POLICY AND GUIDELINE MANUAL-2012

INSTITUTIONAL BIOSAFETY COMMITTEE

INTERNATIONAL LIVESTOCK RESEARCH INSTITUTE

VERSION 1

Contents

SECTION 1: INTRODUCTION

1.0 Purpose

It is the responsibility of ILRI- Institutional Biosafety Committee (IBC) to review, approve and oversee the use of Biological materials and other hazardous materials within ILRI Research facilities. These materials include recombinant DNA (rDNA), biohazardous agents, materials and toxins, hazardous chemicals, radioisotopes and any materials than could be harmful to staff, research animals and environment.

The Institutional Biosafety Committee Policies and Procedures Manual (IBC Policies) provides a review of the relevant regulatory and local requirements. Since laboratory work can involve exposure not only to rDNA, biohazardous agents, materials and toxins, but also to chemical and radiological hazards, the IBC Policies should be used in conjunction with any other pertinent ILRI policies and procedures.

1.1 Mission Statement

To safeguard human health, animal health and the environment by maintaining an adherence with Kenyan reference standards, International regulations and donor requirements used by the committee through a balance of outreach and support for investigators, laboratory staff, and the research community at large.

1.2 Charge and Authority of the IBC

The Deputy Director General-Research (DDG) has charged the committee with review, approval and oversight of research involving rDNA and biohazardous materials, agents and toxins in research activities. Responsibilities of the IBC include assessment of facilities, procedures, practices and training of research personnel to assure compliance with pertinent guidelines and regulations. ILRI-IBC has the authority to approve, require modifications to secure approval, disapprove, suspend or terminate research activities as required to assure adherence to the appropriate regulations and guidelines.

ILRI-IBC has been charged with the planning and implementation of the campus Biosafety program with a purpose to ensure the health and safety of all personnel working with rDNA and hazardous materials, agents and toxins. The IBC makes certain that research conducted at the Institution is in compliance with Country (where research is conducted) regulatory requirements, other international regulations and donor regulatory requirements. The IBC is therefore responsible for establishing and implementing policies that provide for the safe conduct of research involving rDNA and hazardous materials, agents and toxins to ensure adherence with *these requirements*. Also, as delineated by DDG-Research charge to the IBC, the committee is given authority to oversee all research involving rDNA and hazardous materials, agents and toxins including suspension or termination of research that does not comply with IBC Policies.

1.3 Committee Composition

IBC members shall collectively have knowledge and expertise which is appropriate to the functions of the IBC. Members are appointed by the DDG-Research as per SOP IBC membership.

The IBC comprises of a minimum of 6 members, selected such that they collectively have the expertise biological and recombinant DNA technology. They shall also have the capability to assess the safety of research involving hazards and/or recombinant DNA research and any potential risk to public health or environment. The committee will include:

- At least one member of the public (i.e. not affiliated with the institution apart from their membership on the committee) who shall represent the interests of the surrounding community with respect to health and protection of the environment.
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles.
- At least one member that represents Laboratory technical staff.
- At least one member with expertise in DNA technology. Biological safety and physical containment
- The Biological safety officer
- At least one member with expertise in animal containment principles.

The IBC shall comprise members with expertise relevant to the work undertaken within the Institute. If the Institute is also undertaking work involving the intentional release of a GMO into the environment, then the IBC shall include a person with relevant experience (e.g. Agronomist, ecologist etc).
A member of the IBC must be appointed as Chair of the IBC.

Name	Designation	Role In Biosafety Committee
Vish Nene	Chair-Biotechnology Theme Director	Animal Health
Jores Joerg	Scientist Biotechnology Theme ILRI	Animal Health
Steve Kemp	Scientist Biotechnology Theme ILRI	Animal Genetics and Genomics
Rob Skilton	Scientist BecA-Hub	Animal Health
Kassa Semagn	Scientist CIMMYT	Plant breeding
Leena Tripathi	Scientist IITA	Plant Biotechnologist
Joseph Macharia	External Reviewer from Department of Veterinary Service (DVS)	Animal Health
Abed Kagundu	External Reviewer from Kenya Plant Health Inspectorate Service(KEPHIS)	Plant Health/Biosafety regulatory Specialist
Paul Mwangi	Assistant chief-Uthiru	Community Representative
Ephy Khaemba	Environmental, Health and Safety Manager	Biosafety and Occupational Health

Sylvia Kamau	Environmental Health and Safety officer	Secretary

1.4 Scope

The IBC policies apply to all research personnel engaged in activities and/or research involving rDNA, hazardous agents, materials and toxins that are:

Sponsored by ILRI or other donors.
Conducted by ILRI research personnel.
Conducted using ILRI property, and facilities.
Received, stored, used, transferred or disposed of at any ILRI facilities.
Research at other institutions conducted on behalf of ILRI

1.5 Regulations and Guidelines

The IBC Policy guideline is based upon the following regulations and guidelines:

Country guidelines in Kenya where the principle research facilities are located

1. the Kenyan National biotechnology Development Policy 2006,
2. Kenya Biosafety Act 2009,
3. Plant Protection Act
4. Contained use regulations Jan 2011
5. Draft Biosecurity Bill 2011
6. Animal Disease Act
7. National Livestock policy
8. Veterinary Surgeons Act, Cap 366
9. Pharmacy and Poisons Act, Cap 244
10. Rabies Act, Cap 365
11. Public Health Act

International Guidelines:

1. ***NIH Guidelines*** This document specifies practices and provides guidelines for constructing and handling rDNA molecules and organisms containing rDNA molecules. Institutions conducting or sponsoring rDNA research covered by *NIH Guidelines* are responsible, through established policies and its IBC, for ensuring that such research is conducted in compliance with the *NIH Guidelines* are available online at *http://oba.od.nih.gov/rdna/nih_guidelines_oba.html*

2. World Health Organization for Animal health (OIE) guidelines on use of animals for research work http://www.oie.int/

3. World Health Organization (WHO) guidelines

Donor Requirements;

This will depend on the donor of the project and the specific requirements they want the project to adhere to.

1.6 Definitions

Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals or the environment. The risk can be direct through infection or indirect through damage to the environment.

Biohazardous materials include certain types of recombinant DNA; organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia); and biologically active agents (i.e. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community

Human Pathogen means a biological agent that can cause disease in human beings.

IACUC means Institutional Animal Care and Use Committee

IBC means Institutional Biosafety Committee

IREC means Institutional Research Ethics Committee

NBA means National Biosafety Authority

EOHS means Environment occupational Health and Safety.

DVS means Department of Veterinary Services

KEPHIS means Kenya Plant Health Inspectorate Services.

EOHSM means Environment occupational Health and Safety Manager

IBC Secretariat means Environment occupational Health and Safety Department.

Recombinant DNA means (i) DNA molecules that are constructed outside living cells by joining natural or synthetic DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above.

Select Agents are microorganism (viruses, bacteria, fungi, prions) or toxins that have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products.

SECTION 2: RESPONSIBILITIES

2.0 Deputy Director General-Research (DDG-R) Responsibilities

The responsibility for Biosafety Program at ILRI rests with the DDG for Research, who is responsible for:

1. Appointing IBC members.
2. Annually evaluates IBC members with input from the IBC Chair
3. Oversees the IBC and research personnel who obtain, possess or use rDNA and biohazardous materials, agents and toxins.
4. Annually evaluates allocation of resources to the IBC and adjusts as necessary.

TheDDG-R has charged the IBC (See Section 1.2) to review, approve and provide oversight and guidance to those research personnel who seek to use rDNA and biohazardous materials, agents and toxins in experiments or teaching. Any possession and/or use of rDNA and biohazardous materials, agents and toxins at ILRI must be conducted with appropriate safeguards and in accordance to ILRI policies, guidelines and regulations.

2.1 IBC Responsibilities

The responsibilities of the IBC include, but are not limited to, the following:

- To undertake assessment and review of all biosafety issues relating to staff, students and others (i.e. corporate entities for which ILRI is the primary IBC; individuals and corporate entities based on ILRI properties) in ILRI. These issues include, but are not limited to, research proposals, to identify any potential biohazard which may arise in the course of research as a consequence of any type of experiment or manipulations which May result in the release or creation of novel types of nucleic acid with the capacity to multiply or spread to involve man, animals, or plants; or Involves hazardous micro-organisms or potentially tumorigenic viruses; or Involves the use of known or suspected teratogens and carcinogens.

- To assess the actual and potential risks involved in the light of the intrinsic nature of the experiments, the competence of the personnel and the security of the laboratory facilities.

- In accordance with the relevant guidelines issued by the NIH and WHO, to determine containment and procedures for experimental work under its review, and for the housing, storage and transportation of genetically manipulated organisms.

- To ensure appropriate inspection and certification of Biosafety level 2 and 3 facilities before they are used for genetic manipulation work (at least annual inspections of these facilities shall be undertaken).

- To advise research workers and their supervisors of any perceived dangers and to prescribe conditions under which the research may proceed or to forbid it altogether unless or until the committee is satisfied that the work should begin or continue.

- To ensure compliance with requirements of research–granting agencies and with any committees on biohazards which may be established at a national level in supplying information and enforcing all conditions they may lay down for the execution of research conducted under their authority.

- To collect and disseminate information on biohazards to relevant authorities.

- After initial review, approval and commencement of the research, annually review research work involving level 2 & 3 pathogens and recombinant DNA research conducted at the institute.

- Adopt emergency plans covering accidental spills and personnel contamination resulting from research involving level 2&3 pathogens and recombinant DNA.
- Notify the Principal Investigator of the results of the IBC's review, approval, or disapproval.
- Suspend or terminate protocol approval for the possession or use of rDNA and biohazardous materials, agents and toxins, where the IBC finds noncompliance or that such use or possession poses undue risk to research personnel or a threat to the health and safety of the community.
- Periodically review the IBC policies and procedures and modify them as necessary to ensure appropriate biosafety measures and adherence with federal and state requirements.

2.2 IBC Chair Responsibilities

The IBC Chair responsibilities include:

- Serve as a contact for all regulatory agencies (in addition toDDG-R who may delegate this function).
- Act as liaison between the research personnel and IBC.
- Assigns subcommittees as needed to review an issue prior to official committee decisions made at the convened meeting.
- Approve the agenda for the convened meeting of the IBC.
- Calls the meeting and directs the meeting deliberations, requests motions and seconds, and closes the meeting once it has concluded business.

2.3 EOHS Manager Responsibilities

The EOHSM shall be a member of the IBC. The EOHSM responsibilities include:

- Performing periodic inspections of laboratories conducting research using rDNA and biohazardous materials, agents and toxins to ensure that laboratory standards are rigorously followed.
- Report to IBC and DDG-R any problems, violations, research-related accidents or illnesses.
- Performing and reviewing the required risk assessment to determine appropriate Biosafety level for handling an organism.

- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving rDNA and biohazardous materials, agents and toxins.
- Providing advice on laboratory security to the IBC research personnel.
- Providing technical advice to research personnel and the IBC on research safety procedures.

The principal function of the EOHSM should be to advise the research personnel, the IBC and the laboratory worker concerning the most appropriate safety practices that will assure the safe conduct of research with rDNA and biohazardous materials, agents and toxins.

2.4 Principal Investigator Responsibilities

On behalf of ILRI the Principal Investigator is responsible to follow the *regulatory requirments* and IBC Policies when using rDNA and biohazardous materials, agents and toxins.

Along with this understanding, the Principal Investigator will also have the following responsibilities:

- Make the initial risk assessment and determination of required levels of physical and biological containment
- Be adequately trained in good microbiological techniques.
- Provide laboratory research personnel with protocols describing potential biohazards and necessary precautions.
- Instruct, train and supervise research personnel in (1) the practices and techniques required to ensure safety, and (2) the procedures for dealing with spills or potential exposures to the agents described in the research.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics) and correct procedures or conditions that might result in release of or exposure to rDNA and/or biohazardous materials, agents or toxins.
- Develop and obtain IBC approval of and adhere to biosafety plans
- Inform the research personnel of the Occupational Health & Safety Program and provisions for any precautionary medical practices advised or requested, e.g., vaccinations
- Ensure all research personnel, including students, have the required training in the accepted procedures for laboratory practices and safety.
- Obtain IBC approval prior to initiating or modifying any research involving use of rDNA and/or biohazardous materials, agents and toxins.
- Maintain IBC approval for use of rDNA and biohazardous materials, agents and toxins through timely submission of annual updates.
- Immediately report any significant problems or any research-related accidents and/or illnesses to EHS and any other ILRI committees (Institutional Research Ethics Committee (IREC), Institutional Animal Care and Use Committee (IACUC)) that have reviewed and approved the research activity.
- Comply with permit and shipping requirements for biohazardous materials.
- Although some regulations allow exemptions for some types of rDNA use, the Principal Investigator must submit an application for all projects using rDNA and

biohazardous materials, agents and toxins so the IBC can verify that they are exempt or not.

2.5 EOHS Office Responsibilities

EOHS office has been mandated as the secretariat that will provide overall administrative support, and will coordinate IBC reviews and meetings. Their responsibilities include, but are not limited to, the following:

- Provide the necessary liaison between the research personnel, the IBC, and government regulatory agencies.
- Serve as the office of record for documentation involving IBC.
- Provide all necessary documentation, forms, regulatory guidelines and regulations, to Principal Investigators.
- Maintain IBC registration forms and records.
- Assist principal investigators with GMO projects in filing annual updates and other reports to NBA,DVS and KEPHIS
- Communicating with IREC or IACUC when protocols involve human subjects or animals.
- By monitoring government regulations, draft revised policies and procedures to remain in compliance with those regulations.
- Provide administrative support for the IBC by scheduling meetings, arranging for meeting space and taking meeting minutes.

SECTION 3: PROTOCOL/MODIFICATION SUBMISSION AND REVIEW

3.0 Submissions

The IBC is responsible for overseeing and evaluating all aspects of research involving rDNA and biohazardous materials, agents and toxins, and is charged with reviewing proposals that involve rDNA and biohazardous materials, agents and toxins to ensure that the criteria established in the IBC Policy and the government regulations and guidelines are implemented. In its review of the proposals, the primary goal of the IBC is to facilitate research personnel compliance with applicable laws, regulations, guidelines and policies consistent with the performance of appropriate and productive scientific endeavors.

IBC protocol submissions, whether they are new IBC protocol submissions, modifications or renewals, must be submitted to EOHS office by the Principal Investigator for review and IBC approval. No research involving rDNA and biohazardous materials, agents and toxins can be initiated until the Principal Investigator has received the approval of the IBC.

Although governemnt regulations allow exemptions for some types of rDNA used, the Principal Investigator must submit an application for all projects using rDNA and biohazardous materials, agents and toxins so that the IBC is aware of the activities and can verify that they are exempt or not.
No one shall obtain or use rDNA and biohazardous materials, agents and toxins until the protocol has been approved by the IBC. Modifications to approved protocols shall not be implemented until approved by the IBC.

3.1 Experiments Requiring IBC Review

Experiments that require IBC review include, but are not limited to:

- GMO projects
- The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally.
- The deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules.
- The use of RG-2 or RG-3 agents as host-vector systems.
- The use of human etiologic and animal viral etiologic agents.
- The cloning of DNA from RG-2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.
- The use of infectious or defective RG-2 or greater agents.
- Whole animals in which the animal's genome has been altered by stable introduction of rDNA or DNA derived into the germ-line (transgenic animal).
- Viable rDNA-modified micro-organisms or cell lines tested on whole animals.
- Genetically engineered plants by rDNA methods. .
- Experiments using BSL-2 or BSL-3 containment.
- Non-recombinant research using biohazardous materials, agents or toxins.
- All research using biological toxins or bioactive derivatives or subunits of toxins.
- Research collecting or analyzing human or non-human primate cell lines, tissues, fluids or other potentially infectious material.

3.2 New Submissions

The online applications for both Biosafety and rDNA must be accurately completed and submitted for review and IBC approval.

3.2.1For Biosafety Applications:

- A comprehensive risk assessment duly filled will be submitted to EOHS office who will check it for completeness.
- The protocol will be reviewed by the EOHSM to ensure a complete submission, it may be necessary for the Principal Investigator to submit additional information if requested by the IBC EOHSM.
- If the research is rDNA exempt a Biosafety application may still be required.
- Approval/Non-approval will be determined by the IBC.
- The Principal Investigator will be notified of the IBC decision.

3.3 Continuing Review / Renewal

The Principal Investigator is required to resubmit their protocol(s) annually. The Principal Investigator will be notified of pending expiration of approval at 90, 60, 30 and 15 days prior to expiration of study approval. These resubmissions are reviewed in the same manner as new protocol submissions. Research cannot be continued if protocol renewal is not approved prior to the expiration date from the previous approval.

3.4 Failure to Submit Renewal/Respond to IBC Requirements

If the Principal Investigator fails to provide a renewal form to the IBC by the anniversary date, a letter will be sent to the Principal Investigator, and copied to the Head of the department. All research activities pertaining to the research described in the expired protocol must cease. If the Principal Investigator does not provide a renewal by the next IBC meeting, this issue is added to the agenda and the IBC determines whether or not to terminate the IBC protocol. Termination of the IBC protocol may require termination of any related IACUC or IREC protocols, and notification to DDG-R

3.5 Modification Process

Changes or modifications to approved protocols (i.e; change in or additional of research personnel, room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation. If the changes are extensive, or change the scope of the review, a new submission should be made.

3.6 Protocol Termination

The Principal Investigator will notify the EOHS office when a research involving rDNA and biohazardous materials, agents and toxins is completed or no longer active. The IBC shall contact the Principal Investigator if there are any questions or concerns regarding Termination of Approval.

Failure to renew a previously approved IBC protocol may result in termination of the protocol(s). In addition, non-compliance with institutional and government regulations, policies and guidelines or requirements of the IBC that are either serious or ongoing will be evaluated and the IBC may determine that the incidents require protocol termination.

3.7 Relationships to IACUC and IREC

IBC protocols submission involving the use of live animals will require IACUC review and approval prior to initiation.

IBC protocol submissions involving the administration of biohazardous agents or rDNA to humans, or involves the collection of tissues or fluids from humans, requires IREC review and approval prior to initiation.

Current IACUC and IREC protocol numbers must be included on the IBC submission.

SECTION 4: MEETING PROCESS

4.0 Requirements for Quorum

The conduct of official IBC business occurs at convened meetings that must include a quorum of members in order for the meeting to be held. The IBC defines a "quorum" as two thirds the regular voting members. A protocol is approved only if a quorum is present, and if more that 70% of the quorum votes in favor of protocol approval. For reasons other than conflict of interest, abstentions from voting do not alter the quorum or change the number of votes required. Members are expected to attend the convened meetings unless they have notified the IBC Program secretariat (EOHS) that they are unable to do so. Members who fail to attend meetings on a regular basis may be removed from the committee.

4.1 Protocol Review

For the protocol to be reviewed by the IBC the PI must submit his/her application 3weeks before the next meeting to allow ample time for Principal Investigator to respond to any queries asked by EOHS prior to discussion in next IBC meeting. The protocols must be submitted by the submission deadline or the protocol will be held until the next convened meeting.
Risk assessment has to be filled by the PI and protocols and SOPs sent to the IBC secretariat prior to discussion in IBC meeting.

4.2 Procedures

IBC meetings are routinely held once per month on the last Monday of the month. Rescheduling may occur due to inability to achieve a quorum of members and non-scheduled meetings may be called by the IBC Chair to discuss matters that arise and require immediate resolution. The IBC Program Coordinator is responsible for assuring that a meeting room is located and scheduled and that all other arrangements for the meeting are made. All meetings are scheduled to begin at 9am to 10.30am.
At the scheduled time and upon reaching a quorum, the IBC Chair will call the meeting to order and follow an agenda prepared prior to the meeting. The typical order of the agenda is as follows:

- Call to order.
- Approval of the previous month's meeting minutes.
- IBC related announcements.
- Project/Protocol Reviews.
- Educational items for discussion.
- Next meeting announcement.
- Meeting adjournment.

When reviewing protocols for initial review or periodic review of ongoing research activities, there are several activities that the IBC must carry out on behalf of ILRI

- Conduct assessment of the containment levels required
- Assessing the facilities, procedures, practices, and training and expertise of personnel involved in research with rDNA and/or biohazardous materials, agents or toxins.

- Ensure compliance with *ILRI and Government regulations in place.*

In reviewing proposed rDNA research, a number of matters that the IBC will consider include:

- Agent characteristics (e.g. virulence, pathogenicity, environmental stability).
- Types of manipulations planned.
- Source(s) of the inserted DNA sequences (e.g., species).
- Nature of the inserted DNA sequences (e.g., structural gene,).
- Host(s) and vector(s) to be used.
- Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced.
- Containment conditions to be implemented.
- Competency of the workers
- Approval letter and conditions set forth from NBA

4.3 Possible Review Outcomes

Approval – When the IBC has determined that all review criteria, based on the IBC Policies and government-mandated regulations have been adequately addressed by the Principal Investigator, the IBC may approve the research, thus providing the Principal Investigator permission to perform the research.

Approval with conditions – This status is used for protocols for which all required information has not been received, required training has not been completed and/or there are remaining issues or questions regarding the safety of the protocol.

Tabled – If the protocol requires clarification in order for the IBC to make judgment, certain committee members with certain expertise if not present, the IBC wishes to seek external consultation, or any of a number of other reasons prevents the IBC from conducting its review, then the IBC may wish to defer or table review.

Withhold Approval- When the IBC determines that a protocol has not adequately addressed all of the requirements of the IBC Policies and regulations as applicable, the IBC may withhold approval.; this action may only be taken if the review is conducted using the IBC method of review.

All non-exempt protocols are presented and discussed individually and the IBC votes on the disposition of the protocol.

4.4 Conflict of Interest

IBC Polices state that no IBC member may participate in the IBC review or approval who have a conflict of interest in the project (e.g.; are acting as the Principal Investigator, have financial interest in the project). All Principal Investigators and/or IBC members are required to disclose any conflicts of interest before the meeting commences.

Should an IBC member declare involvement in any way in a research protocol under review by the IBC, or state a conflict of interest with a research protocol, then the member(s):

- Are excluded from discussion and voting except to provide information requested by the IBC.
- May be asked to leave the meeting room for discussion and voting.
- Are not counted towards quorum.

4.5 Minutes

Review of protocols by the IBC invokes a deliberative process. IBC meeting minutes should offer sufficient detail about the discussion of the matters that were discussed in order to document the IBC rationale for particular decisions. The IBC has some latitude in the degree of detail in these minutes.

Recorded minutes of IBC meetings are intended to reflect the substantive discussion of protocols. Minutes are intended to contain sufficient information that a reasonable person could understand the nature of the discussion. In general, the minutes should offer sufficient detail to serve as a record of major points of discussion and the Committee's rationale for particular decisions, documenting that the IBC has fulfilled its review and oversight responsibilities .Meeting minutes are not intended to provide a verbatim transcript of discussion nor to reiterate shared knowledge of the Committee such as recent discussions about a protocol in previous minutes. Historical evidence of compliance or non-compliance would be recorded in the minutes if it were germane to the discussion. Minutes may include reference to historical discussion by the IBC from members who have served on the Committee and observed the procedures being proposed, served as reviewers for protocols involving similar procedures (where their questions were answered), or participated in past IBC discussions about the procedures.

Minutes of each IBC meeting are recorded in writing and contain:

- Date and place of meeting,
- Individuals in attendance,
- Whether and why the meeting was open or closed,
- All major motions, major points of order, and whether motions were approved,
- Protocols reviewed,
- The time of meeting adjournment.

All the meeting minutes are signed by the IBC chair and kept in the EOHS department as records .

4.6 Principal Investigator Notification

Upon completion of the review process (Section 3), the Principal Investigator will receive written notification of the review decisions (approved/not approved) and whether any special conditions for approval of work is required. Included in the notification will be the IBC decision on the biocontainment/biosafety level to be used for the proposed research, any special safety considerations, along with the approval period (begin/end dates).

4.7 Meeting Frequency

Convened meetings of the IBC occur monthly unless cancelled by the IBC Chair or IBC secretariat (EOHS). Meeting schedules are typically set one year in advance and posted on the Research compliance website .The Chair may call an emergency meeting of the IBC as necessary to address such issues as noncompliance or serious and/or unexpected events involving rDNA and biohazardous materials, agents and toxins.

4.8 Attendance of Non-Members

IBC meetings are considered open and, as such, members of the community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC

meeting must notify the IBC Program Coordinator in advance at 422-3375 or ibcbox@cgiar.org regarding the desire to attend. While no one will be denied access to a meeting, the IBC Program Coordinator must be made aware of additional attendees in order to schedule a room of appropriate size. Last minute requests may not be honored if the meeting room cannot accommodate additional attendees.

SECTION 5: REPORTING REQUIREMENTS

5.0 Reportable Incidents and Violations

Incidents/problems involving rDNA and biohazardous materials, agents and toxins must be immediately reported to EOHS department. Examples of reportable significant incident include but are not limited to any overt exposure, such as a needle stick, splash, and contamination due to equipment failure, and any potential exposure in a BSL-3 or 2 facilities. A significant event may also occur from a containment breach, which may be subsequently determined to pose either an overt or potential exposure to individuals. It should be noted that waste from rDNA research is also considered biohazardous and incidents involving improper disposal of rDNA must also be reported. Questions regarding reportable incidents should be directed to the EOHS office. Failure by research personnel to follow governement and institutional regulations, guidelines, policies and/or procedures may also require reporting to the appropriate institutional, local, state and/or government agencies. Violations may include but is not limited to conduct of new or ongoing research without appropriate legal or institutional registration, review, approval or oversight.

5.1 Principal Investigator Reporting

The Principal Investigator and their personnel must report any significant incident, violation of *government regulations* or any significant, research-related accidents and illnesses immediately by contacting the EOHS office. Examples of incidents and violations include:

- Overt exposures are defined as exposures that result in direct personnel exposure to biohazardous materials such as injection, spills, splashes or aerosol inhalation.
- Potential exposures are defined as exposures that have a high risk of exposing personnel to biohazardous materials such as spills, containment failure while working with the agent or equipment failure that may produce aerosols.
- Any exposure (overt or potential) in a BSL-3 lab.
- Overt exposure in BSL-1 or BSL-2 labs
- Any illness that may be caused by the agents used in the laboratory incidents involving the improper disposal of rDNA.

In addition, Principal Investigators must report other information to the IBC as soon as they become aware of the information;

- Information to support a new host-vector system.
- Information on change of protocol.

5.2 IBC Reporting

The IBC, through the EOHS department will file an annual report to be presented to Management that includes:

- A roster of all IBC members clearly indicating the Chair, contact person, EOHS manager, plant expert, and animal expert.
- Biographical sketches of all IBC members.

The IBC is required, to report to DDG-R within 30 days any significant incidents, violations or any significant research-related accidents and illnesses. The IBC will be responsible to determine what actions, if any, are necessary. For example the IBC may choose to change the frequency of lab inspections, or change the Biosafety Level of the protocol, based on results of the incident. Other IBC reporting requirements (to management and other agencies) include but are not limited to:

- Research involving rDNA and biohazardous materials, agents and toxins without prior IBC approval.
- Lax security, unsafe procedures used in a laboratory setting, improper disposal of recombinant waste.
- Significant changes to proposed research risk without prior notification and approval by IBC.

Certain types of incidents must be reported to EOHS on an expedited basis. Spills or accidents in BL2 laboratories (involving rDNA) resulting in an overt exposure must be immediately reported to EOHS. In addition, spills or accidents involving rDNA occurring in high containment (BL3) laboratory resulting in an overt or *potential* exposure must be immediately reported to EOHS office. The IBC will report to the appropriate institutional official, any of the above-described incidents.
Institutional violations that will be reported to DDG-R may include but are not limited to:

- Lapses in protocol approval.
- Failure to comply with institutional and government regulations, guidelines, and policies.

5.3 Response to External Requests for Information

Upon request, ILRI_IBC will make available to the public all IBC meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. Redaction of proprietary and private information is allowed but “must be done so judiciously and consistently for all requested documents.” In addition, the IBC will adhere to requirements for providing copies of minutes and files to government agencies as requested on need basis.

SECTION 6: NON-COMPLIANCE

6.0 Allegations

Any allegations of non-compliance or unsafe working conditions shall be made to the IBC Chair, to any member of the IBC, or EOHS office. In all instances, allegations shall be immediately forwarded to the IBC Chair. The IBC Chair is responsible for investigation and resolution of all allegations of non-compliance. The allegations and resulting investigations will remain confidential to the extent possible.

6.1 Investigation and Review Process

The IBC Chair will appoint a subcommittee to investigate the allegation. The subcommittee will inform all persons involved in the investigation of the purpose and the manner in which it will be conducted. The subcommittee, in its investigation, will examine all documents and procedures relating to the allegation and will interview individuals who are named in the allegation and others who may have knowledge of the circumstances surrounding the allegation and determine if there is a basis in fact to support the allegation. The subcommittee will report its findings to the full IBC for the final determinations (see Section 6.2).

6.2 IBC Determination

At a convened meeting, the IBC will discuss the subcommittee report and determine if there is a consensus that the allegation of non-compliance is substantiated and, if so, the seriousness of the incident. All persons involved in the allegation of non-compliance will be given the opportunity to appear to respond to the allegation and/or findings. After all persons who have appeared to respond have left, the report and recommendations will be further discussed and voted upon. The IBC will inform all parties involved, including the submitter of the allegations, if known, of the committee's findings.

6.3 Possible Outcomes

The IBC has the authority to address non-compliance with ILRI and government regulations, policies and procedures and other legal requirements. Findings of non-compliance may result in one or more of the following actions:

- Suspension of use of rDNA and/or biohazardous materials agents or toxins.
- Termination of approval for use of rDNA and/or biohazardous materials agents or toxins.
- Confiscation of the rDNA and/or biohazardous materials agents or toxins.
- Destruction of the rDNA and/or biohazardous materials agents or toxins.
- Any other action necessary to protect the public and ILRI staff including restricting access to the laboratory in order to suspend activities.

SECTION 7: TRAINING

Training is required for all research personnel working with rDNA and biohazardous materials, agents and toxins. Completion of the courses is a requirement for the approval of new and continuing biosafety and rDNA protocols. All existing training materials and course content required by the IBC will be reviewed every two years by a subcommittee of IBC members, and any new training material or course content will be reviewed by a subcommittee of IBC members prior to release.

7.0 IBC Member Training

All IBC members will complete the CITI online training module required under Biosafety for IBC members.
The training program for all members consists of information provided at each IBC meeting. The objectives of providing ongoing training for IBC members is to increase their knowledge, understanding and awareness of current laws and regulations, new directives, best practice guidelines and institutional policies. It also provides a regular forum for the IBC to discuss concerns or questions brought forth by research personnel. Information provided for these sessions will include questions and concerns brought to the attention of the IBC, official directives, and compliance issues. It will be the responsibility of the IBC Program Coordinator to document all training.

7.2 Principal Investigator and Research Personnel Training

General biosafety training from the CITI online module is mandatory for all Principal Investigators and research personnel. Responsible conduct of research is also a required module from CITI online training for Principal Investigators and research personnel performing rDNA research that is non-exempt. It is the Principal Investigator's responsibility to complete and ensure all research personnel has received the required training prior to protocol review by IBC. Documentation of successful completion of training is required in order to receive IBC approval. The IBC training courses can be found on both Research Compliance and EHS websites:

SECTION 8: RECORD RETENTION AND RECORDKEEPING

8.0 IBC

The IBC will retain the following records for at least three (3) years after the project's expiration:

- IBC minutes, including members and vote counts.
- Related IBC Principal Investigator's protocols and any attachments (3 years begins after termination) of protocol.
- List of IBC Members.

The IBC Policies will be maintained on the Research Compliance website until superseded by any updated or revised document gets IBC approval.

8.1 Principal Investigator

The Principal Investigators are required to:

- To keep copies of the research records for a period of three (3) years.
- Keep accessible all records for inspection and copying by authorized representatives.
- Maintain a copy of their laboratory Biosafety Plan in their laboratory. All research personnel should review and document their review.
- Maintain documentation of all safety related training for their research personnel.