

To: Kinchel.Doerner@wku.edu
From: Edward Hammond <hammond@sunshine-project.org>
Subject: IBC Minutes
Cc: "'Johnson, Michelle \ (NIH/OD\) [C]'" <johnsom1@od.nih.gov>
Bcc:

Attachments:

Dear Dr. Doerner:

I have recieved your reply to my request for minutes or, well, errr, my complaint to NIH. I requested minutes since March 2003. You have sent the minutes of one meeting, that of 10 May 2004. Please send the missing minutes covering the entire timeframe of my request.

Sincerely,

Edward Hammond



Biology Department
270-745-3696
FAX: 270-745-6856

Western Kentucky University
1906 College Heights Blvd. #11080
Bowling Green, KY 42101-1080

The Spirit Makes the Master

March 14, 2007

Edward H. Hammond
The Sunshine Project
PO Box 41987
Austin, TX
78704-0545

Dear Dr. Hammond,

I am writing in response to your inquiry about the IBC at Western Kentucky University and your request for minutes.

I have enclosed the minutes for your perusal.

Please do not hesitate to contact me if I can be any further assistance in this manner.

Sincerely,

A handwritten signature in blue ink that reads 'Kinchel C. Doerner'.

Kinchel C. Doerner, Ph.D.
Assoc. Prof. of Biology (Microbiology)
Biology Department
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Cc: Phil Myers
Cc: Sean Rubino
Cc: Michelle Johnson-Lancaster, NIH

Minutes
WKU Institutional Biosafety Committee (IBC)
Monday, May 10, 2004

Call to Order

The WKU Institutional Biosafety Committee (IBC) was called to order by Chair Kinchel Doerner on Monday, May 10, 2004 at 2:10 p.m. in room 216 of the Thompson Complex North Wing.

Members Present

- Kinchel Doerner (Chair)
- Chris Keyser (Community Member)
- Terry Flynn (Community Member)
- Charlotte Reeder
- Barry Woosley
- Mark Clauson
- Pamela Napier (Administrator)

Members Absent

- Rick Fowler

Minutes from the Previous Meeting

The minutes from the Monday, January 12, 2004 meeting were approved as distributed.

Old Business

Charlotte Reeder did work orders to have the doors to Thompson Complex repaired to improve security.

Terry Flynn has talked with the Agricultural Extension Office about people who might be willing and qualified to be ad hoc consultants about plant research. Terry talked with Carol LaFaver who suggested Joanna Coles (trained in animal health and crop health) as being available to consult with the WKU IBC if questions about plant research arise. Contact information for Joanna Coles is 270-843-1681 (telephone) and jcoles@uky.edu (e-mail).

If the IBC proposed bylaws are approved, then ad hoc (temporary) IBC members may be appointed as needed.

The IBC Recognition and Approval Letter which WKU received last month (April 2004) from the National Institutes of Health (NIH) will be posted to the IBC web site. We have to have the approval renewed every year in April.

The IBC members discussed the following points relating to research in various departments which might fall under the oversight of the IBC:

Dental Hygiene: Kinchel Doerner reported that according to Doug Schutte, the Department of Dental Hygiene is already using up-to-date procedures. They have committee meetings every fall to keep up with ADA (American Dental Association) and OSHA (Occupational Safety and Health Administration) regulations. The IBC members agreed that Dental Hygiene faculty members can staple their guidelines to the IBC form, instead of filling out our form.

Nursing: Charlotte Reeder reported that the Department of Nursing does not have an exposure control plan in writing. Since the risk to Nursing students comes during their clinical practice, the Nursing Department uses the plans in place at the various hospitals where students do their clinical rotations. There was one needle-stick incident reported that nursing faculty members could remember, but the hospital where it happened took care of the follow up. Charlotte does not feel comfortable with Nursing's not having a written policy.

Mobile Health Unit: Charlotte reported this unit does have a policy.

WKU Health Services: This unit has very good policies and procedures, according to Charlotte.

Environmental Health and Safety: This unit has a plan that covers Building Services Attendants, Plumbers, Groundskeepers, Police, Athletics, Preston Center, Dental Lab workers, and others. The plan primarily addresses blood borne pathogens.

Physical Education and Recreation: Charlotte will talk to faculty members in PE and Rec to see if the IBC needs to monitor research in this department. She has discovered that some experiments involving humans on treadmills having their temperature taken are taking place, but those experiments are probably being reviewed by the Human Subjects Review Board (HSRB).

Charlotte reported that she had researched the select agents question and that Kinchel is both the WKU BSO (Biological Safety Officer) and the WKU RFO (Responsible Facility Officer). She has also researched the laboratory ventilation question and has determined that if the IBC assumes responsibility for oversight of this, then Environmental Health and Safety and the "Responsible Facility Officer" would inspect the labs and report to the IBC. The IBC would have ultimate responsibility, but would not do the actual inspection.

New Business

Training: Kinchel recommended the IBC commit to training sessions for the members and for WKU faculty members we serve. He suggested having LouAnn Burnett (the Biological Safety Officer at Vanderbilt) come to our campus to do training; that we recruit local experts on relevant topics to address the committee; and that we send an IBC member to an NIH-sponsored IBC meeting and have that person report to the group afterwards.

Standing Research and Teaching: The IBC needs to approve procedures for any standing research (especially the unfunded research) labs and teaching labs. Chris Keyser moved and Mark Clauson seconded that we allow these approvals to stand for three (3) years. After three years we would send a copy of the original application to the faculty member would be asked by the IBC to update his/her approval request form if anything had changed. The description of on-going, standing research should be very broadly written.

New IBC Members: The committee discussed faculty members who might be asked to serve on the IBC beginning fall of 2004, since we now have only one faculty member on the committee. Names suggested were Nevil Speer (Agriculture), Doug Schutte or Lynn Austin (Dental Hygiene), and Karen Powell (Biology at Community College). Someone from Nursing would be a possibility as well.

Policy and Procedure Discussion: Kinchel explained his proposed revision relating to explicit exposure, and the revision concerning who must apply for approval. It was noted that at WKU, research and teaching are intertwined to the point that we really do not make a distinction between the two. This is why the IBC needs to require the same level of oversight for research labs and academic teaching labs and programs. The committee made several suggestions for wording revisions (which would clarify the intent of the policy and form directions) which Kinchel will insert in another draft which will be posted on the web site.

A fifteen minute discussion about safe handling of cow eyeballs and sewage ensued.

Kinchel noted that use of universal precautions and oversight of infection control plans are the responsibility of Environmental Health and Safety (EHS) Office, not the IBC. For example, when a student was cut by broken glass at the Preston Center, EHS was called to supervise the clean up. The IBC should concentrate on activities (in which explicit exposure might occur) relating to research and teaching, not on assisting EHS with university infection control plans.

The committee agreed to "tone down" the language in section 2(d) – we will withdraw the offer to assist EHS with infection control plans and not include language about other academic programs that are not engaged in research (such as Dental Hygiene). Academic programs that are involved in research (such as PE and Rec) will still be included.

Staggered Terms: The committee drew numbers to decide the number of years in the terms – April through March – of the current members (noting that each member may be reappointed for another three-year term at the conclusion of the current term):

Doerner 3 years

Fowler 3 years

Keyser 2 years

Reeder 2 years

Clauson 2 years

Flynn 1 year

Woosley 1 year

Person who will be appointed in Fall 04 1 year

Sponsored Programs Representative – on-going (this will be the new Compliance Manager when he or she is hired)

Adoption of Bylaws: Mark Clauson moved and Chris Keyser seconded that the proposed Bylaws of the IBC, Guidelines, and Approval Request Form (including the changes suggested at this meeting) be adopted. The motion carried.

Dates for Future Meetings

By general consensus, no date was set for the next meeting.

The URL for the **private** IBC web page is

<http://www.wku.edu/Dept/Support/SponsPrg/grants/biolinks.htm>

The URL for the **public** IBC web page is

<http://www.wku.edu/Dept/Support/SponsPrg/grants/biosafe.htm>

Adjournment

The meeting adjourned at 4:02 p.m.

Signed: _____, Recorder

Date minutes approved: _____

Signed: _____, IBC Chair

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The Spirit Makes the Master

17 January 2007

Edward H. Hammond
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PO Box 41987
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Dear Dr. Hammond,

I am writing in response to your inquiry about the IBC at Western Kentucky University and your general inquiry as to our level of bio-security, specifically our implementation of the 'Fink Committee' report recommendations.

I believe WKU has been proactive in addressing the gaps that exist in federal guidelines in regard to the handling and transportation of biological agents which could represent threats to human, animal, and plant health.

Thus the WKU IBC HAS implemented written policies for the identification, review, and oversight of research involving categories of experiments of concern identified by the National Academies of Science in its report Biotechnology Research in an Age of Terror (the "Fink Committee" report).

For your review, and in lieu of committee minutes, I have enclosed a copy of our policies in this area. It is my hope that you will find this policy statement more informative than committee minutes.

Please do not hesitate to contact me if I can be any further assistance in this manner.

Sincerely,

Kinchel C. Doerner, Ph.D.
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Western Kentucky University- Institutional Biosafety Committee
Policies and Bylaws.

Contact: Dr. Kinchel C. Doerner, Assoc. Prof. Biology
270-745-6000

Western Kentucky University recognizes the need for all faculty, staff, students, and visitors to work and meet in an environment free of undue risks to their health and well being. The Institutional Biosafety Committee (IBC) will, in part, ensure the University meets this goal. The IBC will provide oversight for university activities, both instructional and research, involving recombinant DNA, culturing of microorganisms, agents infectious to plants, humans, and animals, incidental exposure to potential infectious agents, human gene therapy, and Select Agents as defined by U.S. federal agencies. To ensure public trust in these activities, the IBC will include no less than two public citizens serving as members. This committee shall serve as the IBC as defined by the National Institutes of Health.

Section 1. Composition and Governance of Committee

I. Selection of IBC Members

The IBC shall be appointed by the Vice President of Academic Affairs-Provost of Western Kentucky University.

II. Composition of the IBC.

The IBC will be collectively capable of assessing the risks to the public or the environment of those activities described above. The IBC must contain persons with expertise in rDNA technology, biological safety, and physical containment.

The IBC shall be composed of a Chair/ Biological Safety Officer (BSO) with no less than seven additional (7) members.

The IBC shall include a Chair, who will also serve as the BSO and is a full-time faculty member of WKU. Duties of the BSO will be as defined by the National Institutes of Health and the IBC.

The WKU-Environmental Health and Safety Department will have committee membership. One person shall be appointed by the Director of the Environmental Health and Safety Department to serve the IBC.

The IBC must contain no less than one person representing laboratory technical staff.

The IBC must contain no less than one WKU faculty member, other than the Chair/BSO.

The IBC must contain no less than two (2) members of the general public unaffiliated with the university.

The IBC will ensure as least one scientist expert in plant, plant pathogen, or plant pest containment principles is on the committee with full voting privileges when experiments utilizing plants are under review.

The IBC will ensure as least one scientist expert in animal containment principles is on the committee with full voting privileges when experiments utilizing animals are under review. Alternatively, the committee reserves the privilege of placing applications under review of the WKU IACUC. In such instances, the recommendation of the IACUC will serve as a single vote.

The IBC reserves the privilege of appointing *ad hoc* temporary members to assist in the review of pending applications. Temporary members will not necessarily be appointed by the VPAA-Provost but as deemed necessary by the committee. An *ad hoc* member has one vote on the consideration of specific proposals. Proposals on which *ad hoc* members may vote must be specifically identified by the committee prior to the appointment of the *ad hoc* member.

III. Term Limits

Members shall be appointed for three (3) years.

Members can serve no more than two (consecutive) terms before reappointment.

The EHS appointee may serve more than two consecutive terms.

Initially, terms of IBC members shall be staggered in such a fashion that a majority of the committee members will not retire simultaneously.

The IBC reserves the privilege to recommend to the Vice-President of Academic Affairs-Provost to shorten appointments to less than three (3) years for the purposes of staggering the retirement dates of the IBC members.

Members of the IBC will appoint the Chair-BSO for three-year appointments. Any person serving as Chair-BSO may serve more than two consecutive terms.

IV. Conflict of Interest

No member of the IBC may be involved (except to provide information required by the committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest.

Members of the IBC may not vote on proposals which list the member as the P.I. or Co-P.I.

V. Training of IBC Members

All IBC committee members must undergo no less than one training session per one three year term. Training sessions will be offered by WKU on an "as needed" basis. Training sessions could cover, but not necessarily limited to, technical training of laboratory methodologies, informational presentations of the current scientific understanding of relevant fields, and/or instruction on the IBC committee structure and function.

VI. The Office of Sponsored Project will provide Administrative Support to the IBC

The WKU Office of Sponsored Programs (OSP) will provide administrative support for the IBC. Duties of the OSP will include but not limited to: assistance in contacting new members, recording, editing, and distributing the minutes of committee meetings, contacting members or potential members with relevant information concerning the committee, collecting, housing, and distributing committee documents and applications.

VII. Public and University Access to IBC Activities

The IBC encourages university personnel and public citizens to participate in IBC activities.

The OSP will make available all meeting minutes, proposals, and actions on proposals to any person making such requests.

To inform the public, all IBC meeting times, dates, and locations will be posted on the OSP website no less than three (3) days prior to the meeting.

Section 2. Who Must Apply

- I. Researchers or academic programs engaged in activities involving any of the following:
 - a. Recombinant DNA: Recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
 - b. Agents known to infect plants, humans, or animals.
 - c. Explicit exposure of any person to potential infectious agents.
 - d. Human gene therapy
 - e. Select Agents
- II. Researchers
 - a. Researchers conducting scientific inquiries outside of formal teaching duties shall be held responsible for completion of all necessary applications.
 - b. For the purposes presented here, scientific inquiries outside of formal teaching duties are defined as external grant or university supported research initiatives and/or individual student or student groups research initiatives (i.e. "399 courses", cooperative education courses, etc)
- III. Academic Programs
 - a. Administrative heads of academic programs shall be responsible for application to the committee of all pertinent materials.

Section 3. Procedures for Application and Approval.

- I. All application materials will be available on the WKU-OSP website and should be downloaded and completed by the P.I. or administrative head.
- II. Completed applications will be submitted to the OSP office or the IBC, Chair-BSO and reviewed for completeness. If the applications are incomplete they may be returned to the P.I. without review. If the application is complete, it will be reviewed by the IBC and the results of the review communicated to the P.I. in a timely manner.

- III. Applications will be scored as follows:
 - a. Accept: allows the researcher to begin immediately with experiments
 - b. Reject: the researcher may not proceed with the experimentation
 - c. Accept with modification: the researcher can proceed with experimentation provided he/she accept modifications provided by the committee.

- IV. The IBC actively encourages any submitting P.I./ administrative head to seek input from the IBC members or the Chair-BSO to prevent undue delays prior to submission. In this vain, the IBC seeks to minimize time and effort required by the P.I./ administrative head to successfully acquire permission for the underlying activities.

- V. "Fast Track Approval". For applications encompassing only Risk Group 1 organisms and/or Biological Safety Containment Level 1, the Chair-BSO may grant approval without seeking immediate full committee consideration. For this approval all applications must still be completed and filed by the applicant. The full committee, however, reserves the privilege of reviewing and re-considering Fast Track Approved Protocols. It is the intention of the IBC to use Fast Track Approval to speed and simplify grant proposal submission of low risk activities without compromising institutional oversight.

- VI. The IBC recognizes that much research and teaching takes place without exterior funding sources. Therefore, applications must also be filed to seek approval for all relevant activities conducted with out a specific sponsor. Research, in this category is defined as a "Standing Research Initiative", similarly a teaching activity, in this category, is defined as a "Standing Teaching Initiative".

- VII. Filing of Applications and Duration of Approval
 - a. Applications must be filed when grant proposal applications are filed with the WKU-OSP.
 - b. Approved applications of grant proposals will remain approved for the entire duration of the granting period.
 - c. Protocols are approved for the Standing Research Initiatives and Standing Teaching Initiatives for 3 year(s), at which time re-submission is required.
 - d. The P.I./ administrative head must re-submit an application if, for any reason, organisms, methodologies, or protocols are changed or modified on any approved protocol. The P.I./administrative head is encouraged to seek guidance for an IBC member or the Chair-BSO, in such instances.

- VIII. Application for Use of Select Agents.
 - a. All applicants will be directed to Environmental Health and Safety for all matter concerning Select Agents.