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Office for Human Research Protections
The Tower Building
1101 Wootton Parkway, Suite 200
Rockville, Maryland 20852
Telephone: 301-496-7005
FAX: 301-492-8537

RECEIVED

FEB 03 2004

VP for Research
MSU - Bozeman

January 29, 2004

Thomes J McCoy, Ph.D.
Vice President for Research & Creativity
Montana State University
207 Montana Hall
Bozeman, MT 59717

Dear Sir or Madam:

The Office for Human Research Protections (OHRP) has approved the Federalwide Assurance (FWA) submitted by your institution. The identification number assigned to your institution's FWA is FWA00000165. This number will be required on certain forms; e.g., for certification of IRB review to funding authorities. A copy of the approved FWA is enclosed. Please be sure that any party within your institution that may have an interest in this document also receives a copy.

Your institution's FWA is approved for a period of 3 years, and must be renewed prior to the expiration date to keep it active. Any change (update) in the information provided in your FWA should be submitted to OHRP when the change occurs. To renew or update the FWA, please submit the FWA form, marking it appropriately in the upper right-hand corner as either a renewal or an update. Renewals and updates may be faxed to OHRP at (301) 402-0527.

Human subjects research for which this FWA applies may not be initiated at your institution until the research is reviewed by one of the institutional review boards (IRB) designated on your FWA. Your institution is responsible for ensuring that all collaborators on federally-conducted or -supported human subjects research, that is not otherwise exempt, have an assurance of compliance approved by OHRP or another OHRP acceptable means of assuring compliance (e.g., Unaffiliated Investigator Agreement).

The Terms of Assurance set out your institution's responsibilities for protecting human subjects in research, as well as the procedures that will be used to ensure these protections. If at any time you have any question about your FWA, please contact OHRP. For your information, federal regulations, policies, and guidance on the conduct of human subjects research may be found on the OHRP website at <http://ohrp.osophs.dhhs.gov/>.

Sincerely,

Janice Ferrara Walden, CIP
Team Leader – Assurances/IRB Registrations
Division of Policy and Assurances

New Filing

Update or Renewal for FWA Number: FWA00000165

**U. S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions**

1. Institution Filing Assurance

Legal Name: Montana State University

City: Bozeman State: MT

DHHS Institution Profile File (IPF) code, if known: 1381004

Federal Entity Identification Number (EIN), if known: 81-6001649

If this Assurance replaces an MPA or CPA, please provide the "M" or "T" number:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official is not legally authorized to represent may not be listed here without the prior approval of OHRP.

Please check here if there are no such components or alternate names.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)

3. Statement of Principles

This Institution assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the following document(s). (*indicate below*)

The Belmont Report

Other: (Please submit copy to OHRP with this Assurance)

4. Applicability

(a) This institution assures that all of its activities related to federally-conducted or -supported human subject research will comply with the **Terms of Assurance for Protection of Human Subjects for Institutions Within the United States**. NOTE: The Terms of Assurance are contained in a separate document on the OHRP website.

(b) *Optional:* This institution elects to apply the following to all of its human subject research regardless of source of support:

45 CFR 46 and all of its subparts (A,B,C,D)

Common Rule (e.g., 45 CFR 46, subpart A)

5. Designation of Institutional Review Boards (IRBs)

This institution designates the following IRB(s) for review of research under this Assurance (*if the IRB is not previously registered with DHHS or has not provided a membership roster to DHHS, please attach the necessary materials available elsewhere on this website*).

NOTE: Reliance on another institution's IRB or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the institutions involved may develop their own agreement. Future designation of other IRBs requires update of the FWA.

DHHS IRB Registration Number	Name of IRB As Registered with DHHS
IRB00000799	Montana State University-Bozeman IRB#1

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Mark Middle Initial: Last Name: Quinn

Degrees or Suffix (e.g., MD, PhD): PhD Institutional Title: Assoc. Prof., Veterinary Molecular Biology

Institution: Montana State University

Telephone: 406-994-5721 FAX: 406-994-4303 E-Mail: mquinn@montana.edu

Address: 247 Biomedical Research Building

City: Bozeman State: MT Zip Code: 59717

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution -- cannot be IRB Chairperson or IRB member)

file NPA

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing all research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide oversight for all research conducted under this Assurance. These IRB(s) will comply with the **Terms of the Assurance** and possess appropriate knowledge of the local context in which this Institution's research will be conducted. I understand that all collaborating institutions engaged in federally-conducted or -supported human subject research must submit their own Assurance.

All information provided with this Assurance is up to date and accurate. *I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.*

Signature 

Date: 1/15/04

First Name: Tom Middle Initial: Last Name: McCoy

Degrees or Suffix (e.g., MD, PhD): PhD Institutional Title: Vice President for Research

Telephone: 406-994-2891 FAX: 406-994-2893 E-Mail: tommccoy@montana.edu

Address: 207 Montana Hall

City: Bozeman State: MT Zip Code: 59717-2460

NOTE: Facilities operated by the U.S. Government may require Department or Agency clearance. Please contact the relevant Department or Agency Human Protections Officer before forwarding this Assurance to OHRP.

(8) DHHS Approval

The Federalwide Assurance of Protection for Human Subjects submitted to DHHS by the above Institution is hereby approved.

Assurance Number: FWA00000165 Expiration Date: 1-21-2007

Signature of DHHS Approving Official:  Date: 1-21-2004

Hal Blatt, D.D.S.
OHRP/OPHS/OS/DHHS
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Rockville, MD 20852
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