

 *Research Administration Use:*

 Protocol #

 Status: Exempt Non-Exempt

Institutional Biosafety Committee (IBC) Protocol Application:

Research Involving Recombinant or Synthetic Nucleic Acid Molecules

This Protocol Application must be completed for all activities which involve:

1. molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means 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;
3. molecules that result from the replication of those described in (i) or (ii) above; or
4. transgenic animals.

Consult (1) [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), (2) [UTA’s Policy and Procedures for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://resources.uta.edu/research/regulatory-services/rdna-ibc/regulations-and-guidelines%20.php), (3) [*CDC’s Biosafety in Microbiological and Biomedical Laboratories, 6th Edition*](https://www.cdc.gov/biosafety/publications/bmbl5/index.htm), and (4) UTA’s [Biosafety Manual](https://www.uta.edu/campus-ops/ehs/biological/index.php) for more information during completion of this application.

Submit the completed Protocol Application to the Office of Regulatory Services at regulatoryservices@uta.edu or ibc@uta.edu.

Questions? Please contact Regulatory Services at 817-272-3723, regulatoryservices@uta.edu, or visit the website: <https://resources.uta.edu/research/regulatory-services/rdna-ibc/index.php>.

## PART I. (Complete for All Recombinant/Synthetic Nucleic Acid Experiments)


## SECTION A: General Information (*All text boxes will expand)*

**1.** Investigator name:

**2.** Contact Information: Office       Lab       Email

**3.** Department:

**4.** Protocol Title:

**5.** Funding Agency/ Grant / Contract Number (Please attach copy of grant abstract):

**6.** Proposed start date:       Proposed end date:

**7.** Location of work: Building       Room

**8.** Personnel - list all faculty, students, and staff who will work on this protocol. (Note: All protocol personnel must complete the online training module, “Recombinant DNA and Transgenic Animals” found at: **https://mentis.uta.edu/public/#trn**)

**9. Conflicts of Interest (COI):** Does the principal investigator or any protocol personnel (internal and external) have an affiliation, arrangement, or financial interest that could be perceived as a conflict of interest? If yes, please describe. If the principal investigator or any protocol personnel (internal and external) have an active research conflict of interest management plan, please describe if the COI may be perceived as related to the research and provide a copy of the management plan.

\*Note: “Financial Interest” is defined as anything of monetary value (existing or potential), whether or not the value is readily ascertainable. “Conflict of Interest” is defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research.

\*Note: All Covered Individuals in GMR research are required to have a current COI disclosure on file in Mentis (this must be complete prior to approval of the protocol). Covered Individuals are those with responsibilities for the conduct, design, or reporting of this research study

**SECTION B: Protocol Information**

10. Please provide a general description (in layperson’s language) of the experiments to be conducted, including a description of any significant risks if appropriate.

**11.** Please provide the following information.

|  |  |  |  |
| --- | --- | --- | --- |
| Nature/Source(s) of Inserted DNA Sequences: include genus/species, name of protein pathway, etc. | Describe the intended use of the rDNA and the function / activity of the DNA or its product.Examples – new protein expression, cloning, transgenic generation, etc. | Hosts for propagation:Examples - E. coli K-12, HeLa Cells, Mouse*Note:* This corresponds to both the production of rDNA and the species into which it will be introduced – include all. | Method of Gene Transfer/Vector(s):Examples - plasmid, virus, amplicons or transposons, naked DNA, conjugation, chemical, etc. |
|       |       |       |       |
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SECTION C: Exemption Determination

12. The *NIH Guidelines* provide a description of recombinant/synthetic nucleic acid experiments that are considered exempt. UTA Policy requires registration of Exempt experiments via submission of Part I of this Application. Non-Exempt research requires completion of Part I and Part II of this Application. Questions 11a – 11b below will help to make the Exempt/Non-Exempt determination.

12a. The following experiments do not qualify for exemption under the NIH Guidelines, and will require submission of Part I and Part II of this protocol application:

* Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see [Section V-B, Footnotes and References of Sections I-IV](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457085)), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture.
* Deliberate formation/cloning of recombinant or synthetic nucleic acid molecules containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin).
* Human gene transfer- the deliberate transfer into human research participants of either:

1. Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or

2. Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:

a. Contain more than 100 nucleotides; or

b. Possess biological properties that enable integration into the genome (e.g., *cis* elements involved in integration); or

c. Have the potential to replicate in a cell; or

d. Can be translated or transcribed.

* Experiments using [Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457040) as host-vector systems.
* Experiments in which DNA from [Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457040) is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
* Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.
* Experiments involving transgenic animals other than rodents. (Transgenic = genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line)
* Breeding of transgenic or knockout rodents requiring [containment *above* BL1](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457043).
* Experiments involving testing of viable recombinant or synthetic nucleic acid molecule-modified microorganisms on whole animals.
* Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant or synthetic nucleic acid molecules.
* Experiments involving more than 10 L of culture.
* Experiments with influenza viruses generated by recombinant or synthetic methods (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations).

***If your research meets one or more of the experiment types described above, please complete Part I and Part II of this Protocol Application for Non-Exempt research. If your research does not meet any of the descriptions above, it may qualify as Exempt - proceed to 11b for exemption determination.***

**12b.** In Table 1 below, please indicate if your research falls under any of the described Exempt Categories. If yes, please select all that apply and proceed to Section D, “Principal Investigator Certification & Signature” **(part II of the Protocol Application is not required for Exempt Research).**

Table 1. Exempt Experiments under [*NIH Guidelines*, Section III-F](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457051).

|  |  |
| --- | --- |
| [ ]  | Exemption 1: Synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.  If a synthetic nucleic acid is deliberately transferred into one or more human research participants and meets the criteria of [Section III-C](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457037), it is not exempt under this Section. |
| [ ]  | Exemption 2: Recombinant/synthetic nucleic acid molecules that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes. |
| [ ]  | Exemption 3: Recombinant/synthetic nucleic acid molecules that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. |
| [ ]  | Exemption 4: Recombinant/synthetic nucleic acid molecules that consist entirely of nucleic acids 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. |
| [ ]  | Exemption 5: Recombinant/synthetic nucleic acid molecules that consist entirely of nucleic acids 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). |
| [ ]  | Exemption 6: Recombinant/synthetic nucleic acid molecules 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.  See [Appendices A-I through A-VI](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457086), *Exemptions under Section III-F-6--Sublists of Natural Exchangers*, for a list of natural exchangers that are exempt. |
| [ ]  | Exemption 7: Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. |
| [ ]  | Exemption 8: Recombinant/synthetic nucleic acid molecules that do not present a significant risk to health or the environment, as determined by the NIH. See NIH Guidelines [Appendix C](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457112) for more details on each type of experiment. Under this category, please select the option(s) below pertaining to your experiment(s): [ ] Recombinant or synthetic nucleic acid molecules containing less than one-half of any eukaryotic viral genome (all viruses from a single family being considered identical -- see [Appendix C-IX-E](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457127), *Footnotes and References of Appendix C*), that are propagated and maintained in cells in tissue culture **except for those** listed in [Appendix C-I-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457114).[ ] Experiments which use *Escherichia* *coli* K-12 host-vector systems, **with the exception** of those experiments listed in [Appendix C-II-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457116), provided that:  (i) the *Escherichia* *coli* host does not contain conjugation proficient plasmids or generalized transducing phages; or (ii) lambda or lambdoid or Ff bacteriophages or non-conjugative plasmids (see [Appendix C-IX-B](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457127), *Footnotes and References of Appendix C*) shall be used as vectors.  Experiments involving the insertion into *Escherichia* *coli* K-12 of DNA from prokaryotes that exchange genetic information (see [Appendix C-IX-C](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457127), *Footnotes and References of Appendix C*) with *Escherichia* *coli* may be performed with any *Escherichia* *coli* K-12 vector (e.g., conjugative plasmid).  When a non-conjugative vector is used, the *Escherichia* *coli* K-12 host may contain conjugation-proficient plasmids either autonomous or integrated, or generalized transducing phages.  [ ] Experiments involving Saccharomyces cerevisiae and Saccharomyces uvarum host-vector systems, **with the exception** of experiments listed in [Appendix C-III-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457118).[ ] Experiments involving *Kluyveromyces lactis*host-vector systems, **with the exception** of experiments listed in [Appendix C-IV-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457120), provided laboratory-adapted strains are used (i.e. strains that have been adapted to growth under optimal or defined laboratory conditions). [ ]  Any asporogenic *Bacillus subtilis* or asporogenic*Bacillus licheniformis* strain which does not revert to a spore-former with a frequency greater than 10-7 may be used for cloning DNA with the exception of those experiments listed in [Appendix C-V-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457122). |

|  |  |
| --- | --- |
|  | [ ]  Recombinant or synthetic nucleic acid molecules derived entirely from extrachromosomal elements of the organisms listed below (including shuttle vectors constructed from vectors described in [Appendix C](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457112)), and *propagated and maintained* in the organisms listed below. Exceptions exist and are listed in [Appendix C-VI-A](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457124). [ ]  Use of BL1 Transgenic/Knockout Rodents – The purchase or transfer of transgenic/knockout rodents maintained at BL1 containment is exempt. Subsequent use of these animals is also exempt providing the experimental protocol does not involve the use of recombinant DNA.[ ]  Generation (breeding) Transgenic/Knockout Rodents – Breeding of transgenic/knockout rodents from one strain and at BL1 containment is exempt. The breeding of two different transgenic/knockout rodents or the breeding of a transgenic/knockout rodent and a non-transgenic rodent with the intent of creating a new strain is exempt if:(1) Both parental rodents can be housed under BL1 containment; **and**(2) neither parental transgenic rodent contains the following genetic modifications:  (i) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses; or (ii) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR); **and**(3) the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. |

**SECTION D: Principal Investigator Certification & Signature**

I am familiar with and agree to abide by the (1) [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), (2) [UTA’s Policy and Procedures for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://resources.uta.edu/research/regulatory-services/rdna-ibc/regulations-and-guidelines%20.php), (3) [*CDC’s Biosafety in Microbiological and Biomedical Laboratories, 6th Edition*](https://www.cdc.gov/biosafety/publications/bmbl5/index.htm), and (4) UTA’s [Biosafety Manual](https://www.uta.edu/campus-ops/ehs/biological/index.php).

I certify that the designations and information provided in this Protocol Application are true and accurate.

In accordance with the *NIH Guidelines*, I accept responsibility for training all personnel involved in the proposed project in matters of potential biohazards, relevant biosafety practices, techniques, laboratory emergency procedures, and the biology of the organisms used in the experiment(s). I understand that I must document this site-specific training (dates, attendees, topics) and have it available to the IBC or Environmental Health & Safety as requested.

I will submit reports to the Institutional Biosafety Committee concerning (i) any accident that results in potentially toxic exposures, or any incident releasing recombinant/synthetic nucleic acid materials into the environment; (ii) any problems with physical or biological containment; and (iii) any novel information bearing on the safety of this work such as new technical data relating to biological hazards of specific recombinant molecules.

I will not carry out the work described in this Protocol Application until it has been acknowledged (Exempt Experiments) or approved (Non-Exempt Experiments) by the IBC.

I understand that I am responsible for the accuracy of the statements made in this protocol and for the responsible conduct of research.

  **Principal Investigator**

**Date**

 **INSTRUCTIONS:**

**The remaining portion of this protocol application form, Part II, is only required for *Non-Exempt* research *as determined by your responses to item #11* in Part I. If you research is *Non-Exempt*, please continue to complete Part II of this application and submit the full, completed application to Regulatory Services as described on page 1.**

**If your research qualifies as *Exempt*, it is *not necessary* to complete Part II of this application. Please submit only the applicable portion, Part I, to complete your application for Exempt rDNA research.**

**PLEASE NOTE that even for Exempt rDNA research, there may be other University or regulatory requirements that will be necessary to conduct your research. These may include or involve laboratory inspections, personnel training, lab registration, etc. Researchers are responsible for contacting the Environmental Health & Safety (EH&S) Office to determine what other requirements may apply. EH&S can be contacted at 817-272-2185 or** **ehsafety@uta.edu****.**

**Overview: Exemption Determination
#12a - #12b, Part I of Protocol Application**

Do the categories listed in #11a of Part I describe your rDNA research?

**If no…**

**If yes…**

Do one or more of the exempt categories listed in #11b describe your research?

Research is Non-Exempt:

1. Complete Section D, “Principal Investigator Certification & Signature.”
2. Complete Part II of the Protocol Application for Non-Exempt rDNA Research.

**If yes…**

**If no…**

Research is Exempt:

1. Indicate the applicable exempt categories in #11b.
2. Complete Section D, “Principal Investigator Certification & Signature.”
3. Contact EH&S to determine other lab requirements (safety, training, etc.).

**PART II. (Non-Exempt Recombinant/Synthetic Nucleic Acid Experiments)**

If your project involves experiments that are not clearly *Exempt* as described in Part I, Item #11a – 11b of the Protocol Application, please proceed with this section – **Part II**.

**SECTION E: The Use of Recombinant/Synthetic Nucleic Acid Molecules**

**13.** **Non-Exempt Experiments**: Please complete Table 2. For multiple sources of DNA, attach additional copies of Table 2 as necessary.

**Table 2.** Non-Exempt Experiments

|  |
| --- |
| **RECOMBINANT INSERT (TRANSGENE) AND VECTORS** |
| Source(s) of DNA sequences (include genus, species, gene name and abbreviation)  |       |
| Agent’s NIH Risk Group ([*NIH Guidelines*, Section II](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457025))\*\*Note: Infectious/pathogenic materials must be registered with Environmental Health & Safety via the [Human Pathogen Registration (HPR Form)](https://www.uta.edu/campus-ops/ehs/biological/index.php). | [ ]  RG1 [ ]  RG2 [ ]  RG3 [ ]  RG4 |
| Will the experiment involve use or production of more than 10L of culture of viable organisms containing rDNA? | [ ]  Yes If yes, specify how you will meet the criteria of [*NIH Guidelines*, Appendix K](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457194) for Large Scale Use:      [ ]  No |
| Will the genetically modified organism (GMO) be released into the environment? | [ ]  Yes If yes, describe:       [ ]  No  |
| Is the inserted sequence or GMO harmful to humans or animals? | [ ]  Yes Describe diseases or symptoms caused by agent and possible routes of exposure:      [ ]  No [ ]  N/A |
| Is the inserted sequence or GMO harmful to plants?(See USDA’s [7 CFR 340](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr340_main_02.tpl)) | [ ]  Yes (please describe appropriate safeguards and address [7 CFR 340](http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title07/7cfr340_main_02.tpl))      [ ]  No[ ]  N/A |
| Physical containment as specified in *NIH Guidelines* [Section II](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457025) and [Appendix G](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm#_Toc3457149). Please note: the CDC classifies work with human and non-primate blood, body fluids, or tissue (e.g. human cell culture) as a minimum of BL-2. | [ ]  BL1 [ ]  BL2 [ ]  BL3 or BL4 (Requires approval of UTA Administration)and/orExperiments Involving Plants: [ ]  BL1-P [ ]  BL2-P [ ]  BL3-P [ ] BL4-Pand/orExperiments Involving Animals: [ ]  BL1-N [ ]  BL2-N [ ]  BL3-N [ ]  BL4-N |
| Is a helper virus required? | [ ]  Yes If yes, specify:       [ ]  No  |
| For experiments involving a deliberate attempt to obtain expression of *a foreign gene*, identify what proteins will be produced and their biological activity (enter “none” if not applicable) |                      |
| **TARGET RECIPIENT** |
| [ ]  Cultured Cells? | Describe:       |
| [ ]  Animals? | Describe:       |
| [ ]  Plants? | Describe:       |
| [ ]  Humans? | Describe:       |
| [ ]  Other? | Describe:       |
| **OTHER CATEGORIES** |
| Check any categories below that pertain to your project:[ ]  Renders a useful vaccine ineffective[ ]  Adds antibiotic resistance affecting response to a clinically useful drug[ ]  Enhances pathogen virulence[ ]  Widens a pathogen’s host range[ ]  Lets a pathogen evade diagnostic or detection modalities[ ]  Weaponization (e.g., environmental stabilization of pathogens)If you checked a category above, please provide an explanation here:       |


## SECTION F: Hazardous Materials and Training

**14.** If your project will utilize human blood, body fluids, tissue, or cells/cell lines please describe the source of these materials and any information relevant to determining its infectious potential. Attach a copy of your Human Pathogen Registration Document (HPRD) approved by Environmental Health & Safety. If this does not apply to your project, please enter “N/A.”

15. Hazardous Materials – List all labs where work will take place, and check the appropriate box(es) if the lab contains any of the materials listed on the left.

Table 3. Hazardous Materials

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Lab Room # |       |       |       |       |       |       |       |
| Recombinant/ Synthetic Nucleic Acids | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Infectious Agents | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| X-ray Equipment  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Lasers | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Radioactive Materials | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Animals  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Hazardous Chemicals | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
| Human Blood, Fluids, Tissue, Cells/Cell Lines | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

**Reminder**: If your project involves the use of **animals**, you must obtain [Institutional Animal Care and Use Committee (IACUC)](https://resources.uta.edu/research/regulatory-services/animal-subjects/index.php) approval prior to commencement of the research. If your project involves the use of **human subjects**, you may require approval from the [Institutional Review Board for the Protection of Human Subjects (IRB)](https://resources.uta.edu/research/regulatory-services/human-subjects/index.php) prior to commencement of the research. If your project involves **human pathogenic material(s)**, you must register with the Environmental Health & Safety Office via the [Human Pathogen Registration (HPR Form)](https://www.uta.edu/campus-ops/ehs/biological/index.php). If your project involves **radioactive material**, you must obtain approval from the Radiation Safety Committee (RSC) prior to commencement. For more information on all of these items and more, please visit the [Regulatory Services](https://resources.uta.edu/research/regulatory-services/index.php) webpage.

16. In accordance with the *NIH Guidelines*, the Principal Investigator is responsible for training all personnel involved in the proposed project in matters of potential biohazards, relevant biosafety practices, techniques, laboratory emergency procedures, and the biology of the organisms used in the experiment(s). Training documentation must be made available to the IBC or Environmental Health & Safety as requested. Please describe how you will perform and document (dates, attendees, topics) this training for all lab personnel.

**ADDITIONAL TRAINING:** The following training is required for each of the hazardous materials listed. \*\*All protocol personnel must complete the online “Recombinant DNA and Transgenic Animals” training module.\*\*

|  |  |  |
| --- | --- | --- |
| Hazardous Material | Training Requirement | How to Obtain Training |
| Recombinant DNA | Online Training Module | [Office of Research Administration Training Site: Recombinant DNA and Transgenic Animals](https://www.uta.edu/ra/real/researchspace.php?view=7&training_view=my_training)  |
| Chemical Hazards | Online Training Module | [Environmental Health & Safety Training Site: Hazard Communication and Waste Management – Academic (Course #CEM200)](https://www.uta.edu/campus-ops/ehs/training/index.php) |
| Radioactive Material & X-Rays | Online Training Modules | [Environmental Health & Safety Training Site: Radiation Awareness (Course #RAD100), Radiation Producing Machine (Xray) – Part 1 (Course #RAD200, & Radiation Producing Machine (Xray) – Part 2 (Course #RAD300)](https://www.uta.edu/campus-ops/ehs/training/index.php) |
| Lasers | Online Training Module | [Environmental Health & Safety Training Site: Laser Safety (Course #LSR100)](https://www.uta.edu/campus-ops/ehs/training/index.php) |
| Animals | Online Training Modules | Regulatory Services, [IACUC Required Training](https://resources.uta.edu/research/regulatory-services/animal-subjects/iacuc-training.php) |
| Human Blood, Body Fluids, Tissue, Cells/Cell Lines | Online Training Modules | [Environmental Health & Safety Training Site:](https://www.uta.edu/campus-ops/ehs/training/index.php) [Bloodborne Pathogens for Laboratory Research Personnel (Course #BIOL200) & Biosafety Level 2 (BSL-2) (Course #BIOL500)](https://www.uta.edu/campus-ops/ehs/training/index.php) |

17. Laboratory Personnel – in Table 4, list all lab workers that use hazardous materials under your jurisdiction (please note training requirements listed above for each of these items).

Table 4. Laboratory Personnel

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Name & Status (Faculty, Staff, or Student?) | rDNA | Chemical Hazards | Radioactive Material & X-Rays | Lasers | Animals | Human Blood, Body Fluids, Tissue, Cells/Cell Lines |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
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|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |
|       | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  | [ ]  |

## SECTION G: Laboratory Safety

18. Reference Materials: Please note the location of laboratory safety information below. The location of this information should be communicated to all laboratory personnel.

Table 5. Reference Materials

|  |  |
| --- | --- |
| LOCATION | **INFORMATION**  |
|       | Biohazard risk, containment, and disposal procedures (UTA’s [Biosafety Manual](https://www.uta.edu/campus-ops/ehs/biological/index.php)) |
|       | Location of Lab Emergency Plan (Specific to PI’s protocol/experiments)  |
|       | Location and availability of known reference material, including MSDS, on the hazards, safe handling, storage, and disposal of hazardous materials |
|       | Location and availability of the [UTA Lab Safety Manual](https://www.uta.edu/campus-ops/ehs/chemical/index.php) |
|       | Posted contact information for research-related accidents, injuries, or emergencies |

**19.** Personal Protective Equipment (PPE): Describe the eye, face, and hand personal protective equipment to be used in the laboratory while performing experiments.

**20.** Containment: Identify additional safety equipment or procedures such as fume hoods, biological safety cabinets, autoclaves, etc.

1. Emergency Procedures: Please describe procedures to be followed in the event of a chemical spill, contamination of biological material, or personnel exposure (\***PI** is responsible for informing all laboratory personnel of the content and location of the Emergency Plan\*).

1. Lab Security: Describe the procedures for site security (How will lab access be limited? How will lab entries be kept secure? Will anyone have access besides personnel listed in this protocol?).

1. Immunizations: Immunization is generally recommended for laboratory workers who will be engaged in research with infectious organisms for which an effective vaccine is available. If your research involves infectious agents, please describe the available vaccines (if any) and the method of obtaining the vaccine for laboratory personnel.

1. Waste Disposal: Describe procedures for inactivation of recombinant DNA materials or biohazards (autoclave, chemical treatment, incineration, etc.).

1. Transfer of Recombinant DNA and Transgenic Materials: If rDNA or transgenic materials will be transferred between laboratories or work locations, please describe the transport procedures, containment, and appropriate safety precautions.

**SECTION H: Environmental Health & Safety (EH&S) Certification & Signature**

The EH&S Office must certify all Biosafety Level 2 (and higher) laboratories before research commences. Please contact the EH&S office at 817-272-2185 or ehsafety@uta.edu to make an appointment to certify your lab and/or biosafety cabinets used in this research protocol. (This process may occur simultaneously with submission and IBC review of your protocol, but EH&S must provide final sign-off below before research can commence.)

I hereby certify that the facilities are in accordance with the regulations and/or recommendations in (1) [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines), (2) [UTA’s Policy and Procedures for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://resources.uta.edu/research/regulatory-services/rdna-ibc/regulations-and-guidelines%20.php), (3) [*CDC’s Biosafety in Microbiological and Biomedical Laboratories, 6th Edition*](https://www.cdc.gov/biosafety/publications/bmbl5/index.htm), and (4) UTA’s [Biosafety Manual](https://www.uta.edu/campus-ops/ehs/biological/index.php).

**EH&S Safety Specialist Date**