

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

This application is to report closure of a human subject’s 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: _____