

North Carolina A&T State University

POLICIES & PROCEDURES FOR THE USE OF RECOMBINANT DNA AND INFECTIOUS AGENTS



The Division of Research and Economic Development
Revised 03/15/05

North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents

TABLE OF CONTENTS

POLICY	4
BIOHAZARDOUS MATERIALS	4
RECOMBINANT DNA	4
INFECTIOUS BIOLOGICAL AGENTS	4
RISK ASSESSMENT AND SELECTION OF APPROPRIATE SAFEGUARDS	5
RISK FACTORS	5
RISK GROUPS	5
CONTAINMENT LEVELS	5
SAFETY AND TRAINING	5
BIOLOGICAL SAFETY PLAN	5
BIOLOGICAL SAFETY WORKSHOPS	6
BIOLOGICAL SAFETY INFORMATION	6
REPORTING LABORATORY ACCIDENTS AND EXPOSURES	6
PRINCIPAL INVESTIGATOR RESPONSIBILITIES	7
RECOMBINANT DNA PROTOCOL	7
INFECTIOUS MATERIALS PROTOCOL	7
COMMITTEE RESPONSIBILITIES	8
APPLICATION MATERIALS	9
A. APPLICATION INVOLVING RECOMBINANT DNA	9
B. APPLICATION INVOLVING INFECTIOUS BIOLOGICAL AGENTS	10
APPLICATION PROCESSING	10
COMMITTEE REVIEW/DECISION	11
REVISED APPLICATIONS	12
CONTINUATION APPLICATIONS	13
RECORDS	13
COMPLIANCE	13
APPENDIX A-1 REGISTRATION FORM FOR RECOMBINANT DNA	13
APPENDIX A-2 RECOMBINANT DNA/INFECTIOUS BIOLOGICAL AGENTS APPLICATION STATUS FORM	17
APPENDIX A-3 EXEMPT RECOMBINANT DNA MOLECULES	19
APPENDIX B-1 BIOLOGICAL ACCIDENT REPORT	20
	2

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

APPENDIX NO. B-2	UTILIZATION OF INFECTIOUS BIOLOGICAL MATERIALS	21
APPENDIX B-3	BIOLOGICAL LABORATORY SAFETY PLAN	22
APPENDIX B-4	ADDENDUM TO LABORATORY SAFETY PLAN	25

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

POLICY

It is the policy of North Carolina A&T State University that all research involving biohazardous agents be reviewed and approved by a Biosafety Committee in accordance with requirements set forth in the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules," Occupational Safety & Health Association (OSHA) "Occupational Exposures to Hazardous Chemicals in Laboratories" (referred to as the "Laboratory Standard") and the Center for Disease Control (CDC). Although the "Laboratory Standard" does not refer to biological agents, the policy of this University is to apply the same basic requirements and responsibilities for training, Laboratory Safety Plan, and reporting of accidents/exposures, to biological agents. This policy applies to research that is:

- sponsored by the University;
- conducted by employees or agents of the University; or
- conducted using the University's property, facilities, students or non-public information.

The University is responsible for ensuring that research and teaching activities are carried out in a manner that protects students, University employees, and the community. The use of Recombinant DNA may or may not require the use of infectious biological agents. Therefore, the regulations and procedures are included for both.

BIOHAZARDOUS MATERIALS

The Institutional Biosafety Committee (IBC) reviews the use of Biohazardous Material, which includes Recombinant DNA and Infectious Biological Agents.

Recombinant DNA

The NIH Guidelines define Recombinant DNA molecules 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.

Infectious Biological Agents

Infectious biological agents or biologically derived infectious materials present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to the potential for large populations in nature when small numbers are released from controlled situations.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Categories of Potentially Infectious Materials

1. Human, animal and plant pathogens (bacteria, parasites, fungi, viruses);
2. All human blood, blood products, tissues and certain body fluids;
3. Cultured cells and potentially infectious agents these cells may contain;
4. Clinical specimens; and
5. Infected animals and animal tissues.

RISK ASSESSMENT AND SELECTION OF APPROPRIATE SAFEGUARDS

Risk Factors

Research involving biohazardous material is classified on the basis of perceived risk (RG1 - RG4) to humans into four biological and physical containment levels (BL1 - BL4). There are no laboratories at North Carolina A&T State University certified to conduct BL-3 or BL-4 research. Risk operating levels are limited to RG1-RG2.

Risk Groups

- Risk Group (RG1) This risk group contains agents that are not associated with disease in healthy adult humans.
- Risk Group (RG2) This risk group contains agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

Containment Levels

Biosafety Level (BL-1): The (BL-1) containment level is suitable for work involving agents of unknown or of a minimal potential hazard to laboratory personnel and the environment.

Biosafety Level (BL-2): This level of containment is suitable for work involving agents of a moderate potential hazard to personnel and the environment. The agents are associated with human disease, which is rarely serious, and for which preventive or therapeutic interventions are often reliable.

SAFETY AND TRAINING

Biological Safety Plan

All laboratory personnel must be informed of the hazards associated with the work and proper safety precautions. It is a continuing process that begins before a new employee starts laboratory work and

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

requires regular supervision and emphasis. Each employee must receive a copy of the written Biological Laboratory Safety Plan (BLSP) describing the safety precautions observed in his/her laboratory. Written information and reference material should be made available to laboratory personnel.

Biological Safety Workshops

Faculty and staff working in a laboratory involved with infectious biological agents are required to attend a Biological Safety Workshop every year. Students working in laboratories where biological research with infectious agents is being conducted are required to attend a biological safety workshop every year.

These workshops will be provided by the university and may consist of topics related to biological research, laboratory safety, waste disposal methods, and state and federal regulations. Attendance at these workshops will be documented in the BLSP. Failure to comply with this training requirement will result in suspension of the research project until compliance is achieved.

Biological Safety Information

The CDC/NIH publication Biological Safety in Microbiological and Biomedical Laboratories, HHS publication No. (NIH) 93-8395, 3rd Edition, May 1993, is an excellent resource for information pertaining to biological safety. This publication is available via the Internet at <http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-1.htm>. Click on <http://www.cdc.gov/> and search “biological safety” to obtain additional information.

Reporting Laboratory Accidents and Exposures

All laboratory accidents, which result in major spills or exposure of laboratory personnel, shall be reported immediately to the departmental chairperson, Dean, the Institutional Biosafety Committee Chairperson and the office of Environmental Health and Safety (EHS). A major reportable spill is a spill in which the principal investigator determines that there is any risk at all that the spill was not contained. Accidents, exposures, potential exposures, and clinical illness must be reported. Reportable accidents include any incident causing serious exposure to personnel or danger of environmental contamination. A written accident report must be submitted to the EHS Office, within 48 hours of the accident, using the "Biological Accident Report Form" (refer to Appendix B-1). The Chairperson of the Institutional Biosafety Committee is available to assist investigators in the selection of appropriate safeguards.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

PRINCIPAL INVESTIGATOR RESPONSIBILITIES

Recombinant DNA Protocol

The principal investigator must adhere to the NIH Guidelines in the conduct of Recombinant DNA (RDNA) research and perform the following responsibilities:

- Assess the risk level in working with RDNA molecules;
- Determine if the procedure is exempt from the NIH Guidelines;
- Select appropriate microbiological practices and laboratory techniques;
- Provide all laboratory staff with protocols and define safety procedures;
- Supervise the safety of the staff;
- Comply with annual reporting requirements and report within 30 days any problems related to the implementation of containment practices to the Chairperson of the Institutional Biosafety Committee;
- Report any new information bearing on the Guidelines to the Recombinant DNA Committee; (The Chairperson of the Committee will notify the Division of Research and Economic Development (DORED) and DORED will notify NIH (ORDA)).
- Provide instruction regarding specific techniques for recombinant DNA research and dangers of materials to be handled and inform all technical personnel of the section(s) of the NIH laboratory Safety Monograph that pertain to techniques being employed;
- Assure that all technical personnel and students attend courses on general laboratory safety organized by the Office of Safety, Health and Environmental Affairs; and
- Comply with shipping requirements for Recombinant DNA molecules; (See Appendix H of the NIH Guide.)

Infectious Materials Protocol

The principal investigator must adhere to the requirements for the safe handling of infectious materials as stated in the NIH Guide, OSHA “Laboratory Standard” and regulations promulgated by the Center for Disease Control (CDC) which include the following responsibilities:

- Assess the risks for the agents used in the laboratory and for selecting the appropriate safeguards;
- Prepare a written Biological Laboratory Safety Plan (BLSPP); and
- Supervise the training of assistants and students in safe practices for biological research prior to an activity involving the handling of research material in the laboratory.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

COMMITTEE CHAIRPERSON'S RESPONSIBILITIES

The Institutional Biosafety Committee Chairperson has the following responsibilities:

- Call and preside over meetings of the Institutional Biosafety Committee;
- Review and insure compliance of all authorized researchers utilizing biohazardous materials;
- Coordinate the review process of researchers seeking use of biohazardous material through research programs at the University;
- Ensure that Committee members are properly trained;
- Review all instances of noncompliance and recommend corrections to the University; and
- Notify the Principal Investigator of the results of the Institutional Biosafety Committee's review.

COMMITTEE RESPONSIBILITIES

The responsibilities of the Institutional Biosafety Committee are:

- Assist the Vice Chancellor for Research and Economic Development in the development of appropriate procedures as required by OSHA and NIH to oversee research involving infectious biological agents;
- Develop a list of the responsibilities and duties of the Institutional Biosafety Committee;
- Recommend to the Chancellor, through the Vice Chancellor for Research and Economic Development, the suspension or termination of any project which it finds in noncompliance or poses a threat to the health and safety of the University community;
- Review the policies and procedures of the Institutional Biosafety Committee on an annual basis and report to the Vice Chancellor for Research and Economic Development;
- Review biohazardous research conducted at or sponsored by University for compliance with the NIH Guidelines, OSHA and CDC, and approve those research projects that are found to conform with the NIH Guidelines, OSHA and the CDC including **(a)** an independent assessment of the containment levels required by the NIH Guidelines for the proposed research; and **(b)** assessment, if applicable, of the facilities, procedures, practices, and training and expertise of personnel involved in the proposed use of infectious biological agents.
- Set containment levels as specified in the NIH Guidelines;
- Conduct periodic review of biological research at the Institution to ensure compliance with the NIH Guidelines;
- Recommend specific training for the use of bio-hazardous materials and;

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

- Adopt emergency plans covering accidental spills and personnel contamination resulting from biological research.

APPLICATION MATERIALS

Select the application materials that are required for either “Recombinant DNA” or “Infectious Biological Agents” unless the study involves RDNA and Infectious Biological Agents. In that case both applications must be completed and submitted to the DORED.

A. Application Involving Recombinant DNA

The Recombinant DNA Application must include the following materials:

- 1. Registration Form for Recombinant DNA (Appendix A-1)**
<http://dor.ncat.edu/compliance/forms/registration.pdf>

This document has been prepared according to the current NIH Guidelines and will contain a description of:

- The source(s) of DNA;
- The nature of the inserted DNA sequences;
- The hosts and vectors to be used;
- Whether a deliberate attempt will be made to obtain expression of a foreign gene in the cloning vehicle and if so, what protein; and
- The containment conditions specified by these guidelines.

The Registration Form must be dated and signed by the Investigator.

2. Research Proposal

3. Lay Summary - The summary should be between one and two pages, single-spaced type, and should be written so as to be understandable by lay persons. It should emphasize the potential pathogenicity of Recombinant DNA to be used, safety precautions to be taken, and the importance of the research project to the furtherance of biological or medical sciences.

B. Application Involving Infectious Biological Agents

The following application materials are required:

1. Utilization of Infectious Biological Materials Form

Reference Appendix B-2. <http://dor.ncat.edu/compliance/forms/utilization.pdf>

2. Biological Laboratory Safety Plan- Reference Appendix B-3.
<http://dor.ncat.edu/compliance/forms/plan.pdf>

A Biological Laboratory Safety Plan (BLSP) must be prepared by the principal investigator and submitted to the EHS Office before initiating the research project. The Biological Laboratory Safety Plan (BLSP) will be reviewed annually by the Institutional Safety Committee (EHS Office) for renewal with revisions for changes that have occurred in the laboratory during that year. Review and approval of a new BLSP required in order to continue research.

3. Biological Laboratory Safety Plan Annual Review

The Biological Laboratory Safety Plan must be reviewed by the EHS Office on an annual basis. If an investigator is currently engaged in research at the same or lower biosafety level as proposed, the BLSP is on record can be referenced. However, if the investigator is not currently involved in such research or intends to increase the biosafety level, a new BLSP must be generated and approved by the Committee within ten (10) days of proposal submission.

4. Use of Hazardous Materials in Laboratory Animals - Addendum to Laboratory Safety Plan - (Reference Appendix B-4) This Form is only required if infectious biological materials are used in animals.

5. Research Proposal

6. Lay Summary - The summary should be between one and two pages, single-spaced type, and should be written so as to be understandable by lay persons. It should emphasize the potential pathogenicity of the agent to be used, safety precautions to be taken, and the importance of the research project to the furtherance of biological or medical science.
http://dor.ncat.edu/under/facultyres/forms/form_2_81.doc

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

The DORED is responsible for coordinating the review process for applications to possess and use Recombinant DNA and infectious biological agents at North Carolina A&T State University.

1. Submit three (3) copies your application materials to the DORED to the attention of:

Director of Sponsored Programs
DORED, Fort IRC Building

Allow two weeks in advance of a proposal deadline to permit time for Committee review. In the event that this is not possible, the proposal will be submitted to the sponsor to accommodate the deadline. However, the application must be completed and submitted to the DORED within 10 days of the proposal deadline. Approval to use Recombinant DNA and Infectious Biological Agents must be obtained prior to initiation of any research project.

The Compliance Officer will prepare an official record file and forward the documents to the Chairperson of the Institutional Biosafety Committee for review.

COMMITTEE REVIEW/DECISION

Experiments at Exempt or BL-1 Level of Containment

Exempt Studies

Certain studies are prohibited by the guidelines; other studies are exempt from review. The committee chairperson should be notified as soon as possible during the development of the proposal. Proposals which require IBC approval should be reviewed two weeks before final submission. It is not always possible for a proposal to receive IBC approval before submission. In these cases, a conditional approval shall be arranged with committee chairperson prior to submission.

All work involving recombinant DNA that is subject to the current NIH Guidelines must be reviewed and approved by the Institutional Biosafety Committee before such work can begin. The Guidelines require that the Committee be petitioned for proposed exemptions from the NIH Guidelines for those experiments, which are exempt from review and approval. The application and review process for such petitions is in accordance with the Recombinant DNA Procedure stated in this document. Refer to Appendix A-3 for a list of Recombinant DNA molecules that are exempt from the NIH Guidelines.

The Chairperson or his/her designee (Committee Member) shall review the documents submitted and render a decision if the application is at the BL-1 level.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Experiments at Containment level BL-2

The Chairperson will select members from the Committee to serve on a subcommittee to conduct a site visit of the investigator's laboratory. The principal investigator may be asked to appear before the Committee to provide additional information. If the application requires a BL-2 level of containment, a Committee meeting will be held to review the documents submitted and to receive a report on the site visit and a certification of the BL level of containment.

No member of the Committee may be involved (except to provide information requested 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.

It is not always possible for a proposal to receive IBC approval before submission. In these cases, a conditional approval shall be arranged with the committee chairperson prior to submission.

3. Notification

The Chairperson shall provide written notification of the Chairperson/Committee's decision to the principal investigator and the DORED.

REVISED APPLICATIONS

1. Revisions to (1) "Registration Form for Recombinant DNA; or (2) Utilization of Infectious Biological Materials Form

"No Changes to Proposal or Summary"

- Submit three copies of the applicable Revised Registration Form to the DORED.
- DORED will forward the Revised Registration Form to the Committee for review and approval.

2. Major Changes to Proposal

Major changes in the proposal will require: (1) a Revised Registration Form (RDNA) - Appendix A-1 or (2) a Revised Utilization of Infectious Biological Materials Form, Appendix B-2; and (3) a revised Summary and Proposal. These should be submitted

to the DORED. Examples of such major changes are (a) a significant change in hosts or vectors; (b) a significant change in the physical location of the experiments; or (c) a change of the responsible investigator. The DORED will forward the materials to the Committee for review and approval.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

3. Minor Changes to Proposal

- Send a written report to the DORED.
- DORED will consult with the Chairperson of the Committee and forward the material to the Committee if required.

CONTINUATION APPLICATIONS

A revised Application does not have to be submitted at the time of grant renewal if no significant changes have occurred. However, an Application Status Form must be filled out and submitted to the DORED. A copy of the Form is attached as Appendix A-2.

RECORDS

The DORED will maintain, for public viewing, minutes of IBC meetings, information about future meetings, a lay summary of each proposal submitted by principal investigators, and a list of reference material helpful to an understanding of the procedures involved in studies of Recombinant DNA molecules and infectious biological agents.

COMPLIANCE

When research with biomaterial is first initiated, rules for observing the proper BL level of containment must be posted in the laboratory. All storage cabinets/refrigerators/freezers that contain Biohazardous Material shall be labeled with a Biohazard Label. Any changes in the names, addresses and phone numbers of persons employed in laboratories engaged in biomaterial studies must be reported to DORED.

(a) Re-inspection of Facilities

The EHS office will make periodic inspections of major equipment items such as biological safety hoods, autoclaves, etc. in order to insure proper containment of agents being used.

(b) Health Surveillance

Minimum requirements are stated in the NIH Guidelines for the reporting of extended illnesses and accidents. The principal investigator may initiate other measures such as those discussed in the NIH Laboratory Safety Monograph. The Institutional Biosafety Committee will determine the necessity, in connection with each project, for health surveillance of recombinant DNA research personnel, and conduct, if found appropriate, a health surveillance program for the project.

Appendix A-1 REGISTRATION FORM FOR RECOMBINANT DNA

RDNA Application Number:

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Principal Investigator: _____ Dept.: _____
Telephone: _____
Sponsoring _____ Agency: _____
Title of Grant Application: _____

CHECK ONE:

New Proposal: _____ Revision of Previously Submitted Proposal: _____
Exempt: _____ Non-Exempt: _____

1. List the highest level of perceived risk to humans: Risk Group (RG): _____ 2.
List the highest containment level: Biosafety Level (BL)
3. If there is a proposed increase in the BL level of containment, have the facilities been certified by the Institutional Biosafety Committee? _____ 4.
Proposed Start Date:
5. Are large-scale experiments (more than 10 liters of culture / experiment) planned?
Yes _____ No _____

Complete the following using a separate sheet if necessary:

List the Source(s) of DNA.

List the Nature of the Inserted DNA Sequences.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

List the Host(s) and Vector(s) to be Used.

Identify the protein if an attempt will be made to obtain expression of a foreign gene in the cloning vehicle.

If the proposed experiments are to be carried out off-campus, are the RDNA assurances from the off-campus site attached to this form? Yes _____ No

Provide the following information to assist the Committee's evaluation:

(a) Names, addresses and phone numbers of persons employed in laboratories engaged in Recombinant DNA studies; if persons have not yet been hired for Recombinant DNA work, list the number of persons proposed in the grant application who could be assigned to Recombinant DNA work and state their position i.e. technician, graduate student, postdoctoral fellow, etc.;

(b) Description of personnel training relative to biohazard control; include background of principal investigator in Recombinant DNA techniques.

Principal Investigator Certification

The information provided in this Application is accurate and complete. I am familiar with and agree to abide by the provisions of the current NIH Guidelines for Research Involving Recombinant DNA Molecules and Biosafety in Microbiological and Biomedical Laboratories. I agree to comply with the requirements specified by the NIH Guidelines pertaining to shipment and transfer of Recombinant DNA and I accept the obligations listed in the current North Carolina A&T State University document "Policies & Procedures for the Use of Recombinant DNA and Infectious Materials"

Signed:

Principal Investigator

Date

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

COMMITTEE DECISION

The following action was taken by the Committee:

- () The proposal was reviewed by the Committee Chairman and found to be exempt.
- () The proposal was reviewed by at least three members of the Institutional Biosafety Committee (not associated with the proposal) and was found to comply with NIH guidelines for BL-2 level containment.
- () The proposal was reviewed by the Institutional Biosafety Committee and found not to comply with NIH Guidelines

Institutional Biosafety Committee Chairman

Date

Institutional Biosafety Committee Proposal Reviewers

1. _____ 2. _____ 3.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

FOR INSTITUTIONAL BIOSAFETY COMMITTEE USE ONLY

Applicant: _____

Date Received:

Approved: _____

Disapproved:

Special Conditions:

Chairperson, Institutional Biosafety Committee

Vice Chancellor for Research

North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents

Appendix A-3 EXEMPT RECOMBINANT DNA MOLECULES

According to the NIH Guide, the following molecules are exempt from the NIH Guidelines:

- (a) Those molecules that are not in organisms or viruses.
- (b) Those molecules that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.
- (c) Those molecules that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.
- (d) Those molecules that consist entirely of DNA from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).
- (e) Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the NIH Recombinant DNA Committee (RAC) after appropriate notice and opportunity for public comment. See Appendices A-1 through A-VI, of the NIH Guidelines for Research Involving Recombinant DNA Molecules, 1/96 (NIH Guidelines).
- (f) Those that do not present a significant risk to health or the environment as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See 1/96 (NIH Guidelines) Appendix C, Exemptions under Section III-E-6, for other classes of experiments, which are exempt from the NIH Guidelines.

All such research must be conducted using Biosafety Level 1 (BL1) containment.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Appendix B-1 BIOLOGICAL ACCIDENT REPORT

**Complete and forward to: EHS Office
Dowdy Building**

EXPOSED PERSONNEL:

NAME: _____ POSITION: _____
DEPARTMENT: _____ CAMPUS ADDRESS: _____
PRINCIPAL INVESTIGATOR:

ACCIDENT INFORMATION:

DATE: _____ TIME: _____ LOCATION: _____

DESCRIPTION OF INCIDENT: (Please specify the agent and route of exposure.)

Personnel Involved in Accident

Principal Investigator

Signature

Date

Signature

Date

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Appendix No. B-2 UTILIZATION OF INFECTIOUS BIOLOGICAL MATERIALS

Date: _____

Biomaterials No. _____

Project Title: _____

Sponsoring Agency: _____

Project Period: _____ to _____

Prin. Investigator: _____ School/Dept: _____

Co-Investigator: _____ School/Dept: _____

1. What is the name of each biological agent and its biological safety classification?

2. List the designated user(s)
3. Has the individual(s) been approved previously by the Institutional Biosafety Committee to possess and use agents in the biological safety classification listed in #1? Yes ___ No ___
If no, please complete and attach a Biological Safety Laboratory Plan(BLSP).

If yes, provide the date that the BLSP was last reviewed.

If you do not have experience with this biological safety level, are you willing to obtain the necessary experience? Yes _____ No _____

Principal investigator/Project Director

Date

Department Chairperson

Date

Dean

Date

Institutional Biosafety Committee Chairperson

Date

Vice Chancellor for Research

Date

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

Appendix B-3 BIOLOGICAL LABORATORY SAFETY PLAN

I. Principal Investigator (PI): _____ Biological Application No.
 Department:
 Room and Building: _____ Campus phone number:
 After-hours / Emergency No.

 List the person responsible for safety in absence of PI:
 Department:
 Room and Building: _____ Campus Phone No.
 After-hours/Emergency No.

Location of laboratories (specify all rooms in which infectious materials are used or stored):

2. LABORATORY PERSONNEL

List all employees and students that use infectious materials under your jurisdiction. Indicate lab supervisor, if applicable, and his/her after-hours/emergency telephone number. Use additional sheets if necessary.

NAME	STATUS (EPA, SPA, Part-time, student)	TRAINING (Last attendance Date)
_____	_____	_____
_____	_____	_____
_____	_____	_____

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

3. BIOLOGICAL LABORATORY SAFETY PLAN ANNUAL REVIEW

CHECK

_____ The remaining sections of the Biological Laboratory Safety Plan (BLSP) remain the same.

_____ Attached is a completely revised BLSP

Signature of Principal Investigator

Date

4. INFORMATION AND TRAINING

In accordance with The Laboratory Standard, information regarding the Laboratory Safety Manual, Laboratory Safety Plan, and Agent Material Safety Data Sheets must be communicated to employees. Indicate the location (Room number) of these items:

Laboratory		Safety		Manual
Laboratory		Safety		Plan
Agent	Material	Safety	Data	Sheets

Note: Permissible exposure information and signs and symptoms of exposure can usually be found in the Agent Material Safety Data Sheet (AMSDS).

Other

(specify):

5. INFECTIOUS AGENTS AND BIOLOGICAL SAFETY LEVEL

Please list all infectious biological materials to be used in the laboratory and the biological safety level required to handle material.

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

INFECTIOUS AGENTS

BIOLOGICAL SAFETY LEVEL

6. DESIGNATED WORK AREAS

Identify designated work areas for infectious biological material, and areas where eating or drinking is allowed, if any. Also indicate locations on the floor plan (in No. 7).

7. LABORATORY PROCEDURES

The North Carolina Agricultural and Technical State University Biological Laboratory Safety Manual provides a basic safety protocol. List the safety procedures that are needed to supplement those in the manual and append them to this Plan. Include special precautions and handling procedures for those infectious biological materials that are used in the laboratory.

8. FLOOR PLAN

Please attach a floor plan of each laboratory, showing location of infectious material storage, location of laboratory benches, desks, laboratory hoods, spill control supplies, and any other items to assist emergency response personnel.

9. WASTE DISPOSAL

Describe measures to decontaminate biological waste. (Indicate storage locations on the floor plan (No. 8)). I understand that I, not my technical staff, am responsible for laboratory safety and the adequacy of safety procedure associated with infectious biological material in the laboratory. I also understand that I must inform the Institutional Biosafety Safety Committee if my procedure for handling these agents changes significantly or I have new employees who will handle these materials.

Signature of Applicant

Date

I have reviewed this application and description of space and facilities of this work and approve the project.

Department Chairperson

Date

*North Carolina A&T State University
Policies & Procedures for the Use of Recombinant DNA
And Infectious Agents*

4. Will animals be removed from Laboratory Animal Research Unit facilities? List the new location.

5. Will animal tissues or other specimens be removed from Laboratory Animal Research Unit (LARU) facilities? Yes _____ No

If “yes”, identify the new location:

6. Describe procedures for transporting animals and/or infectious materials to and from LARU facilities.

7. Indicate appropriate Animal Biological Safety Level for proposed work.

8. List special animal care procedures/precautions to be performed. Use a separate sheet if necessary.