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):