

## Code of Federal Regulations (45 CFR 46)

SECTION A. N/A

### SECTION B. Acknowledgments of Conditions under which Reagents are being shipped by the Repository

#### **Acknowledgment of Source:**

I agree to acknowledge in all publications and presentations of studies utilizing reagents supplied by the Repository both the contributors of the reagents and the Repository. I also agree to provide copies of all articles and abstracts of such presentations to the Repository.

\_\_\_\_\_  
**Initials**

#### **Certification of Use:**

I certify that all reagents provided by the Repository will be used for research purposes only, in my laboratory only, at this institution only. The reagents or materials derived from them will not be allowed to come into the possession of any other person except those engaged in research under my direct supervision who accept these restrictions. The reagents will not be used in the manufacture, marketing or licensing of any commercial product unless written exceptions are granted by the donor and the Repository is notified prior to such activities.

\_\_\_\_\_  
**Initials**

#### **Commercial Discoveries:**

If discoveries of commercial value result through use of any of the reagents supplied by the Repository, I agree to notify the Repository and to negotiate in good faith to provide fair compensation to the donor(s) of the reagents.

\_\_\_\_\_  
**Initials**

#### **Certification of Compliance with Safety Standards:**

I understand that the requested substance(s) may pose health risks to persons handling or in the vicinity of the substance(s), the environment and the community. In that regard, I certify that I am cognizant of and will employ the appropriate biosafety standards including special practices, equipment and facilities as necessary. I will comply with all applicable Institution and Government health and safety regulations. I will directly supervise all users of the reagents and I will assume responsibility for assuring that those users are cognizant of and comply with safety standards and good laboratory practice.

\_\_\_\_\_

Initials

**SECTION B. (cont'd)**

**Responsibilities for Shipping Arrangements:**

I will assume the costs of shipping reagents from the Repository via an appropriate carrier. I assume responsibility for confirming that the carrier is willing to ship biohazardous material and will collect shipments from the Repository. I will supply a shipper account number or will make arrangements for prepaid shipments. No shipments will be made until my proposed shipping arrangements are accepted by the Repository.

\_\_\_\_\_  
Initials

**Reporting Arrangement:**

I agree to provide the Repository with an annual summary of results of research and potential commercial discoveries resulting from the use of the reagents.

\_\_\_\_\_  
Initials

**Qualified User:**

I certify that I am a (Principal Investigator/Laboratory Director) (specify one) of a non-profit research laboratory\_\_\_\_ or Director of Research in a commercial organizations. I have enclosed a Curriculum Vitae or biographical sketch. My research is supported by [specify type and identification number(s)]:

NIH Research Grant Number \_\_\_\_\_  
Other Federal Funding \_\_\_\_\_  
International/Foreign Support \_\_\_\_\_  
Private Foundation \_\_\_\_\_  
Industry \_\_\_\_\_  
Other \_\_\_\_\_

\_\_\_\_\_  
Officer of University or Company  
(Signature)

\_\_\_\_\_  
Requester  
(Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Title)

**SECTION C1: Indemnification Form**

Date \_\_\_\_\_

**INDEMNIFICATION AGREEMENT**

As a Receiving Party of schistosome parasites, snail vectors and infected mammals from the Biomedical Research Institute, the Recipient Institution \_\_\_\_\_, agrees to indemnify and hold harmless the United States, Biomedical Research Institute, their suppliers and contributors of reagents, from any claims, costs, damages or expenses resulting from any injury (including death), damage or loss that may arise from the possession and use of the Materials or any derivative thereof by the Receiving Party. The individual executing this agreement on behalf of the Recipient Institution warrants that the individual has full authority to do so, and to thereby bind the Recipient Institution.

\_\_\_\_\_  
Officer of University or Company

\_\_\_\_\_  
Requester (Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Institution)

\_\_\_\_\_  
Institution)

**NON-ACCEPTANCE OF INDEMNIFICATION AGREEMENT**

The Recipient Institution is unable to comply with the Repository Indemnification Agreement. As a result, the Recipient acknowledges that the Biomedical Research Institute will be unable to provide biohazardous materials.

\_\_\_\_\_  
Officer of University or Company  
(Signature)

\_\_\_\_\_  
Requester (Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Institution)

\_\_\_\_\_  
(Institution)

**SECTION C2: Indemnification Form (TO BE USED BY STATE INSTITUTIONS ONLY)**

**STATE INSTITUTION COMPLIANCE AGREEMENT**

As a Receiving Party of schistosome parasites, snail vectors and infected mammals from the Biomedical Research Institute, the Recipient Institution, \_\_\_\_\_, agrees to be responsible for any claims, costs, damages or expenses resulting from any injury (including death), damage or loss that may arise from the possession and use of the Materials or any derivative thereof by the Receiving Party *to the extent permitted under the laws of this State*. The individual executing this agreement on behalf of the Recipient Institution warrants that the individual has full authority to do so.

\_\_\_\_\_  
Officer of University or Company  
(Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Institution)

\_\_\_\_\_  
Requester (Signature)

\_\_\_\_\_  
(Printed Name)

\_\_\_\_\_  
(Title)

\_\_\_\_\_  
(Institution)

**SECTION D: Use of Repository Reagents in Human Subjects**

ALL REQUESTERS INTENDING TO USE REPOSITORY SUBSTANCES IN HUMAN SUBJECTS MUST SUBMIT AND COMPLETE SECTION D.

Type of Reagent: \_\_\_\_\_

Will the reagent(s) be used in a clinical research protocol?  
\_\_\_\_\_ Yes \_\_\_\_\_ No

If yes, has the protocol been reviewed and approved by an IRB which has an HHS assurance?  
\_\_\_\_\_ Yes \_\_\_\_\_ No

If yes, \_\_\_\_\_ Assurance Identification Number

\_\_\_\_\_ IRB Identification Number

\_\_\_\_\_ Date of IRB Review and Approval

\_\_\_\_\_  
\_\_\_\_\_  
Title and Protocol Number

If no, is the protocol exempt from requirement for IRB review and approval under 45 CFR Part 46 section 101(b)?  
\_\_\_\_\_ Yes \_\_\_\_\_ No

If no, is IRB review and approval not required because *Human Subjects*, as defined in 45 CFR 46 section 102(f), are not involved?

*Human subject* means a living individual about whom an investigator [whether professional or student] conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

\_\_\_\_\_ Yes \_\_\_\_\_ No

If no, please explain. \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Requester (Signature)

\_\_\_\_\_  
Date