RMT-IRB Research Protocol Application Coversheet

(This cover sheet must be submitted with your protocol).

Date: _____

Protocol Title: _____

Funding Agency: _____Funding Period: _____

OVERALL TOTAL GRANT AMOUNT and GRANTEE (if this Protocol is part of a larger grant project):

$_____ Grantee Organization: _____

Total Budget Amount: $_____Total Budget for Participating Tribes: $_____

Name of Principal Investigator/s: _____

Title/Affiliation of the PI: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____

Fax: _____

Email: _____

Name(s) of the Co-Principal Investigator(s):

_____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____

Email: _____

OFFICIAL RMT-IRB USE ONLY

Application Received: ____/____/____

Progress Report/s Received:

RMT-IRB Approval Date:____/____/____

Proposal ID#: RMT-_____-____

Annual Report: __/__/__

I.H.S Action Letter: ____/____/____

Publication Request: ____/____/_____

Continuation Request: __/__/__

Research Final Report:__/__/__

Submit Completed Application to:

Attention: RMT-IRB Coordinator
Rocky Mountain Tribal Leaders Council
2929 3rd Ave N, Suite 300
Billings, MT 59101

Guidelines for Submission

1. The proposal must include all of the necessary documents listed below in the order as listed in the Table of Contents before it will be accepted for review:
    a. 1a. Cover Sheet of the IRB Research Protocol Application
    b. 1b. Abstract
    c. Part 1: Community Involvement
    d. Part 2: Benefits to the Tribe(s)
    e. Part 3: Research Project Description
    f. Part 4: Informed Consent Form
    g. Part 5: Certification by the Principal Investigator
    h. Part 6: Attachments
        i. Curriculum Vitae of PI and or CO-PIs.
        ii. Approving Resolutions /Documents from Tribal Council (s).
        iii. Relevant Support Letters (from CEOs of Service Units, Tribal Program Directors, Tribal College Administration).
        iv. Copies of other approved IRB Letter(s).
        v. Certificate of Confidentiality (if necessary).
        vi. A copy of the written letter to the Tribal Historical Preservation Office (if applicable), and
        vii. Budget
2. One hard copy and one electronic copy of the research proposal/evaluation must be submitted to the RMT-IRB Office one month prior to the anticipated RMT-IRB review date. The office address and express package delivery address is:

    Attention: RMT-IRB Coordinator
    Rocky Mountain Tribal Leaders Council
    2929 3rd Ave N, Suite 300
    Billings, MT 59101

    Send electronic copies to: Irb.coordinator@rmtlc.org
3. Each proposal must follow a table of contents as outline on this page. Each page shall be numbered.
4. For particularly sensitive projects/subject matter or if experimental drugs/devices are to be used in the project, the proposal will be referred to an outside reviewer before the RMT-IRB reviews it.
5. The approval of the study is only for members of the Tribe(s) included in the application.
6. An RMT-IRB meeting schedule will be sent with the RMT-IRB Application.

Principal Investigator Role

The Principal Investigator must provide written responses to all of the following questions on the IRB application. If an item does not apply to your particular proposal, provide a statement as to the reason(s).

1. A one-page abstract written in simple clear language describing your proposed research or evaluation must be submitted to the RMT-IRB by email. The email address is Irb.coordinator@rmtlc.org . A copy may also be submitted by fax at (406) 254-6355 or United States Post Service (USPS). A curriculum vitae or resume for the PI and CO PIs must be submitted as documentation to support the qualifications of the project staff to successfully conduct the proposed research.
2. Documentation of support from duly authorized elected Tribal Leaders within the Tribe(s) included in the research site must be provided before the IRB review process can proceed. Tribal Resolutions supporting the project are preferred.
3. A support letter from the CEO or Director of the facilities where the research will take place must be obtained and included in your research proposal before the IRB review process can proceed.
    a. If your research is going to be conducted at an Indian Health Service facility, a support letter from the CEO must be obtained before the IRB review process can proceed.
    b. If your research is going to be conducted at a school, a support letter from the school principal/superintendent and a school board resolution must be obtained before the IRB review process can proceed.
4. A copy of the approval letter from other Institutional Review Boards that have approved the study or evaluation must be attached to your IRB application.
5. The RMT-IRB request that the PI(s) apply for the Certificate of Confidentiality from the Indian Health Service to ensure maximum protection for their study participants regarding their privacy (if applicable).
6. If any investigator is a federal employee or is conducting research under a contract or cooperative agreement and 10 or more people will be surveyed an or give a questionnaire, clearance from the Office of Management and Budget (OMB) is required for research survey activities.
7. A copy of a written statement to the local Tribal Health Director(s), Service Unit Director(s) and the RMT-IRB may be required depending on the Tribe involved in research. If applicable, the Privacy Act Coordinator attesting to the understanding of and willingness by the PI to abide by the provisions of the Privacy Act must be attached.
8. A copy of the budget for your research project must be attached to the IRB application. RMT-IRB wants to see that all benefit resulting from a project is shared and mutual (between the Tribe and the Researcher/research institution) so be sure to discern and specify amount of financial benefit to the Tribe/s involved.
9. If your research involves collection of historic information, use of ethnographic methods to collect data (focus groups), interviewed audio or video recordings, etc., you must contact the Tribe(s) Historic Preservation Office to secure approval.

10. The PI shall ensure that all contents of the IRB application are submitted prior to requesting placement on the RMT-IRB agenda.

Please answer each question and submit this with your Protocol Application to the RMT-IRB

Part One: Community Involvement

1. Indicate all of the locations where your project will be conducted.
2. Describe how the community members have been involved in the planning of your research/evaluation project.
3. Describe how the community members will be involved in the implementation of your research/evaluation project.
4. Describe how you plan to provide findings of the study/evaluation to health care providers, community agencies, schools, and other interested persons.
5. Briefly explain how you plan to provide technical assistance to the community that will help ameliorate any problems identified within the proposed project (writing grants, conducting in-service training sessions, developing education materials, assisting with the annual community/Tribal conference, and or donation of equipment).

Part Two: Benefits to the Tribe(s)

6. Explain specifically how the results of your study will be used to improve the health status of the Tribe(s).
7. Has this research been conducted elsewhere? If so, explain what the results were.
8. Has the study been conducted on the reservation(s)? If so, explain what the results were.
9. Has this study been coordinated with similar studies currently being conducted? If so, explain what plans will be made to ensure that necessary coordination occurs, and duplication is eliminated.

Part Three: Research Project Description

10. Describe the background and rationale for your research or evaluation project.
11. State the aims, objectives, and/ hypothesis of your proposed research or evaluation project. What are you trying to do or find out? Is your research question clear?
12. Describe the targeted participants who will be recruited for your project.
13. Explain the procedures to be used for participant recruitment, the selection criteria, and the exclusion criteria.
14. Explain the nature and procedures, if any, to be used for incentives for participation.
15. Describe the methods and the procedures for the study design, sampling, data gathering, data analysis, and plans for reporting the study results.
16. Describe the type and content of instrument (s) to be used for data collection. Copies of all instruments (s) to be used must be attached to your IRB application.

Part Four: Informed Consent Form

17. A copy of the Informed Consent Form must be attached to your IRB application that fully describes procedures to be used for Informed Consent to protect study participants from injury or harm or breach of confidentiality.
    a. Disclose the purpose of the research;
    b. State the expected duration of the subject's participation;

c. Describe the procedures to be followed, including the collection and testing of specimens, any reasonably foreseeable risks, or discomforts to the participants;
d. Describe the collection of any specimens (blood/tissue/hair/bodily fluids)
    i. What test(s) will you do;
    ii. How long you will keep the specimens;
    iii. How you will dispose of the specimens collected;
    iv. Ho you will maintain anonymity of the specimen collected, and;
    v. Any other data that will be linked to each specimen collected in your research.
e. Name any benefits from the research to the participants or others;
f. Describe the extent to which confidentiality of records identifying the participants will be protected;
g. Identify an individual to contact for answers to questions about the research and research participant's rights. The contact for the RMT-IRB is: Irb.coordinator@rmtlc.org or (406) 252-2550.
h. Identify a person to contact in the event of a research related injury to the participants, and;
i. Reiterate that participation in the research/evaluation is voluntary and shall not interfere with services available to the individual or to the rest of the population.
j. Explain any potential risks, psychological risks or discomforts to participants that may be associated with or that may result from participation in your research project.

Certification

I, _____, certify that I am the Principal Investigator or Co-Principal Investigator, of this proposed study or evaluation and that the statements made in this application are accurate and complete. I understand that all data collected as a result of this research study/evaluation is first and foremost the property of the Tribe(s).

- If I receive RMT-IRB approval for this project, I agree to inform the RMT-IRB office in writing of any adverse events immediately as they occur.
- If I receive RMT-IRB approval for this project, I agree to submit in writing any proposed procedural changes as amendments. I will be available in person to present modifications.
- I agree not to proceed in the research until the problems have been resolved or the RMT-IRB has reviewed and approved changes.
- I agree to comply with all the requirements of the RMT-IRB regarding the conduct of the approved research.
- I agree to submit three Quarterly Progress Reports and one Annual Report on research activity progress in addition to immediate reports of any significant proposed changes or problems.
- If the results of the research are to be used for an oral presentation at a conference, I agree to submit a copy of the abstract and a power point presentation to RMT-IRB and obtain approval for this presentation prior to making the presentation. Nothing should be published or distributed without said approval. I agree to provide a presentation to the Tribe(s) prior to presenting at a national or international conference.
- If I receive approval for this project and my study will extend beyond the annual approval period, I understand that I will have to submit a written request for continuation sixty days prior to the expiration of the RMT-IRB annual approval.
- I also agree to submit a final copy of a proposed manuscript for review and approval prior to publication to the RMT-IRB. I will disclose the name of the journal/publication; name of editor; address and telephone number and the anticipated date of the publication.

Principal Investigator: _____Date:_____

Informed Consent

Informed consent is a process that is generally documented with a consent form. Because subject understanding is a necessary component of informed consent, information must be presented in a language and at a level that is appropriate for the population. In general, consent documents should be written clearly and in lay language at a 6th - 8th grade level.

A copy of the Informed Consent Form must be attached to the IRB application that fully describes procedures to be used for Informed Consent to protect study participants from injury or harm or breach of confidentiality.

- Disclose the purpose of the research;
- State any risk of harm to the participant;
- State the expected duration of the subject's participation;
- Describe the procedures to be followed, including the collection and testing of specimens, any reasonably foreseeable risks, or discomforts to the participants;
- Describe the collection of any specimens (blood/tissue/hair/bodily fluids)
- What test(s) will you do;
- How long you will keep the specimens secure;
- How you will dispose of the specimens collected;
- How you will maintain anonymity of the specimen collected, and;
- Any other data that will be linked to each specimen collected in your research.
- Name any benefits from the research to the participants or others;
- Describe the extent to which confidentiality of records identifying the participants will be protected;
- Identify an individual to contact for answers to questions about the research and research participant's rights. The contact for the RMT-IRB is: RMT-IRB Coordinator, 2929 3rd Ave N, Suite 300, Billings Montana 59101 (406) 252-2550 and IRB.coordinator@rmtlc.org.
- Identify a person to contact in the event of a research related injury to the participants, and;
- Reiterate that participation in the research/evaluation is voluntary and should not interfere with services available to the rest of the population.
- Explain any potential risks, psychological risks or discomforts to participants that may be associated with or that may result from participation in your research project.
- Documentation of Informed Consent

The IRB may approve procedures for documentation of informed consent that involve either (i) a written consent form signed by the subject or the subject's legally authorized representative (LAR), (ii) short form written consent form with oral presentation, or (iii) a waiver of signed consent.

Written Consent Form Signed by Subject or the Subject's Legally Authorized Representative

In most circumstances, the IRB will require that informed consent be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's LAR [45 CFR 46.117(b)(1)]. This document may also be read to the subject or the subject's LAR. The investigator should allow the subject or LAR adequate opportunity to read and discuss the consent document before being asked to sign. A copy of the consent document must be given to the person signing the form. Subjects who do not speak English should be presented with an informed consent document that is written in a language understandable to them. In cases where the investigator can

anticipate the need for translated consent documents, these documents should be included with the IRB submission packet together with the English versions of the consent documents.

Oral Presentation Using Short Form

In some cases, it may be more appropriate to use the short form procedure to obtain consent from subjects [45 CFR 46.117(b) (2)]. The short form procedure includes the following two pieces:
A "short form" written informed consent document stating that the elements of consent have been presented orally to the subject or the subject's LAR; and

A written summary of the information that is presented orally. A witness to the oral presentation is required. The witness must sign both the short form written informed consent document and a copy of the written summary. The subject or the LAR must sign the short form written consent document. The person obtaining consent must sign a copy of the written summary of the information that is presented orally.

Where informed consent is documented using this short form procedure for non-English speaking subjects, the written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written informed consent document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject. The IRB must review and approve all foreign language versions of the short form document before they can be used.

Waivers and Alterations

Waiver of Documentation of Written Informed Consent

An investigator may request and/or the IRB may grant a waiver of the requirement for the investigator to obtain signed consent for some or all subjects if either of the following two conditions are met:

The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality. When written consent is waived under this section, each subject must be asked if they would like to sign a consent document and the subject's wishes will govern. [45 CFR 46.117(c) (1)]; OR

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. [45 CFR 46.117(c) (2)]

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver or Alteration of Informed Consent

The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration would not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Third Party Consent

When an investigator conducting research obtains identifiable private information about a living individual and or community, that individual/community becomes a research subject, regardless of whether that person/place is the individual/community with whom the investigator is having an interaction. For example, if the research involves asking the primary subject to provide identifiable private information about a third party, that third party then becomes a subject in the research. As such, all of the regulatory requirements for protecting that individual must be obtained.

The IRB can determine whether informed consent needs to be sought from third party subjects, or whether it can be waived. In making this determination, the IRB relies on both the requirements for a waiver (noted earlier in this section) and the importance of the information to the research. Investigators whose research may involve so-called secondary subjects are encouraged to contact the RMT-IRB Staff to discuss how to best protect the rights and welfare of these subjects in a given project.

Privacy and Confidentiality

Investigators sometimes want access to existing records in order to identify potential subjects, or in order to conduct research. If the investigator will record subjects' names (either for further record review or for personal contact), this activity requires IRB review. The IRB will determine whether the consent of subjects should be sought before the researcher gains access to the records (in some cases, a waiver can be granted – see section on waivers). In determining whether it is appropriate to waive the requirement to obtain consent from these subjects, the IRB considers the sensitivity of the information being recorded, the vulnerability of the subject population, and the purpose for which the investigator wants access to the information.

In some cases, consent cannot be waived. For example, the Buckley Amendment [the General Education Provisions Act (20 USC 1232)-also known as FERPA, Appendix A, requires written parental permission for release of records or identifiable information about children in public schools.

Certificate of Confidentiality to protect the data from subpoena, see Appendix B. Research in which the primary risk to subjects is from breach of confidentiality, and in which no identifiable information will be recorded save the consent document, is eligible for a waiver of signed consent (see above).

Appendix A: FERPA

For information regarding FERPA please access the following link:
http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

Appendix B: Certificate of Confidentiality

For information regarding Certificates of Confidentiality please access the following link:
http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm