New Study Discussion Checklist

[Yes/No/NA for each numbered item. Sub-questions expandable/collapsible.]

1. Risks to subjects are minimized by using procedures consistent with sound research design that do not unnecessarily expose subjects to risk.

    Is the hypothesis clear?

    Is the study design appropriate to prove the hypothesis?

    Is there adequate scientific background for the study?

    Would alternative procedures, design, or a different subject population reduce the likelihood or magnitude of harm but still answer the scientific question?

    Does the investigator have adequate resources (facilities, appropriate numbers of trained staff, etc.) to safely conduct the research?

    Does the investigator have access to, or the ability to refer subjects to, appropriate follow-up medical or psychosocial resources that subjects might need as a consequence of the research?

    Is communication regarding information that might be relevant to the protection of subjects managed adequately (between Sponsor, Sites, IRB, etc.)?

2. Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes.

3. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result from the research.

4. Selection of subjects is equitable.

    Consider the purpose of the research.

    Consider the setting in which the research will be conducted.

    Consider the involvement of populations vulnerable to coercion or undue influence.

    Consider inclusion and exclusion criteria.

    Consider recruitment and payment methods.

5. If appropriate, consent will be obtained from the subjects.

    Does the consent process allow for the appropriate level of consideration and discussion?

    Does the consent process describe an exchange of information that will allow subjects to make an informed decision about whether or not to join the study?

    Is there any potential for undue influence or coercion in the consent process? If so, is risk of undue influence or coercion minimized to the extent possible?

6. If appropriate, consent will be documented.

    Are consent materials written in language understandable to the potential subjects?

Are appropriate signature and date lines present?

Is the method of documenting consent adequate?

7. There are adequate provisions for monitoring the data collected to ensure the safety of subjects. (If study is minimal risk, a Data Safety Monitoring Plan is not required.)

    What data will be monitored?

    How frequently?

    Who will monitor?

    What analyses will be performed on the data?

    What is in place to detect unexpected harms promptly?

    What are the stoppage rules?

8. There are adequate provisions to protect the privacy of participants.

    Will subjects have an expectation of privacy?

    How are subjects identified and recruited?

    Will subjects be comfortable in the research setting?

    Are they being photographed or videotaped?

9. There are adequate provisions to maintain the confidentiality of the data. Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.

    Will confidentiality be pledged?

    Are there legal/ethical requirements?

    Will data release cause risk of harm?

    Are appropriate techniques being used to protect confidentiality?

        Inter-file linkage

        Error inoculation

        Statistical strategies

        Top coding

        Restricted public use data

        Restricted access, enclaves, archives

        Certificates of Confidentiality

        Ethical editing of qualitative descriptions

        Data brokering