**CHECKLIST FOR REVIEW OF IRB DOCUMENTATION**

(To be completed by a person who is independent of the IRB)

**January 1, 20 – December 31, 20\_\_**

1. Is there a current letter of appointment signed by the Facility/Institute Director for each IRB Member?

Yes  No

2. Is each appointment for a maximum period of 1 year (members may be reappointed).

Yes  No

3. Has RFMH been notified, in writing, 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. Is there documentation of at least quarterly convened meetings during any period in which research was being conducted?

Yes  No

7. 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

8. Do the minutes document that members are reminded of the conflict of interest policy at the beginning of each meeting?

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. (a) Does the IRB have an adequate process for reminding investigators to submit continuing review applications?

Yes  No

(b) How/when are investigators reminded to submit continuing review applications:

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12. Does the IRB maintain a file of appropriate documentation for each protocol:

* Research protocol, including IRB application form(s), protocol, consent form(s), recruitment tools, e.g. advertisements (if any), investigator’s brochure (if any), grant application (if any) and other related documents
* Minutes of any meetings at which actions were taken on the study or notation of meeting date(s) which permit retrieval of minutes from centralized filing
* IRB approval
* Director’s approval
* Director’s approval of state staff time (not applicable at NKI, NYSPI, IBR)
* RFMH approval
* Continuing review applications and approvals, including written progress reports
* Protocol amendments and approvals
* Correspondence with the investigators, including adverse event reports

Yes  No

13. Is there documentation that confirms that all researchers, staff and others involved in the design and conduct of research involving human subjects (collectively “Key Personnel”), all IRB administrative staff and IRB members and Institutional Officials have completed required CITI Training? Include confirmation that all IRB members and institutional officials have current CITI certificates and that all key personnel (researchers, staff  and others involved in the design and conduct of   research involving human subjects) have provided documentation of current CITI training.

Yes  No

Explain any ‘No’ answer and provide recommendations for strengthening procedures and/or documentation: (Attach an additional sheet if necessary).