MU Institutional Biosafety Committee

TRANSGENIC PLANT RESEARCH POLICY

(5/18/2023—updated policy)

Overview:
The National Institutes of Health (NIH) has established strict guidelines on the proper use and disposal of transgenic plants, seeds, materials and other forms of recombinant or synthetic nucleic acid molecules in research. The document entitled *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), outlines institutional and investigator responsibilities and can be accessed online at: https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

Definition of Transgenic Plants
NIH guideline relevant sections include Section III-D-5 and Section III-E-2.
Transgenic plants are plants possessing single or multiple genes, transferred from a different species or synthetically produced. Nucleic acid molecules from another species or synthetically constructed can be integrated into a plants' genome via natural processes, the term “transgenic plants” refers to any plant created in a laboratory using recombinant technology.

Recombinant technology typically involves the transfer of DNA into a plant through use of *Agrobacterium tumefaciens*. *Agrobacterium tumefaciens* is also frequently used for transient expression studies in plant tissues, a process called agroinfiltration. Transgenic roots, also known as “hairy roots”, created through the use of *Agrobacterium rhizogenes*, also fall within this category. Biolistic approaches involving the use of a “gene gun” may also be used for creation of transgenic plants or for transient expression of transgenes.

The methods listed are not comprehensive and do not preclude the development of new technologies. Consequently, investigators are encouraged to consult Institutional Biosafety Committee (IBC) representatives if they have any questions about the status of their experiments.

The use of recombinant technology has the potential to generate novel genetic variation which does not contain rDNA sequences. These are a special case. For example expression of CRISPR-Cas9 with guide RNA targeted to induce double-stranded cuts or edits in a target sequence, followed by selection against the transgene may result in segregating away the transgene(s) from the induced mutations. However, the risk that such organisms pose should not be determined by the research. A Risk Assessment of such plants may be requested from USDA-APHIS (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/regulatory-status-reviews/rsr).

Note: Transgenic plants that have been granted non-regulated status by a governmental agency are exempt from this IBC policy. USDA-APHIS keeps a list of transgenic plants that have been granted non-regulated status and investigators may consult this list if they have any questions regarding the status of their plants through the USDA-APHIS Biotechnology Regulatory Services webpage (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology).

Compliance with NIH Guidelines
All NIH funded projects involving rDNA must comply with *NIH Guidelines*. As per the *NIH Guidelines*, all non-NIH funded projects involving rDNA conducted at or sponsored by an institution that receives NIH funding must comply with *NIH Guidelines*. Failure to follow *NIH Guidelines* can result in the suspension, limitation, or termination of NIH funds for all recombinant or synthetic nucleic acid molecule research at MU.

As an NIH-funded institution, MU’s Institutional Biosafety Committee (IBC) has developed both a policy and a protocol, outlined below, which investigators may obtain institutional authorization to work with

transgenic plants. As an investigator working with transgenic plants, it is your responsibility to meet these requirements.

MU Policy on Transgenic Research
It is the policy of the MU IBC that all research conducted on the MU campus, other facilities and farms, or sponsored by the University, that involves the use of transgenic plants and seed must receive approval from the IBC prior to the start of any work. This approval also includes transgenic plant materials that have been obtained from cooperators at other institutions or those obtained from commercial sources.
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MU IBC Protocol for Institutional Approval
The IBC is managed by the Office of Research, Innovation and Impact (https://research.missouri.edu/institutional-biosafety-committee/institutional-biosafety-committee). The IBC application process is through the ecompliance portal located at: https://ecompliance.missouri.edu/.

If you have previously received IBC approval for your project, you are required to update the application information with an IBC Amendment whenever there are substantial changes in the experimental procedures (i.e. changes in biosafety levels or other risks, organisms investigated, new genes investigated, and/or changes in research facilities or personnel) associated with the project.

Containment of Transgenic Plants
The NIH guidelines specify several methods to prevent the dissemination of plants. Researchers may find it helpful to review Appendix L-III, particularly Appendix L-III-A, to review standard rDNA containment practices. The type of containment practice and laboratory procedures must be clearly indicated in the IBC Application. https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/

Disposal of Transgenic Plants
Transgenic plants and materials associated with transgenic plants including seeds and soil must be inactivated prior to disposal to prevent accidental environmental release. Typically, autoclave treatment is employed for transgenic plant, soil, and seed inactivation. Disposal procedures must be clearly indicated in the IBC Application. There are no exceptions to this policy without prior notification and approval by the IBC.**NIH guidelines example**: Appendix L-II-A-1-c-(1). Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Environmental Release of Transgenic Plants and Seeds
The IBC is authorized to approve research of transgenic plants grown in labs, growth chambers or greenhouses. Any experiment conducted outside of these environments (i.e. field plots on University farms) constitutes a deliberate environmental release. For such experiments, the researcher must apply for and obtain a USDA APHIS Field Test Permit (https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/permits/permits).

Although field tests are overseen by USDA APHIS, it is essential the IBC is informed of any field tests conducted on University facilities, or which is conducted through research sponsored by the University. Consequently, the IBC requires copies of Field Test permits granted by USDA-APHIS to be added as amendments prior to transgenic field experiments. Since Field Test permits granted by USDA-APHIS are only valid for a single year, researchers will need to file amendments to their IBC protocols as additional permits are granted.

Interstate Transfer
Receiving: Complete an IBC Amendment if you are planning to receive transgenic plants and/or seeds from a previously unidentified collaborator.
Shipping: For shipping transgenic plants and/or seeds, refer to USDA-APHIS permitting and DOT requirements.

Research-related Incidents
NIH and MU policy requires that significant research-related incidents be reported immediately to the IBC via the Biosafety Team at EHS. Incidents include research-related accidents and illnesses as well as

inadvertent release or improper disposal of biohazardous or recombinant or synthetic nucleic acid molecules: (Examples, personal injury, non-decontaminated plant parts, seeds, or roots in soil removed from a greenhouse).