**MONTANA STATE UNIVERSITY**

**Request for Designation of Research as Exempt from the**

**Requirement of Institutional Review Board Review**

*(2/1/2020)*

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THIS AREA IS FOR INSTITUTIONAL REVIEW BOARD USE ONLY. DO NOT WRITE IN THIS AREA.

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**DATE:**

I. INVESTIGATOR(s):

 Name:

 MSU Department:

 Telephone:

 E-Mail Address:

 DATE TRAINING COMPLETED:*[Required training: CITI training; see website for link]*

 Name of Faculty Sponsor (if above is a student; also must complete CITI training):

 SIGNATURE (INVESTIGATOR or ADVISOR): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 (If more than one investigator, repeat information for all investigators or team members.)

**Conflict of Interest Statement**

Do the investigator(s) or other researchers involved in research design, conduct, or reporting (and their family

members) have an outside interest related to the research?

*An “interest” may include compensation such as salary, a payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship), an equity interest, management responsibilities, board membership, or related non-University intellectual property rights and interests (e.g., patents, copyrights).*

\_\_\_\_\_ YES \_\_\_\_\_ NO

*If Yes, please contact the Office of Research Compliance at 406-994-6757 for further guidance.*

II. TITLE OF RESEARCH PROJECT:

III. BRIEF DESCRIPTION OF RESEARCH METHODS (also see section VII). If using a survey/questionnaire,

 provide a copy with this application.

IV. RISKS AND INCONVENIENCES TO SUBJECTS (also see section VII; **do not answer ‘None’**):

V. SUBJECTS:

 A. Expected numbers of subjects: \_\_\_\_\_\_\_\_\_\_

 B. Will research involve minors (age <18 years)? Yes No

 (If 'Yes', please specify and justify.)

 C. Will research involve prisoners? Yes No

1. Will research involve any specific ethnic, racial, religious, etc. groups of people?

 (If 'Yes', please specify and justify.) Yes No

1. Will a consent form be used? (Please use accepted format from our website. Be sure to indicate that participation is voluntary. Provide a stand-alone copy. Do not include the form here.)

VI. FOR RESEARCH INVOLVING SURVEYS OR QUESTIONNAIRES:

 (Be sure to indicate on each instrument, survey or questionnaire that participation is voluntary.)

 A. Is information being collected about:

 Sexual behavior? Yes No

 Criminal behavior? Yes No

 Alcohol or substance abuse? Yes No

 Matters affecting employment? Yes No

 Matters relating to civil litigation? Yes No

1. Will the information obtained be completely anonymous, with no identifying information linked to the responding subjects? Yes No

1. If identifying information will be linked to the responding subjects, how will the subjects be identified? (Please circle or bold your answers)

 By name Yes No

 By code Yes No

 By other identifying information Yes No

1. Does this survey utilize a standardized and/or validated survey tool/questionnaire? Yes No

VII. FOR RESEARCH BEING CONDUCTED IN A CLASSROOM SETTING:

1. Will research involve blood draws? (If Yes, please follow protocol listed in the “Guidelines for Describing Risks: blood, etc.”, section I-VI.)

VIII. FOR RESEARCH INVOLVING PATIENT INFORMATION, MATERIALS, BLOOD OR TISSUE

 SPECIMENS RECEIVED FROM OTHER INSTITUTIONS:

 A. Are these materials linked in any way to the patient (code, identifier, or other link to

 patient identity)? Yes No

 B. Are you involved in the design of the study for which the materials are being collected?

 Yes No

 C. Will your name appear on publications resulting from this research?

 Yes No

 D. Where are the subjects from whom this material is being collected?

 E. Has an IRB at the institution releasing this material reviewed the proposed project?

 (If 'Yes", please provide documentation.) Yes No

F. Regarding the above materials or data, will you be:

 Collecting them Yes No

 Receiving them Yes No

 Sending them Yes No

 G. Do the materials already exist? Yes No

 H. Are the materials being collected for the purpose of this study? Yes No

1. Do the materials come from subjects who are:

 Minors Yes No

 Prisoners Yes No

 Pregnant women Yes No

1. Does this material originate from a patient population that, for religious or other reasons,

 would prohibit its use in biomedical research?

 Yes No Unknown source

IX. FOR RESEARCH INVOLVING MEDICAL AND/OR INSURANCE RECORDS

1. Does this research involve the use of:

 Medical, psychiatric and/or psychological records Yes No

 Health insurance records Yes No

 Any other records containing information regarding personal health and illness Yes No

If you answered "Yes" to any of the items in this section, you must complete the HIPAA Worksheet.