1.0 PURPOSE

1.1 The DHMRI Institutional Biosafety Committee (IBC) has the responsibility for the establishment and maintenance of a system for the control of biological agents within the DHMRI, including the responsibility to review protocols submitted to the DHMRI Institutional Animal Care and Use Committee that propose to use recombinant DNA constructs in animals housed in the Center for Laboratory Animal Sciences (CLAS). The purpose of the IBC is to recommend policies, procedures, and programs for the safe access, handling, and disposal of biological and infectious materials.

1.2 Regulatory compliance and protection of our personnel, facilities, and other resources are integral to this committee's work.

1.3 The policies developed by this committee are submitted to appropriate administrative offices for approval and implementation.

1.4 The DHMRI Environmental Health and Safety Director administers and enforces the policies of the IBC.

1.5 This document is divided into four sections:

1.5.1 Institutional Biosafety Committee (Section 4.1)

1.5.2 Biosafety Officer Authority (Section 4.2)

1.5.3 Biohazard Research Approval Process (Section 4.3)

1.5.4 IBC Committee Procedures (Sections 4.4 – 4.9)

2.0 SCOPE

2.1 The scope of the IBC includes all biological agents brought into and removed from the DHMRI.

Table 2.1 Biological Agents and Regulatory Guidelines

Biological Agents	Regulation
1. Recombinant or Synthetic Nucleic Acids	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
2. Microorganisms and Biological Toxins	Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
3. Humans and other primate-derived substances (blood, body fluids, cell lines or tissues)	OSHA 29 CFR 1910.1030 Bloodborne pathogens.

2.1.1 IBC approval is required before any animal work involving biological agents can commence in the CLAS or any laboratory work involving biological agents can commence in the DHMRI.

2.1.2 The use of biologically active agents (toxins, allergens, or venoms) in animals is under the purview of the IBC.

2.1.3 The DHMRI does not conduct nor support any research involving Select Agents and Toxins (Section 6.0) because they have been determined by the U.S. Department of Health and Human Services (HHS) and by the U.S. Department of Agriculture (USDA) to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products.

2.1.4 Research involving transgenic plants is not within the scope of the DHMRI IBC. University Partners wishing to conduct research in this area must obtain approval from their host or institutional IBC.

3.0 RESPONSIBILITIES

3.1 DHMRI Chief Operating Officer

3.1.1 Providing resources to ensure work requiring Biosafety Committee oversight is executed properly.

3.1.2 Providing at least three technical NCRC staff members to serve on the Biosafety Committee.

3.1.3 Providing administrative support for the Biosafety Committee.

3.2 NCRC Institutions are responsible for:

3.2.1 Ensuring that faculty have completed Biosafety Protocols with their main campus IBC prior to submitting to the DHMRI IBC.

3.3 Institutional Biosafety Committee (IBC) is responsible for:

3.3.1 Providing the required certifications to the NCRC Partner Institutional Research Offices for research grants and contract protocols.

3.3.2 Meeting at least biennially.

3.4 Biosafety Officer is responsible for

3.4.1 Managing the Biosafety Program

3.4.2 Supporting implementation of IBC policies and procedures.

3.5 Principal Investigators (PIs) are responsible for

3.5.1 Fully complying with the NIH Guidelines, CDC BMBL and OSHA Blood pathogen standards and requirements, as applicable to their research project

3.5.2 Making an initial determination of the required levels of physical and biological containment in accordance with NIH Guidelines and/or CDC requirements;

3.5.3 Selecting appropriate microbiological practices and laboratory techniques to be used for the research;

3.5.4 Submitting the Biosafety Protocol (FM-0088) and any subsequent changes to the IBC before initiation of research;

3.5.5 Ensuring the protocols that describe the potential biohazards and the precautions to be taken are available to all laboratory staff.

3.5.6 Being adequately trained in good microbiological techniques;

3.5.7 Instructing and training laboratory staff in:

3.5.7.1 Practices and techniques required to ensure safety, and

3.5.7.2 Procedures for dealing with accidents

3.5.8 Informing the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

3.5.9 Supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

3.5.10 Ensuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

3.5.11 Adhering to IBC approved emergency plans for handling accidental spills and personnel contamination;

3.5.12 Correcting work errors and conditions that may result in the release of recombinant, synthetic nucleic acid molecule materials and/or potentially infectious materials;

3.5.13 Complying with shipping requirements for recombinant or synthetic nucleic acid molecules and infectious microorganisms.

3.5.14 Investigating and reporting any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the following people:

3.5.14.1 Biological Safety Officer

3.5.14.2 Attending Veterinarian

3.5.14.3 Animal Facility Director

3.5.14.4 Institutional Biosafety Committee

3.5.14.5 Other agencies as required

3.6 IBC Chair is responsible for:

3.6.1 Setting meeting agendas, establish meeting dates and conducting meetings.

3.6.2 Prescreening and approving submitted Biosafety Protocols

3.6.3 Reviewing and approving amendments and updates as necessary (see Section 4.7.1).

3.6.4 Assigning Biosafety Protocol reviewers as required.

3.6.5 Ensuring IBC members are trained, although the training may be designated to another qualified individual.

3.7 IBC Vice-Chair is responsible for

3.7.1 Substituting for the Chair as necessary.

3.7.2 Reviewing the IBC Charter annually and proposing updates as needed.

3.8 Quality Systems is responsible for:

3.8.1 Effective document release, storage and retention.

3.8.2 Biennial Review.

4.0 PROCEDURE

4.1 Institutional Biosafety Committee Authority

4.1.1 Establish and monitor policy, practices and procedures for work involving biohazardous agents at DHMRI.

4.1.2 Review and approve research protocols involving the use of biohazardous agents including, but not limited to:

4.1.2.1 Recombinant DNA in organisms,

4.1.2.2 Creation of transgenic animals,

4.1.2.3 Human and other primate-derived substances (blood, body fluids, cell lines or tissues),

4.1.2.4 Organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia);

4.1.2.5 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.

4.1.3 To assess:

4.1.3.1 The PI's qualifications and experience relative to biological agent research

4.1.3.2 The level of containment required, and the containment facilities available.

4.1.3.3 The work procedures for storage, handling, and manipulation of biohazardous agents.

4.1.3.4 Note: This assessment may require an inspection of the facility and the preparation of a document outlining specific recommendations for the management of biohazardous materials and the health surveillance of potentially exposed personnel.

4.1.4 Review biosafety policies and revising/developing appropriate procedures at least every three years.

4.1.5 Report any problems or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate DHMRI official and NIH/ORDA within 30 days, unless the PI has already filed a report.

4.1.5.1 Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.

4.1.6 Not authorizing the initiation of experiments that are not explicitly covered by the NIH Guidelines until NIH (with the advice of the Recombinant DNA Advisory Committee when required) establishes the containment requirement.

4.1.7 Notify the PI of the results of the IBC'S review and approval process.

4.1.8 Develop and maintain emergency plans covering accidental spills and personnel contamination resulting from biological agent research.

4.1.9 Review any findings of any significant violation of policies, practices and procedures; participate in an investigation of any significant research related accidents or illnesses; and recommend to the DHMRI COO or the CLAS Institutional Official appropriate disciplinary action if an investigation reveals significant violations.

4.2 Biosafety Officer Authority:

4.2.1 The NCRC Director, Environmental, Health and Safety is designated by the DHMRI as the Biosafety Officer with the following authorities:

4.2.1.1 Assist laboratories in conforming to pertinent regulatory guidelines and IBC policies by providing training, facility inspections, and communication of Biosafety Program and related regulatory requirements.

4.2.1.2 Assess compliance with NIH, CDC, and OSHA regulations

4.2.1.3 Annual inspection of laboratories conducting research covered by the IBC including BSL-2 and BSL-3 laboratories for compliance.

4.2.1.4 Screen protocols submitted to the Institutional Animal Care and Use Committee (IACUC) for identification of biological agents and research protocols submitted by PIs and make recommendations to the IBC.

4.2.1.5 Consult with animal facility management, Attending Veterinarians and PIs regarding appropriate containment procedures for biohazardous agents.

4.2.1.6 Prepare periodic reports for DHMRI management regarding IBC activities and Biosafety Program status.

4.2.1.7 Recommend disciplinary action to the appropriate DHMRI or University Partner Administrator concerning noncompliance or any type of hazard.

4.2.1.8 Document minutes of IBC meetings.

4.2.1.9 Maintain the IBC website.

4.2.1.10 Monitor federal, state, and local regulatory trends, and communicate any changes to the IBC.

4.2.1.11 Generate annual reports to NIH.

4.2.1.12 Collect chemical and/or biological samples as required.

4.2.1.13 Restrict faculty, staff and students from executing research projects involving the use of biological agents when it:

4.2.1.13.1 Is not covered by an approved Biosafety Protocol (FM-0088)

4.2.1.13.2 Does not conform to submitted and approved Biosafety Protocol (FM-0088) and supporting materials.

4.2.1.13.3 Is noncompliant with current regulations and guidelines

4.3 Biohazard Research Approval Process

Table 4.3 Biosafety Requirements, Documentation and Submittals by Biological Agent Type

Biological Agent type	Requirements	Documentation	Submittals
Transgenic Plants in Laboratory or Greenhouse	The DHMRI IBC does not review projects involving the use of Transgenic Plants in either laboratories or greenhouses. University Partners wishing to conduct research in this area must obtain approval from their host or institutional IBC		
Purchase or transfer of transgenic animals	BSL-1-required containment is exempt from NIH Guidelines. BSL2 or higher-required containment must be approved through the IACUC procedures	Submit IACUC required documentation	No Biosafety Protocol (FM-0088) is required
Creation of transgenic animals (including direct gene delivery, aka transformation, the crossing of two different transgenic strains, or a transgenic strain crossed with a non-progenitor wild-type strain	Must be registered with and approved by the IBC. The creation of transgenic animals.	Complete Biosafety Protocol (FM-0088) and IACUC required documentation	Submit Biosafety Protocol (FM-0088) to the BSO.
Human and other primate-derived substances (blood, body fluids, cell lines or tissues), including unfixed tissues, primary cells and established cell lines	Any studies involving human-derived materials must be regarded as potentially biohazardous and are regulated under the	Complete BBP Model Exposure Control Plan (FM-0089). University partners may use their Institution's ECP which is sent to	Submit both the BBP Exposure Control Plan and Biosafety Protocol (FM-0088) to the BSO, who serves as the BBP

Table 4.3 Biosafety Requirements, Documentation and Submittals by Biological Agent Type			
Biological Agent type	**Requirements**	**Documentation**	**Submittals**
	OSHA BBP Standard and must be manipulated under BSL-2 containment	Director, EH&S for review.	Exposure Control Program Administrator for laboratory research use of human-derived materials
Organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, and rickettsia)	Use of facilities and practices commensurate with risk of the agent used	Complete a Biosafety Protocol (FM-0088)	Submit the Biosafety Protocol (FM-0088) to the BSO
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	IBC review and approval is required.	Complete a Biosafety Protocol (FM-0088).	Submit Biosafety Protocol (FM-0088) to the BSO
Select Agents and Toxins:	The DHMRI IBC does not approve or review projects involving the use of select agents or toxins.		

4.3.1 Biosafety Protocol Submission and Review

4.3.1.1 The PI must submit a completed Biosafety Protocol (FM-0088) and other required documents to the BSO 14 days prior to the next IBC meeting. The BSO will provide a copy of the completed Biosafety Protocol (FM-0088) to IBC members at least 7 days before the meeting.

4.3.1.2 After submission, the BSO will decide whether more information is necessary and, if so, will contact the PI. Once the Biosafety Protocol is complete, the BSO summarizes the characteristics of the study and listing any IBC precedents forwards it the protocol to the IBC.

4.3.2 IBC Biosafety Protocol Approvals: IBC Approval shall be in accordance with the procedures listed in Section 4.3 through 4.88.

4.3.3 Biosafety Protocol Approvals are valid for three (3) years and can be renewed by submitting a new Biosafety Protocol Form (FM-0088).

4.4 Changes, Updates and Amendments to Approved Biosafety Protocols

4.4.1 Any changes to an approved Biosafety Protocols shall be submitted to the BSO using another FM-0088.

4.4.2 The BSO will review the completed FM-0088 and determine if the change requires IBC approval. Changes are processed the same way as original submissions.

4.4.3 The three types of protocol changes include Updates, Amendments and New

4.4.3.1 Updates are changes without safety consequences (for example: staff changes or addition of new strains of previously approved or closely related cell type). Updates are sent to the BSO for approval.

4.4.3.1 Amendments are changes that may have safety consequences but the basic concept of the study stays the same. In general the change will not involve a change in containment (for example, addition of a new pathogen, vector or toxic gene) Amendments are sent to the BSO, who will notify the IBC Chair and provide a recommendation for how to proceed as along with a notification letter to the PI. Amendment approval ultimately sits with the IBC Chair.

4.4.3.2 New Biosafety protocols are required for changes in the basic concept of a project (i.e., a new goal) and require the standard new Biosafety protocol approval (see Section 4.3 through 4.88)

4.5 Biosafety Protocol Termination

4.5.1 Approval may be canceled if the PI is found to be routinely in violation of IBC policies and regulations. Recombinant DNA and infectious agent research noncompliance may cause direct NIH action affecting individual and institutional funding.

4.5.2 If a protocol is terminated for cause the Senior Officer of the PI's home institution will be notified in writing.

4.5.3 Failure to Comply:

4.5.3.1 PIs are expected to comply with the IBC standards outlined in this SOP. Noncompliance includes, but is not necessarily limited to:

4.5.3.1.1 Failure to register biohazardous agents, including non-exempt recombinant DNA molecules;

4.5.3.1.2 Failure to provide annual updates and/or other required documentation within 60 days of the specified due date.

4.5.3.1.3 Failure to allow inspections and audits;

4.5.3.1.4 Poor biological safety/biological containment practices as documented through routine lab inspections; or

4.5.3.2 Failure to correct a documented (confirmed) biological safety complaint or concern. Noncompliance will be reported to the IBC which may result in suspension or termination of all approved Biosafety protocol. The PI's Department Head, Dean, and/or other applicable administrators will be notified of the noncompliance, while granting agencies or regulatory authorities may be notified as required by their respective reporting standards.

4.6 Biosafety Inspections

4.6.1 The BSO is authorized to inspect all laboratories and facilities where activities covered by a particular Biosafety Protocol take place.

4.7 IBC Procedures

4.7.1 Acceptance of this Institutional Biosafety Committee SOP and any future modifications must be approved by the voting members of the IBC. A two-thirds (⅔) majority of the voting membership of the IBC is required to accept any revisions to this document.

4.7.2 Membership of the IBC will be maintained in accordance with NIH Guidelines and will include scientists, clinical investigators and administrators DHMRI, and community representatives. A minimum of five IBC members will be appointed by the DHMRI COO for a renewable term of three years. DHMRI will provide at least two (2) technical members. University Partners will provide at least two (2) members. DHMRI will solicit the community for two community members.

4.7.3 All IBC members are responsible for:

4.7.3.1 Attending scheduled meetings

4.7.3.2 Reviewing all assigned Biosafety Protocols

4.7.3.3 Notifying the BSO if he/she cannot attend meetings.

4.7.3.4 Completing IBC training before participating in voting activities of the committee.

4.7.3.5 Completing annual retraining covering IBC-related topics (Section 4.9).

4.7.4 By virtue of his administrative positions, the Executive Director, North Carolina Research Campus (UNC GA) and the DHMRI Biosafety Officer are all ex-officio members of the IBC. All ex-officio members are non-voting members, except the BSO who is a voting member of the IBC.

4.7.5 Each member is expected to review all Biosafety protocols prior to the meeting. However, the IBC Chair may request a designated member review based on high Biosafety protocol volume and/or subject matter expertise. In the event of a designated member review, the assigned reviewer(s) will summarize the Biosafety protocol(s) and present comments and recommendations. The IBC will decide on all Biosafety protocols by a formal vote. When quorum is established, a simple majority of the voting members present is required to accept or reject a Biosafety Protocol

4.7.5.1 When all deficiencies have been addressed by the PI, the BSO will present the Biosafety Protocol at the next IBC meeting along with his recommendations.

4.7.6 Subject Matter Expertise: IBC members will be asked by the IBC Chair for their input on Biosafety Protocol. The chair will ensure that the views of the IBC members with subject matter expertise are taken into account. If a Biosafety Protocol is outside the area of expertise of IBC members, the IBC Chair will seek counsel from an individual knowledgeable in the subject matter. This person(s) can be someone external to DHMRI if necessary.

4.8 IBC Meetings

4.8.1 The IBC Chair will issue all points of order, summarize Biosafety Protocols as necessary, moderate discussion, and call for motions. Motions, seconds, and/or other propositions may be made by any voting member of the IBC. Motions pass by a simple majority of the voting members present.

4.8.2 The IBC Chair may invite PIs to IBC meetings to present or clarify their Biosafety protocol and respond to member questions as needed.

4.8.3 PIs may communicate with the IBC through the BSO or the IBC Chair.

4.8.3.1 The signature and initials required in the **Statement of Informed Consent** on the Biosafety Protocol (FM-0088) must be in ink

4.8.3.2 Initials for all other sections of Biosafety Protocol (FM-0088) may be electronic.

4.8.3.3 PI responses to IBC inquiries and concerns must be signed by the PI in ink

4.9 IBC Member Training

4.9.1 All new members are required to complete training on the regulatory responsibilities and functions of the IBC. This training must be completed before participation in voting activities of the committee. Training will be administered by the IBC Chair or his/her designee. All IBC members must also complete annual re-training, covering topics that will enhance the committee's understanding of Biosafety-related issues and institutional research review policies. The annual retraining will be administered by the IBC Chair or his/her designee.

5.0 REFERENCES AND RELATED DOCUMENTS

5.1 NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) November 2013 http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html January 8, 2015

5.2 Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition September 2009 http://www.cdc.gov/biosafety/publications/bmbl5/ January 8, 2015

5.3 29 CFR 1910.1030 OSHA Bloodborne Pathogens. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS January 8, 2015

5.4 7 CFR PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=7y5.1.1.1.9&r=PART

5.5 9 CFR PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=b9126e9fba23e3e7933354a1d2630d72&ty=HTML&h=L&n=9y1.0.1.5.58&r=PART

5.6 42 PART 73—SELECT AGENTS AND TOXINS http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61

5.7 SOP-0249, Bloodborne Pathogens Exposure Control Plan

5.8 FM-0088, DHMRI Biosafety Protocol

5.9 FM 0089, DHMRI BSL-2 Checklist

6.0 DEFINITIONS

Term	Description
BSO	Biosafety Officer
Biohazards	Biohazards are defined as any laboratory or animal work involving: 1. Risk Group 1-4 Microorganisms 2. Recombinant DNA as defined in the NIH Guidelines 3. Blood or other potentially infectious microorganisms 4. Animal work involving Risk Group 1 -4 Microorganisms or materials 5. Select agents as defined by the CDC
Biological agent	Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.
Biosafety Level 1 (BSL 1)	Well characterized agents not consistently known to cause disease in healthy adult humans of minimal potential hazard to laboratory personnel and the environment
Biosafety Level 2 (BSL 2)	Agents of moderate potential hazard to personnel and the environment
Biosafety Level 3 (BSL 3)	Indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route (applicable to clinical, diagnostic, teaching, research or

Term	Description
	production facilities).
Biosafety Level 4 (BSL 4)	Dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease
Blood	Includes human blood, human blood components, and products made from human blood.
BSO	Biosafety Officer
Cells Lines	Includes human and non-human primate cell lines
CDC BMBL	Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
COO	Chief Operating Officer
IBC	Institutional Biosafety Committee
NIH Guidelines	NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules November 2013
OPIM	Other Blood Borne Pathogens
Occupational Exposure	Reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's job duties.
Parenteral contact	Includes piercing mucous membranes or the skin by needle sticks, human bites, cuts and abrasions.
Quorum	A quorum is defined as 50 percent plus one of the voting members. Non-voting members are not counted when determining a quorum. Written proxies do not count toward a quorum.
Recombinant and Synthetic Nucleic Acid Molecules	In the context of the *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; (ii) nucleic acid molecules that are chemically or by other means

Term	Description
	synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids. (iii) molecules that result from the replication of those described in (i) or (ii) above.
Select agent and/or toxin.	Unless otherwise specified, all of the biological agents or toxins listed in 42 CFR 73.3 and 42 CFR 73.4
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans.
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).
University Partner	One of the Seven Universities present on the North Carolina Research Campus. This term includes the following institutions: Appalachian State University, North Carolina A&T State University, North Carolina Central University, North Carolina State University, University of North Carolina (Chapel Hill), University of North Carolina – Charlotte, University of North Carolina- Greensboro.
Transgenic animal	An animal that carries a foreign gene that has been deliberately inserted into its genome. The foreign gene is constructed using recombinant DNA methodology. In addition to the gene itself, the DNA usually includes other sequences to

Term	Description
	enable it • to be incorporated into the DNA of the host and • to be expressed correctly by the cells of the host.
Transgenic plants	A transgenic crop plant contains a gene or genes which have been artificially inserted instead of the plant acquiring them through pollination. The inserted gene sequence (known as the **transgene**) may come from another unrelated plant, or from a completely different species

7.0 APPENDICES

7.1 None.

REVISION HISTORY		
Superseded Revisions	**DCO Number**	**Effective Date**
N/A	15-129	20FEB2016

Current Revision:	**R1.0**	
Section Number	**Description of Changes**	**Justification of Changes**
All	Provides framework for DHMRI Biosafety Program.	New DHMRI document.