It is the policy of the University of Alabama IRBs that investigators must report any proposed changes in IRB-approved research to the IRB and receive IRB approval before those changes are implemented, even if the changes are minor. The only exceptions are for correction of spelling or grammatical errors and changes made to eliminate immediate hazards to participants. The latter must be reported to IRB within 5 working days of occurrence.

In accordance with 45 CFR 46.110(b) (2), 38 CFR 16.110 (b) and 21 CFR 56.110, IRBs may use expedited procedures to review modifications to previously approved research if it represents a minor change.

A “minor” change cannot include the addition of procedures that involved more than minimal risk or that did not fall into categories (1) – (7) of research that can be reviewed using the expedited procedure.

1. The level of risk to subjects;
2. The research design or methodology;
3. The subject population;
4. Participant burden;
5. The qualifications of the research team;
6. The facilities available to support the safe conduct of the research;
7. 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:

1. Changes in study research personnel, including principal investigator and staff members if persons are of equivalent skill;
2. Decreasing the amount or frequency of blood drawn already approved by IRB;
3. Adding a standardized test instrument or quality of life survey to a research study;
4. Modifying the subject recruitment plan (unless a vulnerable population is added);
5. Extending the time period of the study to include follow-up of participants without additional invasive procedures such as blood draws;
6. Deletion of questions in a questionnaire;
7. Adding “non-sensitive” questions (those that would not appear to evoke psychological injury or other risk) to a questionnaire;
8. Changing telephone numbers of contact persons on the consent form;
9. Changing the dates for initiating a study—IF they remain within the period of approval;
10. Modifications to an approved subject recruitment flyer;
11. Changes in study title to better reflect study nature (nature of study not changed);
12. Adjusting incentives (as long as changes do not appear coercive)