MCLA IRB Reviewer’s Checklist

Instructions for reviewers: The attached research proposal may place human subjects at risk. Review the proposal and consent form. Complete this form and return it via e-mail to the IRB FirstClass Conference.

Principal Investigator: ________________________________

Title of proposal: ________________________________

Proposal number: ________________________________

Reviewer: ________________________________

DECISION (CHOOSE ONE)

[ ] This proposal should be approved in the form presented

[ ] This proposal should be approved with changes indicated below under numbers: ______________________

[ ] This proposal should be disapproved

PARTICIPANTS

1. Are the participants of this proposal minors or mental incompetents?

   [ ] YES    [ ] NO    Comments:

   (a) If yes, do the potential benefits justify the participants’ participation?

       [ ] YES    [ ] NO    Comments:

   (b) If yes, are there consent procedures for guardians and participants?

       [ ] YES    [ ] NO    Comments:

   (c) If yes and a minor, is there a description of how assent will be obtained?

       [ ] YES    [ ] NO    Comments:

2. Does the proposal contain an assessment of the possible psychological effects and risks of participation?

   [ ] YES    [ ] NO    Comments:

3. Does the proposal, in its recruitment procedures, indicate any possibility of undue influence on participants or participate?

   [ ] YES    [ ] NO    Comments:

ABILITY TO CONSENT

4. Does the proposed participant consent form, in an adequate manner and in layman’s language, contain:

   (a) A fair explanation of the procedures to be followed, including identification of those that might reasonably expected to affect a participant’s willingness to participate?

       [ ] YES    [ ] NO    Comments:

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(b) A description of the attendant discomforts and risks?
[ ] YES  [ ] NO Comments:

(c) A description of the benefits to be expected?
[ ] YES  [ ] NO Comments:

(d) Does the proposed participant consent form contain any language which, in any way would seem to waive a participant’s legal rights against the College, its agents, or the investigator(s) conducting the study from liability for negligence?
[ ] YES  [ ] NO Comments:

RISKS / BENEFITS

5. Does the proposal describe in detail the specific risk(s) to participants?
[ ] YES  [ ] NO Comments:

(a) If yes, does the proposal present only minimal risk?
[ ] YES  [ ] NO Comments:

6. Does the proposal specify the direct benefit(s) that participants will derive from participating?
[ ] YES  [ ] NO Comments:

7. Does the proposal specify the indirect benefit(s) that participants will obtain from participating?
[ ] YES  [ ] NO Comments:

8. Does the benefit to the participant justify the risks of exposure to the treatment variable(s)?
[ ] YES  [ ] NO Comments:

CONFIDENTIALITY

9. Does the proposal contain adequate provision for the protection of participant’s privacy and anonymity in the handling of data (i.e., storage, processing, retrieval, etc.)?
[ ] YES  [ ] NO Comments:

DEBRIEFING

10. Does the proposal provide for complete debriefing of participants following participation?
[ ] YES  [ ] NO Comments:

COMMENTS

________________________________________  ____________________________
Signature                      Date

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