

Guidance on Expedited Review of Minor Changes in Previously Approved Research

Investigators must report to the IRB any proposed changes in IRB-approved research, including proposed changes in informed consent documents. No changes may be initiated without approval of the IRB, except where necessary to eliminate apparent immediate hazards to subjects.

In accordance with 45 CFR 46.110(b) (2), 38 CFR 16.110(b) and 21 CFR 56.110, IRBs may utilize expedited procedures to review a proposed change to previously approved research if it represents a minor change to be implemented during the previously authorized approval period.

A minor change is one which, in the judgment of the IRB reviewer, makes **no substantial** alteration in:

- (1) The level of risk to subjects;
- (2) The research design or methodology;
- (3) The subject population;
- (4) The qualifications of the research team;
- (5) The facilities available to support the safe conduct of the research;
- (6) Any other factor which would warrant review of the proposed changes by the convened IRB.

Examples of minor changes include but are not limited to:

- (a) Changes in study research personnel;
- (b) Adding a blood draw to a research study;
- (c) Decreasing the amount of a blood drawn or the frequency of blood drawn;
- (d) Adding research site(s) to a research study (assuming they are of a similar nature to those previously approved by the IRB);
- (e) Adding a standardized test instrument to a research study;
- (f) Modifying the subject recruitment plan;
- (g) Adding a standard quality of life questionnaire;
- (h) Extending the time period of the study to include follow-up with the research participants (with no additional invasive measures such as blood withdrawals);
- (i) Changing the principal investigator (assuming the proposed PI has similar credentials to the previously approved P.I.);
- (j) Deletion of questions in a questionnaire;
- (k) Adding “non-sensitive” questions (questions that would not appear to invoke psychological injury) to a questionnaire;
- (l) Changing telephone numbers or contact persons on the consent form
- (m) Changing the dates of time for initiating a study;
- (n) Modifications in an already approved subject recruitment flyer;
- (o) Changes in project title;
- (p) Adjusting incentives (so long as these do not appear coercive).

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