

Procedures:

Submission of Allegations: Allegations of non-compliance may be submitted to the IBC in many ways:
• Any individual or organization may submit a written complaint or allegation of non-compliance to the IBC
• Anonymous complaints may be submitted through on-line reporting (EthicsPoint) https://secure.ethicspoint.com/domain/en/report_custom.asp?clientid=9167
• The IBC itself may initiate a review based on information available to the IBC (e.g., deficiencies noted in IBC files, media or scholarly reports of research activity subject to IBC jurisdiction)
• DEHS or OHS or RIOP may raise issues

Administrative Review: All reports of non-compliance are initially evaluated at the administrative level by the Executive Director or delegate (other senior staff who are IBC members). Initial inquiries into non-compliance allegations will be conducted by the IBC Chair in consultation with the HRPP Executive Director and other experts as deemed necessary. The matter may be resolved at this level without further IBC review if the allegation does not represent potential non-compliance, is a factual assertion of non-compliance that is neither serious nor continuing, or reflects a minor administrative problem and is addressed by the investigator by means of a corrective action plan. If a report of non-compliance does not require further IBC review, the incident and any corrective action plan will be documented in writing to the investigator and maintained in IBC files.

IBC Review: If further investigation is warranted, an investigation committee may be formed comprised of the IBC Chair, two members of IBC, RIOP representative, appropriate DEHS or OHS biosafety experts, member of PI’s academic department and HRPP senior staff. Other representatives from regulatory committees may be asked to join the committee. The investigation committee will determine whether the non-compliance is serious or continuing. The IBC investigation committee can include consultation with other University officials. Researchers will be provided the opportunity to communicate with the investigation committee and explain circumstances around alleged non-compliance.

Notification of Outcome and Reporting: The researcher will be notified in writing of the concerns about non-compliance and asked to submit a response to the IBC within 10 working days. The IBC may ask for follow up responses from the researcher and may review all other relevant materials (such as compliance review reports from the RIOP). Communication will include requirement for corrective action which may include additional education, increased supervision or oversight or other actions deemed necessary to ensure the safety of personnel, the environment and the public interest.

Following thorough review, if the investigation committee finds that the allegation was substantiated and serious or continuing non-compliance has occurred, that determination will be provided in writing to the PI and department head and reported to others as required by IBC Policy 407 Reporting Requirements.

4.0 Required approvals for this document

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5.0 Revision History

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<tr>
<th>Revision</th>
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<td>Policy revision</td>
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<td>12/10/09</td>
<td>New format and update content</td>
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To obtain a copy of a historical policy, e-mail ibc@umn.edu or call 612-626-5654