VA Pittsburgh Healthcare System

Research Scientific Evaluation Committee

Checklist for Expedited Modification Review

Principal Investigator: MIRB#

Study Title:

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1. The modification is a minor change that does not substantially change the specific aims or design of the study. Examples may include but are not limited to: Changes in funding, project title, or study staff; small changes in experimental procedures, design, or analysis (as in RSEC SOP)

[ ]  Yes [ ]  No

Comments:

2. Do any of the requested modifications require changes to the protocol, consent form, and/or the Request for Off-site Storage/Transfer with respect to use, storage, and or transfer of VA research information?

[ ]  Yes [ ]  No

Comments:

3. Do any of the requested modifications affect the determination of the study as science-only or human studies exempt?

 [ ]  Yes [ ]  No

 i. If yes, which committee should the project be deferred to:

 1. IRB **[ ]** YES [ ]  NO [ ]  N/A

 2. IACUC……………………………………………………….. **[ ]** YES [ ]  NO [ ]  N/A

Comments:

4. Are there any changes to Privacy/Data Security Risk level?

[ ]  Yes [ ]  No

Comments:

**Recommendation:**

**[ ]**  Approve all modifications

**[ ]**  Approve contingent on changes in items numbered

 (Changes Required (All suggested changes must be stated with explicit and unambiguous writing that requires a simple concurrence for the investigator and should refer to the corresponding modification request form number):

**[ ]**  Defer to full RSEC (One or more modifications is not approvable or the modification is determined to be major) Comment(s):

**[ ]**  Refer to other committee (name):

Additional reviewer comments / list of contingencies:

Reviewer name:       Date:

Reviewer signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_