Reviewer Questionnaire for Expedited Continuing Reviews

Reviewer name: Signature:

IRB Meeting Date: IRB Control #: PI:

Please verify review category:

1. **FULL BOARD REVIEW:** This study was initially reviewed by the convened IRB and does not meet the expedited criteria below.
2. **EXPEDITED REVIEW: 45 CFR 46.110, List of Categories (8)** Continuing review of research previously approved by the convened IRB as follows:

**45 CFR 46.110, List of Categories (8a)** Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects [This review category meets the no further continuing review provision. Please check appropriate box in item #5.]; or

**45 CFR 46.110, List of Categories (8b)** Where no subjects have been enrolled and no additional risks have been identified [Continuing review is required.]; or

**45 CFR 46.110, List of Categories (8c)** Where the remaining research activities are limited to data analysis. [This review category meets the no further continuing review provision. Please check appropriate box in item #5.]

1. **EXPEDITED REVIEW: 45 CFR 46.110, List of Categories (9)** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) (from 45 CFR 46.110) do not apply **but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.** [Continuing review is required.]
2. **EXPEDITED REVIEW:** This study initially received expedited review and no significant changes have been made. [This review category meets the no further continuing review provision. Please check appropriate box in item #5.].

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| 1. **CONTINUING REVIEW NO LONGER REQUIRED:** **Note:** This provision cannot currently be applied to FDA-Regulated Studies.   Study meets one or more expedited criteria as indicated above in items #2 (8a and/or 8c) or #4  **OR** **research has progressed to the point that it involves one or both of the following, which are part of the IRB-approved study:**  Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;  Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.  If you feel that Continuing Review is still warranted, please provide your written rationale in space provided below. |

**MCARE Signature Line for All Reviews**

**Is the appropriate MCARE investigator signature line included in the consent form?**

Use the information in the MCARE investigator signature line sections of the OHR-2/OHR-9 and OHR-8 to make this determination.

**Reviewer Comments** (Use other side of page if needed):