# Rocky Mountain Tribal IRB (RMT-IRB) Final Report /Study Closure Form

This application is to report closure of a human subjects research project that has been approved by the RMTIRB. Complete and submit only one copy of the next pages.

IRB Protocol No:Due Date:

Title:

**CHECK THE APPROPRIATE CHOICES:** (Please type or print legibly)

 **Research project is completed / closed**

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

 **There have been changes to study protocol since last review (describe)**

Factors Pertaining to Closure of Study (check the one that applies):

\_\_ Research completed: Identifiable data or human biological specimens are stored according to plan already approved by the IRB.

\_\_ Research completed: All data or human biological specimens are deidentified.

\_\_ Lack of funding or other *(specify):*

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

**Part A:** Basic current information.

## A1. Principal Investigator

Name:

PI 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 who withdrew before they completed the protocol:

B3. Number of subjects who withdrew from the project in past 12 months:

 (Include reasons for withdrawal for each on separate sheet)

B4. Specifically identify all instances of untoward effects, complications or unexpected results of study activity. (append sheet and label “B4.” And include a short descriptive title)

B5. 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)

B6. Number and details of complaints by subjects or other entities. Describe how each was handled. (append sheet)

B7. 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 or community 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. Did you make any changes in this study or Consent Form? No Yes

If yes, please describe \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**P.I. Signature:** Date: