University of Idaho
2009-2010
FACULTY SENATE AGENDA

Meeting #22

3:30 p.m.
Tuesday, March 2, 2010
BRINK HALL FACULTY LOUNGE

Order of Business

I. Call to Order.

II. Minutes.
   • Minutes of the 2009-10 Faculty Senate Meeting #21, February 23, 2010

III. Chair’s Report.

IV. Provost’s Report.

V. Other Announcements and Communications.
   • FS-10-037:  APM 45.01 Animal Care & Use (McConnell)
   • FS-10-038a: FSH 1640.12 Animal Care & Use Committee (McConnell)
   • FS-10-038b: 1640.14 Biosafety Committee
   • FS-10-038c: 1640.54 Institutional Review Board
   • FS-10-039: FSH 5200: Human Participant Research (McConnell)

VI. Committee Reports.

VII. Special Orders.
   • Furlough Discussion Plan Q&A (Ickes, Mues)

VIII. Unfinished Business and General Orders.

IX. New Business.

X. Adjournment.

Professor Jack Miller, Chair 2009-2010, Faculty Senate

Attachments:
FS 2009-10 Minutes #21
FS-10-037 through FS-10-039
University of Idaho  
Faculty Senate Meeting Minutes  
2009-10 Meeting #21  
Tuesday February 23, 2010

Present: Baillargeon, Baird, Baker (w/o vote), Barlow, Battaglia, Edwards, Eveleth, Fritz, Graden, Hill (w/o vote), Holbrook, Huber, Joyce, Marshall, Mihelich, Miller (chair), Padaghm-Albrecht, Williams.  
Campus Center Senators: Budwig (Boise), Dakins (Idaho Falls), Newcombe (Coeur d’Alene).  
Absent: Geist, Guilfoyle, Limbaugh, Murphy, Stark, Horn, Wilson.  
Guests: 5.

A quorum being present, the Chair opened the meeting at 3:30 p.m.

Minutes: It was moved (Marshall/Battaglia) to accept the minutes of meeting #20 of the Faculty Senate. Approved.

Chair’s Report: Having attended the State Board of Education meeting last week to present on behalf of the faculty during hearings concerning policy changes to SECTION: II. HUMAN RESOURCES POLICIES AND PROCEDURES Subsection: B. Appointment Authority and Procedures. The chair reported that the essence of the action were minor changes, including some procedural changes, compared to the first reading. Language was inserted under II. B. 2 (c) Without limiting the general description of b. above, the authority delegated to each chief executive officer includes the authority, in the chief executive officer’s discretion, to reduce expenditures to respond to financial challenges (without a financial exigency declaration by the Board) and to maintain sound fiscal management. In such cases, the chief executive officer may take employment actions which are uniform across the entire institution, or uniform across institution budgetary units, but may not include actions requiring a financial exigency declaration by the Board. Such actions may include work hour adjustments such as furloughs or other unpaid leave as long as such are uniform across budgetary units or uniformly tiered as applied to certain salary levels or classifications. Work hour adjustments may be pro-rated based on annual salary levels to equitably reduce the financial hardship of the adjustments on lower level employees. Institutions shall adopt internal policies for implementing the employment actions in a manner consistent with the Board’s policies and procedures, and furnish these policies to the Board.” providing for the development of a written policy within the institution that would presumably be reviewed by the senate during the implementation process. With this structure around the implementation of furloughs, there would be checks and balances that would allow faculty and staff input.

To summarize, the changes to the SBOE policy affect employees in three groups: faculty, exempt and non-classified employees. For all groups there are two major aspects enabled in the policy: employees are not guaranteed next year’s salary at the level of this year’s salary and subject to financial exigency, salaries are subject to adjustment within a year.

The Provost believed that this change in policy changed very little in the previously existing situation. Provision for furloughs were built into faculty contracts that were implemented at the beginning of the academic year.

The Chair was concerned because if there was an intent to reduce salaries from one year to the next, there was little structure, checks or balances around the language in sub-sections F and G, unlike subsection B, describing furloughs as outlined above. He added that in the policy description in this section there was nothing to stop a president from singling out individuals for salary cuts.
The Provost responded wanting to go on record to say that he could not see any case in which a president would single out any individual. The Chair agreed.

The Chair also described the session he attended with state legislators. Only three legislators attended the function. These were representatives of the Republican Party that he understood to have widespread ties to a majority of state legislators. The messages that they conveyed were: Their role in the budget process is to ensure a balanced budget. This would be achieved by cutting expenditures to match the predicted revenues for FY11. Furthermore, the legislators did not support the notion of fee increases and proposed that the university would need to cope with much reduced revenues until the economy self-recovered. It was not up to government to intervene in the financial recovery, rather this should be a process driven by free market forces.

The Chair noted that his view was that we would clearly need to tighten our belts and look to finding solutions ourselves. He saw the factors that would affect the UI budget in FY11 and would be a central focus for us to be: changes in enrollment, fee increases and the possibility of further mid-year state hold-backs.

**Provost’s Report:** The Provost noted that the UI had dealt with state funding cuts totaling close to 20% in the last two years. The collaboration of the senate through faculty governance with administration had been very effective in reducing the impact of the cuts with over 40 programs cut in the previous year. He foresaw that we are well-positioned to move forward, giving the examples of the new research initiatives presently being implemented by VPR McIver.

In reflecting the position of Idaho legislators, the Provosts view was consistent with that expressed by the Chair. He considered that the total hold-back for FY10 was likely to be of the order of 10%, and state budget discussions in Boise were still in progress.

Next week, UI will provide $11 million in scholarships to our students. The ways that scholarships are awarded does require review such that those students with the greatest need receive priority.

The Provost thanked the student body for collaboration in the recent fee-setting exercise that proposes an overall 12% increase in student fees for FY11. The Chair added that the SBOE standing policy with a cap on allowable requests for fee increases of 10% had been temporarily lifted. The Provost thanked the students for thoughtful insight into fee requests: for example the request for the activity fee was increased only 1.8% to help offset the matriculation fee request that was considerably higher. This was reasoned on a sound basis to support increases in areas where they were most needed.

The work that had been done on student retention was paying dividends. One of few times in UI history, spring enrollment had exceeded fall enrollment numbers. Vandal Friday marks a very important student recruitment period coming up. In addition, there will be three follow-up enrollment days in April to provide assistance to students who could not make the Vandal Friday date.

In referring to his Efficiency Memo of last August, the Provost provided a brief outline of his comments in response to senate recommendations that will soon be followed up with a more complete written response.

- Course sections/class sizes: This needed much better management as UI had hundreds of small sections. Changes had been made including consolidating classes, increasing collaboration with WSU with a few classes possibly being eliminated.
• Department/Unit size: Presently the College of Education was considering reducing the number of departments from four to two. The College of Art and Architecture would soon be bringing an NOI forward that would eliminate all departments in the college. The College of Natural Resources changes had just recently been passed by the senate. The change in department chair appointments to nine-month contract appointments with equitable remuneration for additional summer time worked had been implemented.

• Y accounts: The Provost noted that the UI carry-forward funds, of which Y accounts were a part, had recently been in the news under the notice of the legislature. It was very important to be clear that these funds would be budgeted over the next three years. He wished to implement a system that would not be onerously heavy with documentation and was seeking advice from the Budget Office to develop a workable tracking system.

• Open salary lines: He agreed with senate’s support for the first 25% of funds from open lines to be directed to a reserve fund.

A senator asked whether all Y accounts would be treated in the same way or would only accounts holding funds in excess of the senate recommended $25,000 limit be budgeted? The Provost would prefer to see the floor lower. It is important to be able to justify the purposes intended for funds being held in these accounts.

The Lionel Hampton Jazz Festival is to be held this week. This is the world’s best educational jazz festival with over 10,000 visiting students coming to campus this week. The Provost encouraged the community to attend as many of the activities possible. He noted that there would be some high profile visitors whose visits were timed to coincide with the festival. Former Chief Counsel of the Securities and Exchange Commission, Larry Grimes, would be a visitor this week. He encouraged senators to go out to visit the student training sessions.

Senator Baird (Dean of the Library) also noted that Art and Architecture students had done an outstanding job at decorating the library with Jazz Clocks and encouraged all to visit the display.

In closing, the Provost noted that he would be attending the National Society of Black Engineering Students’ guest seminar to be given by Dr. Gary S. May, the Steve Chaddick Endowed Chair in Computer and Electrical Engineering at Georgia Institute of Technology. The presentation was this evening at the Best Western Hotel and he encouraged attendance.

The Chair added that it was expected that next week the President would announce details of furloughs. His impression was that the target figure to be funded from savings from furloughs was $1.4 million.

The Provost noted that the President had held a meeting with the faculty leadership yesterday and was continuing to seek feedback from groups across the UI community.

College of Art and Architecture – forthcoming NOI. The Provost spoke on behalf of Dean Hoversten. The College had been working for about a year on a new structure. The announcement was to let senate know that an NOI would be forthcoming. The intention was to have the proposed changes in place for next fall.

FS-10-036 – Distinguished Professorship. It was noted that this item had come to senate without a vote from Faculty Affairs Committee. FAC was neither in support nor against the proposal. Their recommendations were: 1) that the stipend associated with the award, as proposed ($5,000) was too little to be meaningful and suggested that $10,000 to $15,000 per year would be a more suitable
It was moved (Miller/Eveleth) to adopt the University Distinguished Professor award in policy as distributed.

The intention of the award was to honor distinguished faculty who had gained national/international recognition in their field. The honor would be bestowed with a stipend for five years and the title would be held for the remainder of active service of the recipient. The President favored such awards and would fund them through private discretionary funds. Thus, there would be no burden on institutional budgets. The Provost noted that the award had first been suggested several years ago by the Goal 2 strategic plan implementation team. Two senators had served on that team and supported the notion of the award. There being no further discussion, the question was called. Eighteen in favor. Approved.

**FS Meeting Start Time (for fall 2010).** It had previously been suggested that a 2:30 start time would be a courtesy to Center senators in southern Idaho (Mountain time-zone). Several Moscow senators suggested that the earlier start time was problematic for many faculty who were locked into class times and a 2:30 start would prevent them from running for senate membership. The southern Idaho senators noted that many faculty in southern Idaho taught night classes and the usual 6:00 pm finish was not a problem for them. It was decided by consensus to no longer pursue the earlier meeting start time.

**Furlough Discussion – benefits status.** It was considered that health benefits contributions would not be affected by implementation of furloughs. There was uncertainty about whether there might be an effect on retirement benefits. The Provost would investigate and report back to senate on this issue.

**Adjournment:** It was moved (Fritz/Edwards) to adjourn at 4:28 p.m. The motion carried unanimously.

Respectfully submitted,

Rodney A. Hill, Faculty Secretary and Secretary to Faculty Senate.
POLICY COVER SHEET
(See Faculty Staff Handbook 1460 for instructions at UI policy website: www.webs.uidaho.edu/uipolicy)

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<td>Chapter &amp; Title:</td>
<td>Chapter 45.1 -- Animal Care and Use</td>
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All policies must be reviewed, approved and returned by a policy sponsor, with a cover sheet attached to apm@uidaho.edu or fsh@uidaho.edu respectively.

*Note: If revision/deletion request original document from apm@uidaho.edu or fsh@uidaho.edu, all changes must be made using “track changes.”

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<tr>
<th>Originator(s):</th>
<th>Brad Williams, DVM 10/20/2009</th>
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<tr>
<td>Telephone &amp; Email:</td>
<td>208-885-8958 <a href="mailto:bradw@uidaho.edu">bradw@uidaho.edu</a></td>
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<tr>
<td>Telephone &amp; Email:</td>
<td>208-885-6340 <a href="mailto:lmcconnell@uidaho.edu">lmcconnell@uidaho.edu</a></td>
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| Reviewed by General Counsel | ____Yes ____No Name & Date: Kent Nelson 12/20/09 |

I. Policy/Procedure Statement: Briefly explain the purpose/reason of proposed addition, revision, and/or deletion to the Faculty/Staff Handbook or the Administrative Procedures Manual.

This policy sets forth the policy and procedures for the University of Idaho to ensure compliance with federal and state laws, statutes and regulations regarding the care and use of animal in research, teaching, demonstrations, and testing.

II. Fiscal Impact: What fiscal impact, if any, will this addition, revision, or deletion have?

No change from currently implemented policies and procedures. Policy provides written authority and procedures for practices currently implemented.

III. Related Policies/Procedures: Describe other policies or procedures existing that are related or similar to this proposed change.

Ensures conditions of sponsors are met under APM Chapter 45 – Office of Sponsored Programs. Purchasing Services APM 60.44 – Animal Purchases; FSH 1640.12 – include reference to this policy.

IV. Effective Date: This policy shall be effective on July 1, or January 1, whichever arrives first after final approval (see FSH 1460 D) unless otherwise specified in the policy.

If not a minor amendment forward to: ___________________________

Track #: UP-10-036

Date Rec.: __12/21/09___

Register: ______________

(Faculty Use Only)
Chapter 45.01 -- Animal Care and Use
January 7, 2010

Preamble: This policy sets forth the policy and procedures for the University of Idaho to ensure compliance with federal and state laws, statutes and regulations regarding the care and use of animals in research, teaching, demonstrations, and testing.

Contents:

A. Definitions
B. Authority
C. Components
D. Animal Procurement and Care
E. Occupational Health
F. Exceptions
G. Contact Information

A. Definitions.


A-2. Animal Activity. Animal activity means teaching, research, demonstration or testing procedures using live or dead animals that are performed on University owned property or engaged in by University personnel. University Owned Property excludes land and facilities leased to third parties for commercial enterprise purposes.

A-3. Personnel. Personnel includes all University employees, students, and volunteers working on University sanctioned activities.

B. Authority.

B-1. The University maintains policies and procedures to ensure compliance with the Animal Welfare Act (Title 7 CFR, Chapter 54), the Health Research Extension Act of 1985 (Public Law 99-158), the U.S. Government Principles for the Utilization and Care of Vertebrate Animals in Testing, Research and Training, and Title 25 (Animals) of the Idaho Statutes.

B-2. All personnel engaged in animal activities must comply with this policy.

C. Components.

C-1. Institutional Official.

a. The Institutional Official is appointed in writing by the President. The Institutional Official is authorized on behalf of the President to ensure that all programmatic and regulatory requirements of animal activities are met.
C-2. **Institutional Animal Care and Use Committee** (see FSH 1640.12).

   a. The University’s institutional Animal Care and Use Committee (IACUC) is granted all rights and responsibilities as defined under federal, state and local law by the President.

   b. The IACUC’s responsibilities include but are not limited to:

      (1) Reviewing, at least once every six months, the University’s program for the humane care and use of animals and the status of the institution’s animal facilities, including satellite facilities, laboratories and areas where survival surgery is conducted.  
      (2) Reviewing and approving, requiring modifications to secure approval, or withholding approval of animal activities.  
      (3) Development of procedures and guidelines based on Federal, State, and University policies.  
      (4) Investigating reported concerns regarding the care and use of animals within the University.
      (5) Advising the Institutional Official regarding all aspects of the University of Idaho animal care and use program.

   c. Only procedures reviewed and approved by the IACUC may be conducted. IACUC approved activities may be subject to further review and approval by university officials; however, those officials may not approve any animal activity if it has not been approved by the IACUC.

C-3. **Attending Veterinarian**

   a. The Attending Veterinarian (AV) has direct or delegated authority for animal activities in the University. The AV is responsible for oversight of animal disease control and prevention, euthanasia, the appropriate use of pain relieving drugs, and other aspects of veterinary care.

   b. The AV is an ex officio member of the IACUC.

   c. The AV has appropriate authority to ensure the provision of adequate veterinary care and oversee the adequacy of other aspects of animal care and use.

D. **Animal Procurement, Care and Disposition.**

D-1. **Procurement**

   a. Animals may not be procured for, or transferred to, personnel who do not have IACUC approval.

   b. Animal procurement and disposition must be in accordance with Purchasing Services (APM 60.44) and IACUC policies and procedures.
D-2. Housing, Care and Disposition.
   a. The housing and care of animals must be in accordance with IACUC policies and procedures.
   b. Animals must be disposed in accordance with federal, state and IACUC policies and procedures.

E. Occupational Health
   E-1. An occupational health and safety program is provided through the Safety Office.
   E-2. Paid personnel participating in animal activities may not be denied participation in the occupational health and safety program.

F. Exceptions
   F-1. Veterinary Teaching Curriculum.
      a. Veterinary medical care provided by veterinarians and veterinary staff and students under veterinary supervision at the Caine Veterinary Teaching Center to client owned animals is not regulated by this policy.
   F-2. Authority to Grant Exceptions.
      a. Exceptions to this policy may only be granted by the Institutional Official for Animal Care and Use.

G. Contact Information. For further information regarding implementation of this policy see the institutional animal care and use committee website or contact the committee (iacuc@uidaho.edu, 208-885-8958).
POLICY COVER SHEET

(See Faculty Staff Handbook 1460 for instructions at UI policy website: www.webs.uidaho.edu/uipolicy) [3/09]

Faculty/Staff Handbook [FSH] ☐ Addition X Revision* ☐ Deletion* ☐ Emergency

Minor Amendment ☐

Chapter & Title: 1640.54, “Institutional Review Board (IRB); 1640.14, “Institutional Biosafety Committee (IBC)”;& 1640.12, “Institutional Animal Care and Use Committee (IACUC)”

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*Note: If revision/deletion request original document from apm@uidaho.edu or fsh@uidaho.edu, all changes must be made using “track changes.”

Originator(s): (Please see FSH 1460 C)

Office of Research Assurances Feb. 25, 2010

Name Date
208-885-6340 lmconnell@uidaho.edu

Policy Sponsor: (If different than originator.)

Research Council, IRB, IBC & IACUC committees

Name Date
208-885-4989 jmcliver@uidaho.edu

Reviewed by General Counsel

X Yes No Name & Date: Kent Nelson February 12, 2010

I. Policy/Procedure Statement: Briefly explain the purpose/reason of proposed addition, revision, and/or deletion to the Faculty/Staff Handbook or the Administrative Procedures Manual.

Revisions were made to align committee structures and functions with federal regulations, current UI: Federal Wide Assurance for Human Subjects/Participants Research. Animal Welfare Assurance for Animal Research and University policy. The IRB board reviewed and approved the proposed function and structure changes; for IBC and IACUC only the chairs were consulted: Eva Top and Scott (Sam) Minnich.

II. Fiscal Impact: What fiscal impact, if any, will this addition, revision, or deletion have?

None

III. Related Policies/Procedures: Describe other policies or procedures existing that are related or similar to this proposed change.

FSH 5200, APM 45.01, APM 35.11

IV. Effective Date: This policy shall be effective on July 1, or January 1, whichever arrives first after final approval (see FSH 1460 D) unless otherwise specified in the policy.

If not a minor amendment forward to: ________________________________

Track #: ______________

Date Rec.: ______________

Posted: t-sheet __________ h/c

web ______________

Register: ______________

(Office Use Only)

Policy Coordinator

Appr. & Date:

FSH

Appr. ______________

FC ______________

GFM ______________

Pres./Prov. ______________

[Office Use Only]

APM

F&A Appr.: ______________

[Office Use Only]
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

A. FUNCTION. To perform the functions of the IACUC as defined in Chapter 45.1 of the Administrative Procedure Manual.

To recommend policies and procedures to the vice president for research regarding care of experimental animals, allocations that will ensure accreditation of UI as an agency using experimental animals, and criteria for the allocation of resources in the Laboratory Animal Research Facility.[ed. 7-06, rev. 2-10]

B. STRUCTURE.

B-1. Members are appointed to three year terms by the Institutional Official (IO). To provide the necessary expertise and continuity members may serve successive terms with reappointment by the IO.

B-2. The committee is composed of not less than seven voting members including the Campus Veterinarian; the Manager of the Laboratory Animal Research Facility; a public member who is not employed by the UI, is not a laboratory animal user, is not an immediate family member of an individual affiliated with the UI, and is not a practicing scientist experienced in research involving animals; one member of the faculty or staff with responsibilities involving the utilization of animals in teaching or research from each of the following - the College of Agriculture and Life Sciences, the College of Natural Resources, the College of Science, and one member at large. The public member/non-scientist position may be fulfilled by two individuals at the discretion of the IO, (Guide for the Care and Use of Laboratory Animals).

B-3. Alternates that meet the criteria for each of the specified positions may be appointed by the IO.

B-4. The Chief Research Compliance Officer serves as a standing member without vote.

B-5. The IO may remove and replace a committee member at any time when the IO has determined that the member is unwilling or unable to perform committee member functions.
A member of the faculty or staff of the College of Agricultural and Life Sciences, one from the College of Natural Resources, one from the College of Science, one member-at-large (these college representatives must have responsibilities involving the utilization of animals in teaching or research); one person who holds the D.V.M. degree and is trained and experienced in the proper care, handling, and use of the species being maintained or studied; one person who is not employed by UI and is not a scientist; the supervisor of the Laboratory Animal Research Facility; and the following without vote: vice president for research, or designee, and head of the Department of Animal and Veterinary Science. Members are nominated by the vice president for research and, to provide necessary expertise and continuity, may serve successive terms. [ed. 7-00, 7-03, 7-06, rev. 7-08, rev. 2-10]
INSTITUTIONAL BIOSAFETY HAZARDS COMMITTEE (IBC)

A. FUNCTION.
On behalf of the University, the Institutional Biosafety Committee (IBC) is responsible for:

1. Reviewing and approving potentially biohazardous material research, including infectious agents (humans, plants, animals) or biological agents with potential harm to the environment, Select Agent and Toxins and recombinant DNA activities conducted at or sponsored by the institution for compliance with the Select Agent Regulations, the NIH Guidelines, (NIH) and alignment with best practices as provided in the Biosafety in Microbiological and Biomedical Laboratories, (BMBL) and other appropriate best practices. This review shall include: (i) independent assessment of the containment levels appropriate for the proposed research; (ii) assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research. As appropriate consultants may be utilized to assist the IBC. (NIH section IV-B-2-b-1) & (University Biosafety Policy).

2. Notifying the Principal Investigator of the results of the Biohazard Committee’s review and approval. (NIH section IV-B-2-b-2)

3. Lowering containment levels for certain experiments as specified in NIH section III-D-2-a, Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or restricted agents cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems. (NIH section IV-B-2-b-3).

4. Setting containment levels as specified in NIH Sections III-D-4-b, Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants. (NIH section IV-B-2-b-4).

5. Periodically reviewing recombinant DNA research and potentially infectious material research conducted at the institution to ensure compliance with the NIH Guidelines and BMBL best practices. These reviews occur every three years. (NIH section IV-B-2-b-5).

6. Adopting emergency plans covering accidental spills and personnel contamination resulting from potentially infectious material and recombinant DNA research. (NIH section IV-B-2-b-6)

The committee also serves as an advisory body to the Vice President for biohazardous research activities.
To serve as an advisory body that reports to the vice president for research concerning research on living organisms, including viruses, when a potential hazard to any life form or the environment is posed by such research. The committee collectively is to have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. [ed 7-06, rev.2-10]

B. STRUCTURE.
The IBC is a faculty chaired committee. In accordance with NIH Guidelines, the IBC must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. These members are nominated by the Vice President of Research and Economic Development. Three members of the committee serve as standing members of the committee as part of their job role: 1.) The Biosafety Officer, 2.) The Chief Research Compliance Officer and 3.) The Campus Veterinarian. At least two members shall not be affiliated with the University (apart from their membership on the Institutional Biosafety Committee) and represent the interest of the surrounding community with respect to health and protection of the environment. The IBC shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P of the NIH Guidelines, Physical and Biological Containment for Recombinant DNA Research Involving Plants, require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q of the NIH Guidelines, Physical and Biological Containment for Recombinant DNA Research Involving Animals, require Institutional Biosafety Committee prior approval. When the institution conducts recombinant DNA research at BL3, BL4, or Large Scale (greater than 10 liters), a Biological Safety Officer is mandatory and shall be a member of the IBC. In order to ensure the competence necessary to review and approve research protocols, every effort is made to ensure that the committee also includes expertise in infectious materials, biological safety, physical containment, a person knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, and a member of the laboratory technical staff. When changes in NIH guidelines require change in committee structure, such changes will
become effective at the time required by federal law, (NIH Section IV-B-2-a). To provide the necessary expertise and continuity of operation, members may serve consecutive three-year terms.

The Responsible Official (RO) who is the VP of Research and Economic Development may remove and replace a committee member at any time when the RO has determined that the member is unwilling or unable to perform committee member functions.

In accordance with NIH guidelines, the committee consists of five faculty members, nominated by the vice president for research, from biologically oriented disciplines, each of whom is familiar with biohazards and one of whom is considered to be an environmental scientist; a physician; a laboratory research person familiar with potentially biohazardous research; two members not associated with UI; safety officer; and (w/o vote) industrial hygiene specialist. When changes in NIH guidelines require change in committee structure, such changes will become effective when approved by the Committee on Committees. To provide the necessary expertise and continuity of operation, members may serve consecutive three-year terms. [rev. 7-06, rev. 2-10]
A. FUNCTION.

1. The federal government requires the University to designate an Institutional Review Board (IRB) to ensure that human participant research conducted under the auspices of the University meets federal requirements. Under the approved federal-wide assurance (FWA00005639) for the University, the IRB shall apply the regulations set forth by HHS at 45 CFR 46 to all human participant research, regardless of funding source, and shall be guided by the ethical principles set forth in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects*. The IRB shall also apply the human participant research regulations established by the Food and Drug Administration for clinical investigations involving drugs, biologics, medical devices, and other test articles. (21 CFR 50; 56; 312, and 812). The IRB shall act in conformance with other federal laws and regulations germane to human participant research and with state and local law that serves to elucidate and supplement federal regulations for human subject research.

2. Research that has been approved by the IRB may be subject to further review and approval or disapproval by UI officials. However, university officials may not approve research that has not been approved by the IRB. (45 CFR 46.112).

The committee also serves as an advisory body to the VP of Research and Economic Development for Human Subjects/Participants Research Matters.

B. The Institutional Review Board, which functions as a committee of the Research Council, has the responsibility of ensuring that, for each activity planned or conducted: (a) the rights and welfare of human subjects are adequately protected; (b) the risks to the subjects are outweighed by the potential benefits, either to the subject directly or to scientific understanding in general; and (c) the informed consent of all subjects is obtained through methods that are both adequate and proper. [See 5200 D and E.]
B. STRUCTURE AND MEMBERSHIP.

1. The IRB is a faculty-chaired committee.
2. It shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at the University of Idaho [45 CFR 46.107(a)].
3. The position of Chief Research Compliance Officer serves in the capacity of a non-voting standing committee member to assist in representing institutional commitments and regulations, [45 CFR 46.107(a)].
4. The IRB shall include one member whose primary concerns are in scientific areas and one member whose main concerns are in nonscientific areas [45 CFR 46.107(c)].
5. The IRB shall include one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution [45 CFR 46.107(d)].
6. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB [45 CFR 46.107(f)].
7. The Signatory Official, who is the VP of Research and Economic Development may remove and replace a committee member at any time. If and when he/she determines that the member is unwilling or unable to carry out committee functions.

The members of the IRB represent a variety of disciplines, such as law, medicine, sociology, psychology, social sciences, and zoology, and include two non-UI member who serves as community representative (one serving as an alternate), and one prisoner advocate, when necessary, to review all applications that have prisoners as human subjects. The vice president for research, or designee, is a member of IRB. [ed. 7-06, 8-07, rev. 7-08, ed. 12-08, rev. 2-10]
POLICY COVER SHEET
(See Faculty Staff Handbook 1460 for instructions at UI policy website: www.webs.uidaho.edu/uipolicy) [3/09]

Facility/Staff Handbook [FSH] ☐ Addition X Revision* ☐ Deletion* ☐ Emergency
Minor Amendment ☐ Chapter & Title: FSH 5200 Human Participant Research

Minor Amendment ☐ Chapter & Title:

All policies must be reviewed, approved and returned by a policy sponsor, with a cover sheet attached to apm@uidaho.edu or fsh@uidaho.edu respectively.

*Note: If revision/deletion request original document from apm@uidaho.edu or fsh@uidaho.edu, all changes must be made using “track changes.”

Originator(s): Office of Research Assurances Feb, 25, 2010
(Please see FSH 1460 C) Name Date
Telephone & Email: 208-885-6340 lmconnell@uidaho.edu

Policy Sponsor: (If different than originator.) IRB & Research Council
Name Date
Telephone & Email: 208-885-4989 lmciver@uidaho.edu

Reviewed by General Counsel ☒ Yes ☒ No Name & Date: Kent Nelson February 12, 2010

I. Policy/Procedure Statement: Briefly explain the purpose/reason of proposed addition, revision, and/or deletion to the Faculty/Staff Handbook or the Administrative Procedures Manual.
Align policy with University of Idaho policy guidance, and in accordance with federal regulations as well as the University of Idaho’s Federal Wide Assurance under which the University is authorized to perform Human Participant Research. The Institutional Review Board was involved in the review and edits of this policy.

II. Fiscal Impact: What fiscal impact, if any, will this addition, revision, or deletion have?
None

III. Related Policies/Procedures: Describe other policies or procedures existing that are related or similar to this proposed change.
FSH 1640.54 Institutional Review Board

IV. Effective Date: This policy shall be effective on July 1, or January 1, whichever arrives first after final approval (see FSH 1460 D) unless otherwise specified in the policy.

If not a minor amendment forward to: ________________________________
Track # _______________
Date Rec.: _____________
Posted: t-sheet ________
h/c ___________
web ___________
Register: ______________ (Office Use Only)
INVESTIGATIONS INVOLVING HUMAN PARTICIPANT RESEARCH SUBJECTS

PREAMBLE: This section outlines the considerations, legal and ethical, that need to be taken into account in any research that involves human subjects. It was original to the 1979 Handbook and was revised in July of 1995, and again in July 2003, to reflect changes in applicable federal law. In 2009 the Human Assurances Committee (HAC) was renamed the Institutional Review Board (IRB). In February of 2010 it has been revised in accordance with federal law and University policies. For further information, contact the Research Office of Research Assurances at (208-885-6340). [rev. 7-03, 1-09, 2-10]

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A. General Policy, Legal Authority and Ethical Principles
B. Covered Activities "Subject at Risk"
C. Scope of Responsibility and Authority Direct or Indirect Participation
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A. GENERAL POLICY: LEGAL AUTHORITY AND ETHICAL PRINCIPLES

A-1 GENERAL POLICY
The University of Idaho, in the course of carrying out its teaching, research, and service missions, engages in human subject or participant research across a wide array of academic disciplines [and administrative functions]. Recognizing that engaging in research involving human participants imposes responsibility for safeguarding the rights and welfare of these persons, the University of Idaho (University) is committed to the protection of human research participants through compliance with applicable federal and state regulations and observance of ethical principles for the conduct of human research, (that are recognized and adopted by the University through its federal-wide assurance). This policy governs all human participant research performed under the auspices of the University.

A-2 LEGAL AUTHORITY
All research subject to this policy shall be conducted in accordance with federal, state, and local law. In fulfilling its commitment to protect the rights and welfare of human research participants, the University applies the regulations promulgated by the United States Department of Health and Human Services (HHS) for Protection of Human Subjects (45 C.F.R. 46). Under the approved federal-wide assurance (FWA00005639) provided by the University to HHS, all human participant research, regardless of funding source, and the oversight of such research shall be performed in a manner that complies with the regulations set forth by HHS at 45 C.F.R. 46. The University also complies with human participant research regulations established by the Food and Drug Administration for clinical investigations involving drugs, biologics, medical devices, and other test articles. (21 C.F.R. 50; 56; 312, and 812). The University acts in conformance with other federal laws and regulations germane to human participant research and with state and local law that serves to elucidate and supplement federal regulations for human subject research.

A-3 ETHICAL PRINCIPLES
Consistent with its federal-wide assurance, the University shall be guided by the ethical principles governing the evaluation and conduct of research involving human participants, whether or not such research is subject to federal regulation, set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. While the principles announced in The Belmont Report serve to guide human participant research at the University, these principles are never held to or construed so as to supersede any local, state, or federal law or to supersede any regulations or policies promulgated by federal agencies.
UI complies with the policy of the U.S. Department of Health and Human Services (HHS) concerning the protection of human subjects in all activities in which human subjects may be at risk. In the execution of this policy, UI is guided by the ethical principles promulgated in the “Declaration of Helsinki.” Nonetheless, these principles are never held to or construed so as to supersede any local, state, or federal law. It is also understood that, in respect to any activities supported in part or in full by grants from or contracts with HHS, the Helsinki principles and UI policies are never held to, or construed so as to, supersede any HHS policies or regulations.

B. COVERED ACTIVITIES

“SUBJECT AT RISK.” The term, “subject at risk,” refers to any person who may be exposed to the possibility of physical, psychological, sociological, or any other harm as a consequence of his or her participation as a subject in any activity that goes beyond or falls short of the application of those established and accepted methods necessary to meet the subject’s needs.

B.-1. HUMAN PARTICIPANT RESEARCH ACTIVITIES

Irrespective of funding source, all activities that meet the criteria for: (i) “research” involving “human subjects,” as defined in HHS regulations (45 CFR 46.102), or (ii) a “clinical investigation” involving “human subjects” or “subjects,” as defined in FDA regulations (21 CFR 50.3; 21 CFR 56.103; 21 CFR 312.3; 21 CFR 812.3), shall be subject to this policy.

1. HHS Definition of “Research” Involving “Human Subjects:”

   a. “research:” a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)].

   b. “human subject:” a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction, or (ii) identifiable private information [45 CFR 46.102(f)].

      i. “Intervention” includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

      ii. “Interaction” includes communication or interpersonal contact between investigator and subject.

      iii. “Private information” includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

2. FDA Definition of “Clinical Investigation” Involving “Human Subjects” or “Subjects:”

   a. “clinical investigation” (deemed by the FDA to be synonymous with “research”): any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3(c); 21 CFR 102(c); 21 CFR 312.3(h); and 21 CFR 812(h)].
i. “Test article” is defined as any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation. [21 CFR 50.3(j) and 56.102(l)].

b. “human subject” or “subject:” an individual who becomes a participant in research, either as a recipient of a test article or as a control. [21 CFR 50.3(g) and 56.102(e)]; a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. [21 CFR 312.3(b)]; or a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. (21 CFR 812.3).

B.-2. EXEMPT HUMAN PARTICIPANT RESEARCH
Activities that meet the criteria for “human subject research” described above may nevertheless be exempted from compliance with federal human participant regulations, if the only involvement of human participants will be in one or more prescribed categories. For a list of “exempt” research categories see, [45 CFR 46.101(b)]. The IRB, or designee of the IRB, shall make the determination as to whether a particular research activity involving human participants is exempt. Even when research is determined by the IRB to be exempt, the ethical principles of The Belmont Report shall be applied by the investigator to the research activities.

C. SCOPE OF AUTHORITY AND DIRECT RESPONSIBILITY OR INDIRECT PARTICIPATION. A subject’s participation may be either direct or indirect. Direct participation implies an immediate or proximate physical or psychological involvement of the subject in an activity; for example, application of an experimental vaccine or of a procedure designed to test the subject’s response to experimental therapy. Indirect participation involves use of a subject’s body fluids, tissues, or other physical materials, or of any personal information obtained from the subject, for any therapeutic or diagnostic purposes. Indirect participation also includes use of tissues, body fluids, or other physical materials from spontaneously aborted fetuses and deceased subjects. The fact that a subject’s participation may be indirect, however, does not in any way diminish the fundamental responsibility of UI investigators to protect adequately the rights and sensibilities of a human subject, or, in the case of a deceased subject, the subject’s next of kin.

C.-1. INSTITUTIONAL REVIEW BOARD (IRB)

1. The IRB is the principle mechanism by which the University ensures that all human participant research activity is planned and conducted in a manner consistent with applicable law and policy and that the rights and welfare of human research participants are adequately protected.

2. The responsibilities of the IRB include but are not limited to:

a. reviewing, approving, requesting modifications, as well as disapproving human subject/participant research, [45 CFR 46.109(a)];

i. research that has been approved by the IRB may be subject to further review and approval or disapproval by University officials. University officials may not approve research that has not been approved by the IRB (45 CFR 112);

b. conducting continuing review of research approved by the IRB, at intervals not less than once per year, including as necessary observing, or having a third party observe, the consent process and research activity; or requesting and inspecting information related to human participant research activity [45 CFR 46.109(e)];

c. investigating instances of non-compliance, whether discovered during monitoring by the IRB or reported to the IRB, including unanticipated problems involving risks to research participants or others and serious or continuing noncompliance with this policy or the requirements or determinations of the IRB;

d. suspending or terminating approval of research activity that is not being conducted in accordance with the requirements established by the IRB for a particular research activity or has been
associated with serious harm to research participants or that is not otherwise in accordance with 
federal human subject research regulations or University policy (45 CFR 46.113):

e. reporting to appropriate University and federal government officials:

i. unanticipated problems involving risks to research participants or others and serious or 
continuing noncompliance; and

ii. suspension or termination of IRB Approval [45 CFR 46.103(b)(5)];

f. developing and implementing administrative policies and procedures to implement this policy.

C.-2. SIGNATORY OFFICIAL
The Signatory Official is the VP of Research and Economic Development or designee. This individual cannot be a 
voting member of the IRB and shall have the legal authority to represent the University in providing assurance to 
the federal government that the University will comply with federal human subject research regulations and shall be 
responsible for ensuring that all regulatory and programmatic requirements for the conduct of human participant 
research at the University are met. [45 CFR 46.103(b)(2)(c)].

C.-3. OFFICE OF RESEARCH ASSURANCES
The Office of Research Assurances shall provide administrative support necessary for the IRB to fulfill its duties. 
[45 CFR 46.103(b)(2)].

C.-4. UNIVERSITY INVESTIGATORS (FACULTY, STUDENTS, AND STAFF)
Any person who engages in human participant research (See B. Covered Activities, above) under the auspices of the 
University (including faculty, students, and staff) shall comply with applicable federal, state, and local law, with 
University policy, and with the requirements of the IRB.

D. INSTITUTIONAL REVIEW BOARD (IRB), rev. 1/09
ORGANIZATION AND MEMBERSHIP OF THE IRB

The IRB shall be organized and its membership determined in accordance with federal 
regulations and University policy (45 CFR 46.107, 21 CFR 56.107, and FSH 1640.54).

D-1. The IRB, which functions as a committee of the Research Council, has the responsibility of ensuring that, for 
each activity planned or conducted: (a) the rights and welfare of human subjects are adequately protected; (b) the 
risks to the subjects are outweighed by the potential benefits, either to the subject directly or to scientific 
understanding in general; and (c) the informed consent of all subjects is obtained through methods that are both 
adequate and proper. [NOTE: The responsibilities of IRB are elaborated in E; see also 1640.54.]

D-2. The members of the IRB represent a variety of disciplines, such as law, medicine, sociology, psychology, soil 
sciences, and zoology, and include one non-UI member who serves as community representative. This diversity 
brings to the review process a wide range of perspectives and ensures that each proposed project in which there 
may be human subjects at risk will be reviewed not only in terms of UI policies on human protection, but also in 
terms of applicable law, standards of professional conduct and practice, the ethical principles of the Helsinki 
declaration, and the consensus of responsible contemporary community opinion.
D-3. A quorum for IRB meetings shall be a majority of the total membership. When any proposal for the investigational use of a new drug is being reviewed, at least two members who are licensed to administer drugs in the state of Idaho and at least one member not so licensed will be consulted. Any IRB member who has a professional responsibility for, or involvement in, any proposed activity is disqualified from participating in any review of that activity, except that he or she may provide information or explanation to IRB.

D-4. IRB will meet as frequently as required to review new and continuing research proposals involving human subjects, but not less than one time per year.

E. RESPONSIBILITIES OF THE INSTITUTIONAL REVIEW BOARD REVIEW OF HUMAN PARTICIPANT RESEARCH.

E.-1. The IRB shall conduct initial and continuing review of human participant research activity, following established procedures appropriate to the degree of risk involved in the research. IRB review of research shall be prospective, and no human participant research activity may be carried out by an investigator without prior approval from the IRB. The IRB shall not provide retrospective approval of human participant research.

E.-2. The IRB, or its designee, shall review all research that meets the regulatory definition for human subject research but may be eligible for exemption from further review and oversight (See B. COVERED ACTIVITIES, above.). The IRB shall make the final determination as to whether a particular research activity involving human participants is exempt. For activities determined to be exempt, the IRB shall provide the investigator with a certification of exemption from continuing IRB oversight.

E.-3. The IRB, or its designee, shall provide guidance to investigators as to what activities do not constitute human subject research and, therefore, do not require IRB oversight. The IRB shall provide, as necessary, certification to investigators that research activity is not human subject research.

E-1. IRB was established to review all projects and activities that involve human subjects.

E-2. To increase efficiency and to ensure that all such projects are in compliance with UI and HHS regulations, HAC members should familiarize themselves with the regulations described herein.

a. IRB members are selected by the vice president for research and graduate studies to represent UI and community interests and to encompass a broad base of interest.

b. The vice president for research and graduate studies [see 5100 B-8] is a member of IRB.

e. The IRB chair or designated representative will receive and preliminarily review proposals submitted by investigators. If any information is lacking, or if other requirements of this policy have not been sufficiently met, IRB will request additional information.

d. The IRB chair or designated representative will forward a copy of the complete protocol and attachments to selected members of IRB, chosen on the basis of their special competence, for detailed review. (“Protocol” is used in this policy in its sense as “the plan of a scientific experiment or treatment.”) The chair may also use consultants in an advisory capacity who are not IRB members. These consultants may or may not be UI employees.

e. As part of the detailed review, IRB or its consultants may request additional information about the proposed activity. These requests should be transmitted by the IRB chair to the investigators.

f. At the next regular meeting of IRB, or one called for this specific purpose, the protocol will be presented by
IRB members or consultants chosen to carry out this function to the committee for review. The principal investigator of the proposed activity must be present to give additional information. IRB will discuss the human protection issues raised and will decide by two-thirds vote or more: (1) to approve the proposal; (2) to approve the proposal with restrictions; or (3) to defer approval pending changes in the protocol. Otherwise, the proposal is disapproved. If the proposal qualifies for "expedited" review according to federal guidelines, the IRB chair will review the proposal, either alone or in consultation with one or more members of the IRB. In case of "expedited review", written approval will be sent to the investigator as indication of approval or disapproval of the project according to Federal Code Title 45, Part 46.101.

g. Minutes must be taken of IRB meetings and copies distributed to members.

h. IRB will send its decision in writing to the principal investigator, who in turn will inform the appropriate department members.

I. Adverse decisions of IRB concerning any proposed activity may be appealed by the principal investigator through his or her departmental administrator to the vice president for research and graduate studies. Adverse decisions or restrictions imposed by IRB, however, can be reversed or modified only by a two-thirds majority of IRB.

j. IRB must receive all reports, annual reviews, and proposed changes in protocols from investigators. It must receive and transmit to the investigators all requests for additional information. IRB will ensure that projects are reviewed at least annually.

k. Once an activity is underway, the IRB chair must receive in writing from the investigator notification of any change or proposed change in the protocol, any emergent problems or potential problems, or any injury or harm suffered by a subject as a consequence of his or her involvement in the activity.

l. IRB will notify HHS of emergent problems that might affect the rights, safety, or welfare of human subjects involved in any activities covered by these procedures as reported by either the departmental administrator or IRB.

m. IRB will receive and consider complaints or questions from staff members or subjects that are referred to IRB by the vice president for research and graduate studies, departmental administrators, or principal investigators.

n. IRB must ensure that the safeguards specified in public law are followed to maintain the confidentiality and security of all information obtained from human subjects. IRB should familiarize itself with the provisions concerning confidentiality published in the Federal Register of June 18, 1991. IRB should also familiarize itself through legal counsel with those statutes and common-law precedents that may bear on these decisions. The provisions of this policy may not be construed in any manner or sense that would abrogate, supersede, or moderate more restrictive applicable law or legal precedents. fed. 7-03]

o. IRB will be provided legal counsel by the university counsel.

F. INFORMED CONSENT

The administrative policies, guidelines, and procedures developed to implement this policy shall be set forth in the University of Idaho IRB Standard Operating Procedures, which shall be maintained and made available to investigators by the Office of Research Assurances. The University of Idaho IRB Standard Operating Procedures shall be reviewed and approved by the Signatory Official or designee in consultation with the IRB.

E.1. Whenever any research activity involves human subjects, it is mandatory that the investigator, or his or her duly certified representative, obtain the informed consent of any and all such subjects. The informed consent procedures and documents employed for this purpose should not contain exculpatory language through which the subject is made to waive, or to appear to waive, any of his or her legal rights, or to release UI or its representatives.
from any liability for negligence.

F-2. It is the policy of UI that any consent given by a subject is “informed consent” only if the disclosure by the investigator, or his or her duly certified representative, to the subject contains all of the following elements:

a. An explanation of the procedures that are to be used, including the identification of those that are experimental, in language and in a way comprehensible by any layman.

b. A fair disclosure of any potential risk or discomforts attending or potentially stemming from the subject’s participation in, or premature withdrawal from, the activity without prejudice.

c. A fair description of the sought-for benefits to the subject directly, or to scientific understanding in general.

d. A full disclosure of any extant alternative procedures that would or might be advantageous to the subject.

e. An offer to answer any inquiries concerning the procedure, its potential or possible effects, and its risks, and a description of the proper and most expeditious means for making such inquiries and obtaining a response.

f. A clear statement to the effect that the subject is free to withdraw his or her consent and to terminate participation in the project or activity at any time, for any reason, without notice.

F-3. A subject’s informed consent will not be sought or obtained in a coercive or manipulative manner. Informed consent will be obtained in one of two ways:

a. The subject, or authorized representative, may be asked to sign a written-consent document that embodies the six elements described above.

b. The subject, or authorized representative, may be asked to sign a document indicating that the subject has had the six basic elements of consent explained orally, that he or she understands this oral description, and that, in awareness thereof, the subject agrees to participate in the activity described. If such a “short form” is used, however, it must be countersigned by an auditor witness to the oral presentation and to the signature of either the subject or the subject’s representative. Whenever an oral presentation is to be given to the subject in lieu of written disclosure, a written summary of the information to be orally transmitted should be prepared and submitted to IRB for prior review and approval.

F-4. Regardless of which of the above approved methods of consent is used, a full and complete oral explanation must be given, including, where applicable, a full reading to the subject of the consent document.

F-5. There may be cases in which the use of either of these procedures for obtaining informed consent may be considered inappropriate by UI’s investigator, either because the potential risks to human subjects may seem minimal or because the use of either procedure would adversely affect the experimental design or preclude the possibility of obtaining legitimate or reliable results. Modification to the two approved informed consent procedures can be suggested. However, any modification must be approved, before implementation, by IRB. This approval must be recorded in the minutes of the IRB and the minutes must be signed by the chair. No such modifications will be approved by the IRB unless and until the IRB determines:

a. that the risk to any human subject is in fact minimal, justifying a less full disclosure in the informed-consent procedures than would normally be required; or

b. that the use of either of the prescribed procedures for obtaining informed consent would in fact invalidate objectives of considerable immediate consequence and that the use of any reasonable alternative means for attaining these objectives would be less advantageous to the subject.
F-6. In no case, however, shall an investigator propose, or IRB approve, an informed consent procedure in which any possible or potential risk is knowingly or purposely minimized, misrepresented, or otherwise distorted.

F-7. Copies of the informed consent documents will be submitted to IRB as part of the application for approval. The executed forms will be kept by the principal investigator. Storage of informed consent documents and any other material that contains names, or other identifying characteristics of subjects, will be in locked files in the safety deposit box in Business and Accounting Services. The identity of subjects in research must be protected as specified in public law. 

G. RESPONSIBILITIES OF DEPARTMENTAL ADMINISTRATORS.

G-1. To ensure maximum protection of human subjects and to ensure compliance with UI and HHS regulations, departmental administrators must follow the procedures outlined herein. These procedures may be amended to cover new activities at UI and collaborating institutions and to comply with changes in applicable federal regulations.

G-2. Departmental administrators must familiarize themselves with these and all regulations pertaining to the use of human subjects, because the administrators will serve as intermediaries between principal investigators in their respective departments and IRB. The departmental administrator may be the principal investigator of a proposed activity that involves human subjects. In either case, departmental administrators must be aware of their responsibilities in studies performed in part or in full by members of their department. Departmental administrators must:

a. Review all proposals involving human subjects that are submitted by department members (this should be done as early in the planning stage as possible) and ensure that the studies meet requirements for protection of human subjects. If such protection is not adequate, they must suggest ways to bring the proposed studies into compliance.

b. Forward two copies of the approved proposal to the IRB chair. A grant or contract application to HHS may serve this purpose. Allow for a minimum of one week between submission to IRB and IRB review.

c. As required, obtain additional information from the principal investigator concerning proposals under review by IRB.

d. Appear before IRB for review of the proposed activity. The principal investigator may also be asked to appear by IRB or the departmental administrator.

e. After approval and initiation of the project or activity, report in writing to the IRB chair any proposed change in the protocol, any emergent or potential problems, or any physical or psychological harm or injury suffered by a subject as a consequence of involvement in the activity.

f. Provide information to IRB as requested to ensure periodic review of activities directed by department members. They must further ensure that a report covering the project’s effects concerning human subjects is submitted annually, upon completion of the project, or more frequently if requested by IRB.

H. CONTACT RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS. To ensure maximum protection of human subjects and to ensure compliance with UI and HHS regulations, principal investigators must follow the procedures outlined herein. These procedures may be amended to cover new activities at UI or collaborating institutions and to comply with new federal regulations.

H-1. Write a detailed protocol for the proposed activity. Grant or contract applications submitted to HHS are acceptable. This protocol should contain a completed “Human Subjects Form,” copies of informed consent documents to be used, and a complete explanation of how informed consent will be obtained. These forms are available from
H-2. For each proposed activity, the investigator should inform his or her staff and all prospective subjects, if these are available, of UI’s concern for the subjects’ welfare, of the regulations governing the use of human subjects, and of UI’s policy on the protection of human subjects, as filed with HHS. Copies of the regulations and policy should be made available to staff or prospective subjects upon request.

H-3. Two copies of the complete protocol are to be forwarded to the departmental administrator.

H-4. The principal investigator must provide additional information concerning the protocol to the departmental administrator on request. The investigator may be asked to appear with the departmental administrator before IRB, to present a full explanation of risks and protection for human subjects, describe the procedure to be used to achieve informed consent, and answer questions.

H-5. Following IRB approval and the initiation of the activity, the principal investigator must notify the departmental administrator, for forwarding to IRB, of any proposed change that will or may affect human subjects. There should be no change in studies with human subjects until IRB has reviewed and approved the change. Changes that must be made in emergencies should be made at the discretion of the principal investigator. Consultation should be had with the departmental administrator, the vice president for research and graduate studies, and/or the IRB chair if this is possible. Changes in protocol must be reported in writing to the IRB chair as soon as possible.

H-6. The principal investigator must notify the departmental administrator of any injury or harm, physical or psychological, suffered by a subject because of participation in the study or of any emergent or potential problems.

H-7. Periodic review of the protocol is essential. The principal investigator must submit a full report concerning human subjects at least annually and upon completion of the project. This report must be given to the departmental administrator who will forward it to IRB. IRB, at its discretion may request more frequent reports.

H-8. The principal investigator must make provisions for the safe retention of complete records of human subjects for at least three years following the completion of the project or activity. This period may be extended for certain studies at the discretion of IRB.

H-9. Investigators must follow the safeguards specified in public law to ensure the confidentiality and security of all information obtained from human subjects. Questionnaires, inventories, interview schedules, and other data-gathering procedures must be carefully designed to ensure that only information relevant to the project will be obtained. When body tissues, fluids, or other similar materials are brought to UI from a hospital or physician’s office, only a code or hospital number should be used, not the patient’s name. The principal investigator would then have access to the patient only through the referring physician or hospital. If subjects’ names are submitted to UI, they should be stored in the safety deposit box in Business and Accounting Services. Under no circumstances should subjects’ names be maintained in the investigator’s files. Master codes and ciphers must be kept in secure places, distinctly separate from encoded and enciphered data. The shipment, delivery, and transfer of all data, printouts, and files between offices and institutions may require careful controls. Computer-to-computer transmission of identifiable data is forbidden without the express consent of IRB. Provisions should also be made for the destruction of all edited, obsolete, or depleted data on punched cards, tapes, discs, and other records. The investigator should notify IRB before this action. IRB may also determine a future date for destruction of all stored primary data pertaining to a project or activity. Particularly relevant to the decision of IRB are those rights of the subject that are defined by law. [ed. 7.03]

H-10. In collaborative activities with other institutions, the investigator must give supportive evidence that rights of human subjects are being adequately protected in any activity performed in those institutions.

H-11. The investigator should inform his or her staff and prospective subjects that complaints or questions concerning any activity in which they are involved can be sent in writing to the investigator, to the departmental administrator, and
to the vice president for research and graduate studies. The staff and subjects should be informed that they may go directly to IRB if they are not satisfied with the disposition of the matter. The investigator should inform the subject or staff member of the most expeditious manner in which the matter might be brought to the consideration of IRB.

H-12. When research involving human consumption of alcohol is contemplated, it is the responsibility of the applicant to obtain a copy of the “University of Idaho Guidelines on the Administration of Ethyl Alcohol in Human Experimentation.” Each item in the guidelines must be addressed in the protocol before submitting it to the institutional review board (IRB). In addition, all investigators should obtain a copy of the “Recommended Council Guidelines on Ethyl Alcohol Administration in Human Experimentation” of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) available from the UI Research Office. The NIAAA-recommended guidelines will be used by the institutional review board (IRB) in evaluating the protocol.

INFORMATION
For further information regarding implementation of this policy you may contact the Office of Research Assurances or visit the IRB website.