RMTIRB
STATUS REPORT, CHANGES AND RENEWAL APPLICATION REPORT

Protocol No: **«number»** Due Date: Before ,

Title: «Title»

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

_____**Research project is completed / closed (please choose)**

_____**There have been no changes to study protocol since date of last review.**

_____**There have been changes to study protocol since last review**

Complete parts A, B, C, and D ~ sign, date and send us this form along with your most current Consent form. Include your changed Research Protocol with changes marked.

Part A: Basic current information.

A1. Principal Investigator

Name:_____

Address 1:_____

Address 2:_____

Address 3:_____

Fax:_____ E-mail:_____

A2. Current Title of Protocol:_____

_____

_____

Part B: Findings

B1. Total number of subjects enrolled to date: _____

B2. Total number of subjects projected to enroll in the next 12 months: _____

B3. Total number of subjects who withdrew before they completed the protocol: _____

B4. Number of subjects who withdrew from the project in past 12 months: _____
(Include reasons for withdrawal for each on separate sheet)

B5. Specifically identify all instances of untoward effects, complications, or unexpected results of study activity. (append sheet)

B6. Provide documentary evidence of internal or external review of results to date. Present all interim results which would influence a reasonable person to choose to participate or not or to choose one limb of the project over any other.(append sheet)

B7. Number and details of complaints by subjects or other entities. Describe how each was handled. (append sheet)

B8. Provide summary of recent literature or findings (non-published) relevant to this research topic (including reports of multi-center trials) with attention to risks (append sheets).

Part C: Reporting results or progress of the research in the past year. **Please include copies of all abstracts, handouts, etc.…** (add sheets if necessary)

C1. Dates and audience of presentations, reports, etc. to **Tribal governments, Health Boards, lay groups**

_____

_____

C2. Dates and audience of presentations, reports, newsletters, etc. to **research participants**

_____

_____

C3. Dates and audience of presentations, reports, etc. to **clinicians and caregivers**

_____

_____

C4. Dates and audience of presentations, reports, etc. to **researchers** or anyone else not mentioned above._____

_____

Part D: Changes

D1. Do you propose, or did you make any changes in this study or Consent Form? No Yes

If yes, please describe (use additional space or attachments if needed _____

_____

_____

_____

_____

P.I. Signature:_____ Date:_____