Appendix A

Institutional Biosafety Committee (IBC)
Roles and Responsibilities

The policies, rules, and procedures set forth in the UAB Safety Manuals have a single, straightforward purpose: to promote a safe environment for the protection of University of Alabama at Birmingham employees, students, and visitors as well as our community and the environment. For these rules and procedures to be effective, it is important to have a structured administrative format in place that defines the roles and responsibilities of each person or administrative office.

The UAB Vice President for Research in conjunction with the Associate Provost for Research are responsible for ensuring that research is conducted in full conformity with the provisions of the safety manuals and all federal, state, and local regulations.

The Institutional Biosafety Committee (IBC) is one of several committees that reports to the UAB Vice President for Research. Various University committees (i.e., IACUC, IBC, IRB) have overlapping responsibilities for safety issues in research and teaching. The IBC coordinates the biosafety-related activities of these committees and administrative units. The IBC works with and is advisory to the Institutional Biosafety Officer and OH&S, which have institutional responsibility and enforcement authority in matters of workplace safety.

A. Charge of the Institutional Biosafety Committee

The IBC and the Department of Occupational Health and Safety (OH&S) have been charged with the planning and implementation of the campus Safety Programs. Membership is appointed by the Vice President for Research and is comprised of the Chair and members representing the community and a variety of university interests as well as members who are knowledgeable in microbiology and infectious disease, chemistry, occupational health and safety, recombinant and synthetic nucleic acid technology, animal experimentation, public health, law, and UAB policy. The Committee is structured to ensure that collective experience and expertise exists to evaluate the occupational risks associated with the wide variety of research conducted at UAB. The Committee has the authority to impose disciplinary measures in cases where there is violation of UAB's established practices and procedures.

B. Membership

The IBC composition meets the criteria prescribed in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and is responsible for ensuring that research conducted at UAB is in compliance with the Guidelines. Members are generally appointed for two-year terms but frequently serve more than one term. Two members represent the health and environmental interests of the surrounding community and have no affiliation with UAB other than membership on the IBC. Also included in the membership is at least one scientist with expertise in biological safety containment principles, one representing the laboratory technical staff, a representative from the

Animal Resources Program, and member(s) with expertise and training in human gene transfer, biological safety, physical containment, public health, law, and UAB policy. Each member is responsible for naming an alternate to act on their behalf in their absence. See Section F below for Membership Composition.

C. Responsibilities

The IBC reviews all institutional research activities involving the use of biohazardous agents and recombinant or synthetic nucleic acid material that require approval for "biosafety activities" as described in current governmental regulatory requirements. These regulatory requirements include, but are not limited to, the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, the Centers for Disease Control and Prevention (CDC) Guidelines, the Department of Homeland Security, the United States Department of Agriculture (USDA), and the Occupational Safety and Health Administration (OSHA) regulations and compliance directives as adopted and adhered to by UAB. The IBC provides consultation on policies related to the use of recombinant or synthetic nucleic acid material in UAB hospitals, clinics or clinical laboratories and works collaboratively with the groups who have primary responsibility for them.

The IBC is authorized by the President through the Vice President for Research to limit or suspend any research that is not in compliance with UAB biosafety policies and procedures. The IBC advises and works with OH&S in administering the various aspects of the campus Biosafety Program. The Committee is also responsible for drafting campus policies and procedures under their purview and for ensuring that all aspects of Appendix M, *Points to Consider,* for human gene transfer have been appropriately addressed by the Principal Investigator.

Principal Investigators who wish to perform research using recombinant or synthetic nucleic acid material or work with material classified as Risk Group 2 or above must register their project with OH&S using the appropriate forms (see OH&S website www.uab.edu/ohs for project registration forms). A detailed description of the proposed work (equivalent to the methodology section of the grant) must be submitted with the registration, and a copy of grant may be requested.

Principal Investigators who propose work involving Human Gene Transfer must submit the above documentation as well as a copy of the Investigator's Brochure, a complete copy of the Study Protocol, a copy of the NIH Recombinant Advisory Committee (RAC) determination letter, and any additional documentation from the sponsor. Any Serious Adverse Event reports must be submitted to NIH OBA as well as the IBC (See http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_M.htm#_Toc7255836 for more information). Further, any modifications or any documentation submitted to or from the Sponsor regarding the project must also be provided for review.

OH&S forwards proposals involving work performed by UAB faculty, to the IBC for review at its monthly meeting (see section 5 of this document). Electronic comments may be submitted. The IBC reviews and approves UAB campus research projects, research involving UAB faculty members who work off-campus, UAB sponsored private business initiatives conducted within UAB owned facilities, work performed on campus by outside

entities, and Veterans Administration-funded projects conducted within UAB owned facilities.

Completed registration documents and a summary that includes the methodologies proposed in the protocol must be received by OH&S by the last working day of the month, in order to be included in the next month's IBC review.

1. Non-Exempt Recombinant Research

The IBC reviews applications that involve non-exempt recombinant or synthetic nucleic acid material work. This review includes an independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research, an assessment of the laboratory facilities, compliance with policies, regulations and guidelines, and of the training, expertise, and enrollment and compliance with the OHS Employee Health Program for all personnel involved with the project. PIs may be asked to present new research applications or novel approaches in person to the committee. IBC approval is required as specified in the NIH Guidelines for all non-exempt recombinant research.

2. Risk Group 2 or Higher Research

The IBC is responsible for assuring the safe use of biological material and will review applications that involve work at Biosafety Level 2 or above. This review includes an independent assessment of the containment levels for the proposed research, an assessment of the laboratory facilities, compliance with policies, regulations and guidelines, and of the training, expertise, and enrollment and compliance with the OHS Employee Health Program for all personnel involved with the project. PIs may be asked to present new research applications or novel approaches in person to the IBC. The IBC will determine the level of medical surveillance for programs in conjunction with the recommendations from OH&S Employee Health. IBC approval is required prior to work with the proposed agent.

3. Human Gene Transfer Research

The IBC reviews applications that involve Human Gene Transfer work. This review includes an independent assessment of the containment levels for the proposed work, an assessment of the laboratory and clinical facilities, compliance with policies, regulations, and guidelines, training and expertise of personnel, and Appendix M, *Points to Consider,* for human gene transfer. PIs may be asked to present new research applications or novel approaches in person to the IBC. IBC approval is required for all Human Gene Transfer protocols prior to patient enrollment in the study.

D. Additional Responsibilities

The IBC will set required containment for research projects and may, at its discretion, increase or reduce the Biosafety Level depending on the circumstances presented by a specific project.

Accidents and near-accidents shall be carefully analyzed by the Committee in conjunction with OH&S with results and recommendations for the prevention of similar occurrences distributed to all who might benefit. The intent shall not be in attributing blame but contributing to a safer environment.

The IBC shall adopt emergency plans to cover accidental hazardous material spills and personnel contamination. The IBC will coordinate with institutional officials and will cooperate with state and local public health departments and provide reports to the UAB Vice President for Research.

The IBC shall periodically review the UAB Biosafety manual and ascertain compliance with the policies and procedures outlined in the manual. The IBC shall review the effectiveness of the UAB Biosafety program and make recommendations for improvements.

The IBC shall assure that Deans, Chairs, and other administrators are aware of and require compliance with the safety policies and procedures outlined in the UAB safety manuals.

E. Meeting Schedule – 2015

The IBC proposed meeting dates for 2015 are as follows:

- January 26
- February 23
- March 23 (4th Monday)
- April 27
- May 18 (3rd Monday due to Memorial Day)
- June 29
- July 27
- August 31
- September 28
- October 26
- November 30
- December 21 (3rd Monday due to holiday schedule)

F. Membership Composition

Suzanne M. Michalek, Ph.D., IBC Chair
Department of Microbiology
258 BBRB – 2170

Donna S. Williamson, M.S. in Microbiology, Director Research Safety Committees and Employee Health (IBC Contact Person)
Occupational Health & Safety
Ch19 445, -2041

Carolyn Dobbs, M.P.H., M.D., Ph.D., Non-UAB Affiliated Member
Jefferson County Department of Public Health
1400 6th Avenue South

Birmingham, Alabama 35205

Julie Cobb, R.N., Non-UAB Affiliated Member Alternate
Jefferson County Department of Public Health
1400 6th Avenue South
Birmingham, Alabama 35205

James J. Odom, Jr., M.S. L.L.B., Non-Affiliated Member
Practicing Attorney
P.O. Box 11244
Birmingham, Alabama 35202-1244

Michael B. Odom, B.A., J.D., Non-Affiliated Member Alternate
Haskell Slaughter Young & Rediker, LLC
1400 Park Place Tower
2001 Park Place North
Birmingham, Alabama 35203

H. Joseph Ronsisvalle., Non-Affiliated Member
Special Agent
WMD Coordinator
Federal Bureau of Investigation
US Department of Justice
1000 18th Street North
Birmingham, Alabama 35203

Pam Bounelis, Ph.D., Assistant Dean for Biomedical Research
School of Medicine Dean Office
FOT 1203 – 3412

Kyle Boyett, Assistant Director of Biosafety
Assistant Director of Biosafety
CH19 445 – 2041

Elaine E. Broussard, M.P.H., Executive Director OH&S, Research Health and Safety (Biosafety Officer)
Occupational Health & Safety
CH19 445 – 2041

David G. Cannon, BA, CPIA
Director
Institutional Animal Care and Use Committee
CH19 403, 2041

Samuel C. Cartner, D.V.M., M.P.H., Ph.D., Animal Expert
Assistant VP Animal Research Services
Animal Resources Program
RSB 220L, -2800

Erik D. Dohm, D.V.M., Animal Expert Alternate Member
Senior Clinical Veterinarian

Animal Resources Program
RSB 220, -2800

Julie Gibbs-Erwin, B.S., B.S., MT (ASCP)
Office of the Vice President for Research and Economic Development
RSB 220, -2800

Joel N. Glasgow, Ph.D.
Assistant Professor
Department of Medicine
BMR2 572, -2180

Meredith Preuss, Ph.D., Alternate Member
Assistant Professor
Endocrinology, Diabetes, & Metabolism
SHEL 1207, -2182

Harry G. Johnson, B.S.
Occupational Health & Safety
CH19 – 2041

Stephen A. Moser, Ph.D.
Professor, Laboratory Medicine
WP P230, -7331

Max L. Richard, B.S., M.P.H.
Assistant Vice President
Occupational Health & Safety
445 CH19 1- 2041

Justin Roth, Ph.D.
Instructor
Department of Pediatrics
CHB 140A2

Theresa V. Strong, Ph.D.
Professor
Department of Medicine
WTI 510H, -3300

Amanda Watts, MS, CPIA, Alternate Member
Assistant Director
Institutional Animal Care and Use Committee
CH19 403, -2041

Ad Hoc Members:
(UAB Faculty and Staff)

Mitchell S. Pate, Ph.D., RBP, SM (NRCM), CBSP, Corporate Biosafety Officer, Southern Research Institute
Birmingham, AL 35224

Judith McBride, CIH, Director Institutional Chemical Safety and Environmental Management Committee
CH19 445 - 2041

J. Daniel Lynn, M.S., School of Medicine, Chairman's Office
409A BDB – 0012

Michael A. Markiewicz, PHA
Pharmacist
JT 1728 – 6860

Margaret M. Lawson, CIM, Institutional Review Board (IRB) Assistant Director
AB 470 – 0111

Alan M. Stamm, MD, Infection Control Committee (ICC) Chair
MEB 612 – 3296

Ex-Officio Members:
(UAB Occupational Health & Safety Staff)

Robert Heath
Director of Radiation Safety
CH19 445 - 2041

Randy Pewitt
Executive Director OH&S, Emergency Management, Campus, and Health Care Safety
CH19 445 – 2041