

(Name of Facility)

INSTITUTIONAL REVIEW BOARD
MEMBER CONFIDENTIALITY AGREEMENT

I, _____ (please print), understand that documents and other information which I acquire as an IRB member are provided to me solely for use in fulfilling my responsibilities on the Institutional Review Board (IRB) and are to be kept confidential. Examples of such information are: human subject identifying data or medical information; proprietary information; trade secrets, medical or scientific data; research designs, concepts, discoveries or inventions; or any other information designated as, or reasonably understood to be, confidential. I agree to handle them accordingly.

I agree to not to discuss, disclose, or reproduce any confidential information except to carry out my functions as an IRB member, or as otherwise required by law. I agree to direct any requests for information that I receive to a person designated by the Office of Mental Health(or Office of Mental Retardation and Developmental Disabilities) as the Central Office Records Access Officer under the New York Public Officers Law, and to obtain written authorization from the Principal Investigator or the sponsoring organization before using any information from or about a protocol for any personal purpose. However, if I have also received information which would otherwise be deemed confidential under this agreement through other lawful means for other lawful purposes, this agreement does not restrict my use of such information for such purposes.

I understand that the disclosure of information could violate the privacy rights of research subjects, the intellectual property rights of investigators and/or the proprietary rights of research sponsors, and that irreparable harm could result. I also understand that such disclosure could result in my removal from the IRB and the loss of my rights to indemnification and representation under the New York Public Officers Law. I agree that the duty of confidentiality with regard to information I obtain as an IRB member continues after my IRB membership ends.

I further understand that this agreement does not preclude appropriate oversight agencies, such as the federal Office for Human Research Protections, from lawfully obtaining such information through their existing authority as required for the proper discharge of their duties.

Signature

Date

CHECKLIST FOR REVIEW OF IRB DOCUMENTATION

1. Is there a current letter of appointment signed by the Director for each IRB member?
Yes No
2. Is each appointment for a period of 1 year (members may be reappointed).
Yes No
3. Has RFMH been notified of all appointments?
Yes No
4. Is a signed Member Confidentiality Agreement on file for each member?
Yes No
5. Have all non-affiliated members been enrolled as volunteers?
Yes No
6. Are there at least monthly meetings, unless noted in the prior or subsequent minutes?
Yes No
7. Have meetings of the IRB been held at least quarterly during any period in which research was being conducted?
Yes No
8. Do the minutes record that for each protocol approved at a convened meeting a quorum existed (a majority of the members including at least one non-scientific member)?
Yes No
9. Have any expedited approvals been recorded in the subsequent minutes or otherwise reported, in writing, to the members of the IRB?
Yes No

10. Have continuing reviews of each ongoing protocol been conducted in a timely fashion? (At least annually).
Yes [] No []
11. Does the IRB have an adequate process for triggering continuing reviews?
Yes [] No []
12. Does the IRB maintain documentation for each protocol:
- Research protocol
 - IRB approval
 - Director's approval
 - Director's approval of state staff time (not applicable at NKI, NYSPI, IBR)
 - RFMH approval
 - Continuing review applications and IRB approval
 - Protocol amendments and IRB approvals
 - Correspondence with the investigator, including adverse event reports
- Yes [] No []
13. Is there documentation of IRB member and investigator training?
Yes [] No []

Explain any No answer: Attach an additional sheet, if necessary.