



Office of Regulatory Compliance

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May 18, 2006

To: Edward Hammond  
Director – Sunshine Project  
P.O. Box 41987  
Austin, Texas 78704

From: Barbara Fox Nellis  
IBC Secretary  
Northern Arizona University

*Barbara Fox Nellis*

Re: Request for IBC Meeting Minutes from May 2003 to the Present

As requested, I am providing you with the minutes of all meetings of the Northern Arizona University Institutional BioSafety Committee for calendar year 2003 through the present time. You will note that there were no NIH recombinant DNA projects or activity during 2003 and 2004.

Copies: Dr. Carl Fox (Vice Provost), Mr. Mark Neumayr (NAU Legal Counsel),  
Dr. Matthew Gage (IBC Chairperson), IBC File

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**Northern Arizona University Institutional BioSafety Committee (IBC)  
Meeting Held January 4, 2006**

Attendees: Barbara Fox Nellis, Linda Fitchett, Matthew Gage, Fernando Monroy,  
Adam Kramer, Cindy Roth, Carl Fox

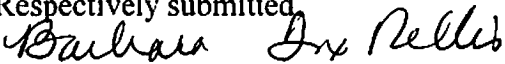
Meeting Notes:

Meeting was called to order at 1:10 pm with a quorum present. Members were introduced and a discussion took place for recommended additions and changes to the registration forms that would facilitate review by the IBC. Suggestions were made to add additional check boxes to section #9, additional emphasis on the safety description in sections 15-16, addition of an IRB box to the top section, addition of comment section for each construct to address replication competence and to address material transfer issues in a new section of the registration forms.

The Dr. Matthew Gage recombinant protocols were discussed following an explanation of the protocols and science by Dr. Gage. Titles: Folding and Assembly of the P22 Tailspike Protein and Folding and Aggregation of p53. The associated biological agent registrations were also reviewed for both these rDNA protocols. Both Biological Agent registrations and the Folding and Assembly of the P22 Tailspike Protein were unanimously approved by the committee. Additional information for the p53 protocol was requested from Dr. Gage including the safety information expansion and additional information on the lenti-viral vector.

The meeting was adjourned at 2 pm.

Respectively submitted

  
Barbara Fox Nellis  
Secretary NAU IBC



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## **Northern Arizona University Institutional BioSafety Committee (IBC) Meeting Held December 9, 2005**

**Attendees:** Barbara Fox Nellis, Marlene Gaither, Linda Fitchett, James Biddle, Matthew Gage, Fernando Monroy, Roger Van Andel, Cindy Roth

### **Meeting Notes:**

Meeting was called to order at 9:10 am with a quorum present. Members were introduced and a discussion took place for recommendations for a second community member. The consensus was to contact Adam Kramer of the Coconino Parks Service as a possible community member.

The IBC secretary, Barbara Fox Nellis, reviewed the NIH guidelines and handed out notebooks to each member with the current guidelines for their use and reference. Clarification of member roles and responsibilities were also reviewed.

The group discussed the requirement that any associated IACUC protocol be included with the IBC submission. For the yearly renewal process, minor changes to people will be approved by the IBC Chair and Secretary while changes to animals or the protocol will come back to the full IBC.

Additional meeting protocol was discussed for inviting the PI to the meeting to describe the protocol and that he/she would be asked to leave the room during the voting process. The committee also asked that section 9 of the protocol form be expanded to include check boxes for the various potential aerosol formation activities and equipment.

### **Protocols reviewed:**

Dr. Alice Gibb – Title: The Development & Evolution of Premaxillary Protrusion, species fish, use of exempt quantities of Botulinum Toxin Type A to investigate the function if various muscles used by fish during premaxillary protrusion. The engineering controls were verified and with no other concerns, the committee voted unanimously to approve the protocol as written. The associated IACUC protocol 02-066 was found to be complete and in order.

Dr. Kiissa Nishikawa – Title: Musculoskeletal Morphology, Function and Behavior, species toads, use of exempt quantities of Botulinum Toxin Type A to investigate the function if various muscles in ballistic prey capture as a study of ballistic movements. There were no concerns with this protocol and the committee voted unanimously to approve the protocol as written. The associated IACUC protocol 00-014 was found to be complete and in order.

Dr. Jeffrey Leid – Title: Human Immune Interactions with Bacterial Biofilms, no animal work. Biological agent registration only for use in investigating the role of biofilm resistance to the human immune system. All agents fall into risk group 2. The committee had numerous questions from needing additional safety information to medical surveillance and training requirements. The committee voted unanimously to table this protocol until additional information was obtained from the PI.

Dr. Fernando Monroy – Title: Toxoplasma Gondii – Neuro-Endocrine Regulation of Intestinal Infection, species mouse. Biological agent registration only using fibroblast cell lines. Committee requested that the cell lines be added to section 5 and that blood-borne pathogens training was required and the HBV vaccine series offered in conjunction with this work. There were no concerns with this protocol and the committee voted unanimously to approve the protocol as written. The associated IACUC protocol 01-037-R1 was found to be complete and in order.

Dr. Richard Shand – Title: Characterization of Various Parts of Halocin Preproteins, no animals work. Committee felt the protocol was incomplete and voted unanimously to table until more information was received from the PI.

With time running out the meeting was adjourned at 11:15 am with the comment that the next meeting would begin with the Gage protocols.

Respectively submitted,



Barbara Fox Nellis  
Secretary NAU IBC

# Northern Arizona University

## Institutional BioSafety Committee

### Minutes

November 17, 2003  
3:30 p.m. – 5:00 p.m.

Present: Jeff Leid  
Richard Shand  
Scott Nichols  
Jim Biddle  
Richard Foust  
Carl Fox  
Melanie Birck – administrative support

Absent: Maria Denny  
Kiisa Nishikawa  
Fernando Monroy

- IV. Biosafety Office job description – (Taken out of original agenda order to accommodate Dr. Fox’s schedule.) Dr. Fox presented the BioSafety Officer position description to the committee. The committee agreed that the BioSafety Officer should really report to the Vice Provost for Research and not Risk Management although this position will work with staff in Risk Management and Environmental Safety. The committee requested to be notified when the position was posted and advertised.

Dr. Fox asked for committee involvement in the search for the BioSafety Officer. Members will e-mail Melanie Birck if they wish to participate on the Search Committee.

Melanie Birck will verify job description and salary range of BioSafety Officer positions at other institutions.

Dr. Fox will consult with the BioSafety Office at the University of Arizona as well.

Comments on position description should be sent to Dr. Fox as soon as possible.

- I. IBC Process/Procedures – Richard Shand lead the discussion of the new revisions to the Process/Procedures manual. Several sections were discussed and Richard will make the appropriate changes to the document and re-send to committee members for review. This review of the manual took the rest of the scheduled meeting time.
- II. Jeff Leid Walkthrough Inspection – This item tabled until next meeting.
- III. Banking Serum – This item tabled until next meeting
- V. Risk Assessment Form – Richard Shand and Jim Biddle are still working on this form. This item tabled until next meeting.
- VI. Committee Membership – Replacement for Jeff Creedon. This item tabled until next meeting.
- VII. Other Business – No other business.
- VIII. Adjourn – Motion to adjourn by Jeff Leid, seconded by Richard Foust. Meeting adjourned at 5:10 p.m.

# Northern Arizona University

## Institutional BioSafety Committee

### Minutes

October 13, 2003  
2:00 p.m. - 3:30 p.m.

**Present:** Fernando Monroy  
Richard Shand  
Scott Nichols  
Jim Biddle  
Richard Foust  
Melanie Birck – administrative support

**Absent:** Maria Denny  
Kiisa Nishikawa  
Jeff Creedon  
Jeff Leid

- I. Keim Lab Annual Inspection – Fernando Monroy, Jim Biddle and Scott Nichols inspected Dr. Keim’s lab on April 16, 2003. (See letter from Fernando Monroy dated April 28, 2003.) The laboratory was found to be in compliance with minor comments. Motion to accept and approve the inspection made by Richard Foust, seconded by Richard Shand. Unanimous vote by committee to accept and approve inspection.
- II. IBC Process/Procedures – Richard Shand reviewed the current draft version of the Policy and Procedures Manual with the committee. Discussion centered around modifying the protocol application form(s) and including a Chemical Hygiene Plan in the IBC manual.

The committee determined that an IBC protocol application must be submitted at the same time an external proposal for funding is submitted.

Richard Shand and Jim Biddle will work together to develop a “Risk Assessment Form”.

Fernando Monroy will contact former chair Roger Van Andel to secure copies of old IBC forms. Other committee members will find and e-mail copies of forms to Melanie Birck.

Richard Shand asked committee members to read the current draft of the policy/procedure manual and provide comments to him before the next IBC meeting.

- III. Committee Membership – Membership policy and rules were discussed. One current member is unable to attend meetings due to current workload. Should we ask her to resign from committee? No decision made at this meeting.

Jeff Creedon, community member from APS has resigned from the committee. Please think about appropriate person to fill his slot.

- IV. Other Business – Jim Biddle asked, Is there any “banking serum” for baseline policy or procedure? Fernando Monroy will gather guidelines from the Keim Lab and sent to Jim Biddle.

- V. Adjourn – Motion to adjourn by Jim Biddle, seconded by Richard Shand. Meeting adjourned at 3:35 p.m.



# Northern Arizona University

## Institutional BioSafety Committee

### Minutes

March 26, 2003  
3:30 p.m. – 5:00 p.m.

**Present:** Fernando Monroy  
Kiisa Nishikawa  
Richard Shand  
Scott Nichols  
Jeff Creedon  
Jeff Leid  
Jim Biddle  
Richard Foust  
Melanie Birck – administrative support

**Absent:** Maria Denny

- I. Welcome and installation of Co-Chairs and New Members – Motion by Jeff Creedon to appoint Fernando Monroy and Scott Nichols as Co-Chairs of the committee. Seconded by Richard Shand. Unanimous vote of committee. Fernando and Scott installed as Co-Chairs.  
  
Motion by Fernando Monroy to appoint Richard Foust and Jeff Leid as new members to the committee. Seconded by Scott Nichols. Unanimous vote by committee. Richard Foust and Jeff Leid installed as new members.
- II. Discussion of term of appointments - Term of membership was discussed. Each member will serve for three years with an option to renew. Because each member joined the committee at different times, rotation of membership will be staggered. (See committee appointment letters for details on individual term dates.)
- III. Discussion of IBC Policy and Procedure Manual and IBC Forms – Richard Shand will continue as the lead on the documents project. Revisions and additions will be sent to committee members by Richard Shand.
- IV. Discussion and schedule of Laboratory Inspections – Fernando Monroy and Jim Biddle will organize and conduct the inspection of Keim’s lab, coordinating with Jim Schupp. Fernando, Scott and Jim will attend the inspection. Fernando will

schedule and send information as appropriate. Inspection likely to occur in April 2003. Must do inspection before USDA inspection.

Kiisa Nishikawa recommends a sub-committee be formed to produce policy and procedure for lab inspections by the IBC. Richard Shand will lead this group.

Inspection will include spot checking bar codes on samples with written paperwork as well as a visual inspection of the inventory.

Melanie Birck will supply copies of the Patriot Act to committee members with relevant passages marked.

- V. Other New Business – Jim Biddle will be acting BioSafety Officer and work with Dr. Carl Fox, Keim Lab and IBC.

All of Dr. Keim's IBC records now reside in the Office of the Vice Provost for Research and Graduate Studies.

Fernando will research the regulations on inspections and report to the committee.

- VI. Adjourn – Motion to adjourn by Richard Shand, seconded by Jim Biddle.  
Meeting adjourned at 4:35 p.m.

# Northern Arizona University

## Institutional BioSafety Committee

### Minutes

January 24, 2003  
2:00 p.m. – 3:30 p.m.

Meeting was called to order by Dr. Carl Fox, Ex-Officio Member.

Present: Fernando Monroy  
Kiisa Nishikawa  
Richard Shand  
Carl Fox  
Scott Nichols  
Jeff Creedon  
Melanie Birck – administrative support

Absent: Jim Biddle  
Maria Denny

- I. Old Business – The committee decided to continue working on the IBC policies, procedures and forms documents. Richard Shand will begin to make revisions and send to the committee for comment.
- II. Committee Membership – The current members discussed adding new members to the committee. Suggestions included Jeff Leid in Biology, Tim Vail in Chemistry, Richard Foust in Chemistry (and a former member). It was determined that the committee might at some point ask for a representative from the Flagstaff Medical Center to join the group. Fernando Monroy will invite Jeff Leid to become a member. Melanie Birck will invite Richard Foust to become a member.
- III. Recommendations for new Chair – Carl Fox recommended Fernando Monroy to assume the role of Chair. Upon discussion, Fernando asked if he could consider the appointment. Scott Nichols suggested a Co-Chair arrangement and agreed to be Co-Chair. The Co-Chairs will work through Melanie Birck to conduct business.
- IV. New Administrative Support – Melanie Birck was introduced as the new administrative support person for the committee. All files related to IBC activities and protocols will be transferred to the Office of the Vice Provost for Research and Graduate Studies. Melanie will assist the Co-Chairs in scheduling

meetings, preparing agendas and other documents as appropriate, creating meeting minutes and filing of IBC documents and protocols.

- V. Other New Business – There was no other New Business
- VI. Adjourn – Motion to adjourn by Richard Shand, seconded by Jeff Creedon. Meeting adjourned at 3:15 p.m.