

1.32 Confidentiality of the Review Process

1.0 Purpose

The purpose of this policy and procedure is to describe the Organization's requirements and practices for assuring confidentiality of the process of review of human subjects research

2.0 Policy

- **2.1.** It is the policy of the Organization that the deliberations of the IRB in a convened meeting or subcommittee meeting, or of an expedited reviewer, are confidential, and details of such discussions and deliberations may not be shared with the investigator or any other person outside the IRB or the ORA.
 - **2.2.** It is the policy of the Organization that findings and decisions of the IRB, or of a subcommittee of the IRB, or of an expedited reviewer, will be shared with the investigator or with the investigator's staff verbally, by email or by letter, following that meeting or review. The details of the deliberations will not be shared as per section 2.1 above.
 - **2.3.** It is the policy of the Organization that violation of this policy, and especially the deliberate communication of the details of the deliberation of the IRB, the subcommittee or the expedited reviewer, is cause for action against that IRB member, ORA staff member or other responsible party as described below.
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3.0 Process

- **3.1.** IRB members will sign a Confidentiality Agreement at the time they are appointed to the board, and again at every re-appointment. The signed agreement will be retained by the ORA.
- **3.2.** ORA Staff will sign a Confidentiality agreement at the time they are hired. The signed agreement will be retained by the ORA.
- **3.3.** Guests to the IRB meeting will sign a Confidentiality agreement prior to attending the meeting in accordance with HRPP policy 1.31 (Observers at IRB Meetings). The signed agreement will be retained by the ORA.
- **3.4.** Consultants to the IRB will sign a Confidentiality Agreement prior to attending the meeting. The signed agreement will be retained by the ORA.

- **3.5.** Allegations of violation of this policy will be handled and investigated as described in HRPP policy 8.5 (Noncompliance by the IRB or Other Components of the HRPP).
 - **3.5.1.** The event, however, will not be considered “non-compliance” as per that policy, and is not reportable outside the Organization.
 - **3.6.** Violation of this policy may lead to actions against the IRB member, the ORA Staff, or other responsible party, as determined by the IO. These actions could include, but are not limited to, dismissal from the board, disciplinary actions, or termination of employment.
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