

Portland Area IHS Institutional Review Board (IRB)

STATUS REPORT and RENEWAL APPLICATION REPORT

REPORT on Research Protocol No. _____ Due Date:

Title: _____

CHECK THE APPROPRIATE CHOICE: (Please type or print legibly)

_____ **To be RENEWED--NO CHANGES and have NOT STARTED PROJECT yet:**
Please complete Parts A, B9, C, & E--if applicable; sign & date; return this Form.

_____ **To be RENEWED with MINOR or NO CHANGES:**
Please complete Parts A, B, C, D, & E--if applicable; sign & date; return Form with changed materials (with changes marked) & your most current consent document.

_____ **To be RENEWED with CHANGES in procedures, population, purpose, etc.:**
Please complete parts A, B, C, D, & E--if applicable; sign & date; return Form with research protocol (with changes marked) & your most current consent document.

_____ **NOT to be RENEWED -- FINAL STATUS REPORT:**
Please complete Parts A, B, & C; sign & date; return this Form.

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Part A: Basic current information.

A1. Principal Investigator's name, address, telephone, fax, & e-mail:

A2. Current Title of Protocol: _____

Part B: Findings.

B1. Brief summary of findings to date (add sheets if needed): _

B2. Total number of participants you have enrolled to date: _____

Total number you project to enroll: _____

B3. Number and description of complaints by participants or others (add sheets if needed):

B4. Total number who withdrew or were discharged before they completed the protocol: ____

Give date and reason for each withdrawal or discharge (add sheets if needed): _____

B5. Number, type, and description of adverse events/harms (add sheets if needed): _____

B6. Describe how each adverse event/harm was handled (add sheets if needed): _____

B7. Number and description of unanticipated benefits (add sheets if needed): _____

B8. Number and description of any other unanticipated event (add sheets if needed): _____

B9. Summary of recent relevant literature or findings about research topic, including reports of multi-center trials, with particular attention to risks (include citations)

(add sheets if needed): _____

Part C: How you and your team have reported results or progress of the research in the past year. Please include a copy of all abstracts, handouts, etc.

- C1. Dates and audience of presentations, reports, etc. to Tribal governments, Health Boards, lay groups, etc.
(add sheets if needed): _____
- C2. Dates and audiences of all presentations, reports, newsletters, etc. to research participants or their families
(add sheets if needed): _____
- C3. Dates and audiences of all presentations, reports, etc. to clinicians and caregivers
(add sheets if needed): _____
- C4. Dates and audiences of all presentations, reports, etc. to researchers or anyone else not mentioned above
(add sheets if needed): _____

Part D: Changes.

- D1. Do you propose, or did you make, any changes in this study or consent document?
_____ No _____ Yes (If yes, please describe; add sheets if needed.)

Part E: New funding.

Please provide information for all additional funding, awarded or proposed, in the past year related to this research. Add sheets if needed.

- 1. Name of Principal Investigator:
- 2. Name of funding Agency: Agency's No. (if assigned):
- 3. Title of Protocol:
- 4. Inclusive dates: from _____ through _____

Signature: _____ **Date:** _____