SAINT LOUIS UNIVERSITY

Checklist: Determining Eligibility for Expedited Continuing Review

This worksheet is intended to provide support for individuals in determining whether a research protocol undergoing continuing review is eligible for expedited review procedures. Complete this worksheet by working through each question in numerical order. This worksheet is not meant to be completed or retained on record.

Expedited Review Conditions

1) Has the research been previously approved using expedited procedures? ☐Yes ☐No
   a. If "Yes", have conditions changed such that the research is no longer eligible for expedited review? (e.g. protocol changes, risk level changes, etc.) (OHRP) ☐Yes ☐No

(If "Yes' to 1 and "No" to 1a, then research is eligible for continuing review under expedited procedures; otherwise please continue with this form)

2) Have any subjects been enrolled at this site? (Category 8b) ☐Yes ☐No
   a. If No, have any additional risks been identified? (Category 8b) ☐Yes ☐No

(If "No" for both questions, then research is eligible for continuing review via expedited procedures; otherwise please continue with this form)

3) Was research determined to be no more than minimal risk at the full IRB meeting where it was initially approved? (Category 9) ☐Yes ☐No
   a. If Yes, have any additional risks been identified? ☐Yes ☐No

(If "Yes" to 3 and "No" to 3a then research is eligible for continuing review under expedited procedures; otherwise please continue with this form.)

4) Has research progressed to a point that all human subject activities fall under Categories 2-7 (See Checklist: Determining Eligibility for Expedited Review for Initial Approval) (OHRP) ☐Yes ☐No

(If "Yes" research is eligible for continuing review under expedited procedures. If "No" please continue with this form)

5) Is research permanently closed to enrollment of new subjects at *this site*? (Category 8a(i)) ☐Yes ☐No
   a. Have all subjects at *this site* completed all research-related interventions*? (Category 8a(ii)) ☐Yes ☐No
   b. Does the research remain active at *this site* only for long term follow-up** of patients? (Category 8a(iii)) ☐Yes ☐No

***Intervention:** physical procedure by which data are gathered **or** manipulations of the subject or the subject's environment that are performed for research purposes (OHRP)
****Long term follow-up**: research ***interactions*** that involve no more than minimal risk (e.g. Quality of Life Surveys) as well as collection of follow-up data from procedures *that would have been done as part of routine clinical practice to monitor for disease progression or recurrence*. Long term follow-up **excludes** research ***interventions*** that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk. (OHRP)
Interaction: communication or interpersonal contact with the individuals (including electronic interaction) (OHRP)

(If, "Yes" to 5, 5a and 5b, the research is eligible for continuing review under expedited procedures. If "No" to any of these questions please continue this form)

6) Are remaining research activities at *this site* limited to data analysis? (Category 8c) ☐Yes ☐No

(If "Yes" research is eligible for continuing review under expedited procedures, otherwise research should be sent to a full board for continuing review.)

NOTES: In questions 5 and 6, *this site* refers to the SLU site or SLU researcher-led site. For studies in which SLU is the coordinating center for multi-site research, questions 5, 5a, 5b and 6 should be answered for *all sites.* Protocols up for continuing review in which the SLU investigator holds the IND or IDE need careful consideration beyond this checklist.

Research protocols determined to be ineligible for expedited review procedures will be reviewed by the convened board.