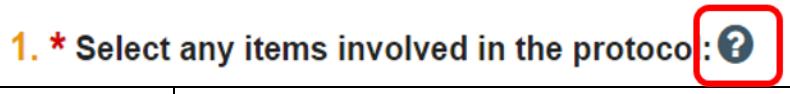
PI Guidance for completing IBC Protocol in BiosafetyNet

Look for Help Text indicated by the Blue Question Marks throughout the protocol for guidance and assistance on some questions.

Click on the Blue Question Marks for Help Text to assist in answering the questions.



Section	Item
Basic Information	**Question 1:** The main Title is limited to 255 characters. Please include any additional titles in Question 2. These will all be listed on approval letters. **Question 3:** Very briefly summarize **(in 150 words or less),** in lay terms, the purpose/objectives of this study. The summary should include: The central question the research is intended to answer. The methods or approach used. **Question 4:** PI must have current training Note Section III-E and III-F NIH guidelines- PI biosafety training recommended, but not required. Biosafety staff will update the training in BiosafetyNet.
Protocol Team Members-	**Question 1:** • All personnel's training must be current unless indicated as Administrative personnel or listed as "No" to the question "Involved with Procedures" • Please indicate whether personnel will be "Involved with Procedures. " This would be any personnel who will handle/manipulate the agent/product. • Training can be registered for on our website: • (https://www.usf.edu/research-innovation/research-integrity-compliance/ric- • programs/biosafety-program/education.aspx) • BSL-1 protocols: Biosafety training is recommended but not required. Note: Biosafety staff will update the training in BiosafetyNet.
Funding Sources	**Question 2:** This should indicate where any funds would be administered**.**
Biosafety Summary	**Question 1**-Check all applicable items. The protocol is branched and the sections will open for completion based on the items selected here. a. Does your work involve Tissues/blood or other body fluids? If so, select **Tissues, Blood or Body Fluids** section. b. Does your work involve primary cells (e.g. human lung tissues) or cell lines (e.g. H293 cell line) mentioned then complete **Primary Cells or Cell Lines** section c. Does the work involve Bacteria/Virus/?- If so, select **Bacteria, Yeasts, Fungi, or Parasites** and/or **Viruses or Prions** sections d. Does your work involve viral vectors? If so, select **Viruses or Prions** and **Recombinant or Synthetic Acids** sections.

e. Does your work involve either *in vivo* work or administering transduced cell lines into animals? If so, select **Animals** section.
f. Will the project involve work with human subjects then **Human Research Participants** section should be checked

NOTE: you only need to select **Genetically Modified Animals** if you will be creating transgenic animals

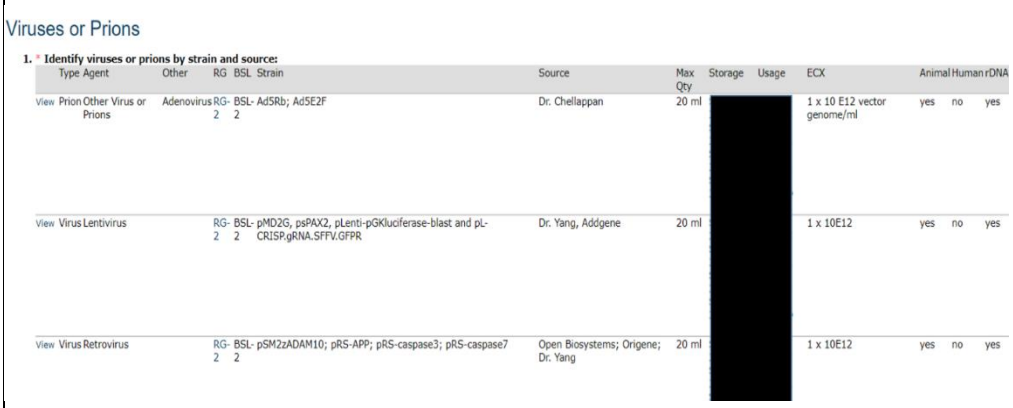
Question 2:
In order to perform a complete biosafety risk assessment for your research protocol, please provide sequential details of the experimental procedures from the beginning of the study to its conclusion. Include any human subject/animal and/or tissue(s) handling procedures that will be used.

Clearly delineate each group of procedures. Viral vector procedures for each viral vector used (include growth, tittering of virus, what cells will be transduced); animal procedures (what will be administered to the animals and how). If administering transduced cells/cell lines to animals describe the test/assay that will be used to demonstrate no viral particles are present. Please include the biosafety precautions that will be used and where procedures will be completed (i.e. in Biological Safety Cabinet (BSC).

If viral vectors will be purchased and there will be no manipulations, (dilutions, etc.), clearly indicate that there is no manipulation of the virus that it is purchased and administered directly to the animals.

- When there are several [projects/experiments included in the protocol, please separate out each experiment and describe them clearly delineating what is being done in each.
- For example:
  Project 1) cell lines will be transduced and administered to animals;
  Project 2) Virus will be directly administered to animals;
  Project 3) Cell lines are being transduced and used for in vitro studies only.
- Please include a brief description of any animal procedures. This should include the how the agents/transduced cell lines will be administered (e.g. intravenously, intranasal, etc.)
- Describe the safety precautions and where the procedures will be performed. (e.g. will they be done in a BSC)
- If there are any steps in the research procedures that may produce aerosols that cannot be performed inside a BSC (e.g. administration of vectors to animals). Provide a description of PPE/precautions that will be taken.
- There needs to be enough description to allow the committee to determine what is being done?
- Some things to consider:
  - Viral tittering
  - Transfection procedures
  - Culturing of virus and or bacteria
  - Description of procedures with equipment that can generate aerosols or represent a high risk of contaminant dispersal?

	• Flow cytometry/cell Sorting? • Sonication? • Homogenizing? • Vortexing? • Centrifuge rotor and/or safety cups should be loaded/unloaded inside the BSC. Please provide a flow chart or Excel sheet that clearly shows what will be done with the infectious agent, rDNA samples, including *in vitro* and *in vivo* procedures, groups or cohorts involving biohazardous agents with frequency, timelines, from start until euthanasia/tissues collection or final disposition of biohazardous agents.
Tissues, Blood, or Body Fluids	**Question 1:** Make sure that all items are answered for each item a. Tissues type name and type of agent b. Agent RG and BSL c. Maximum quantity is the maximum that will be handled (e.g. 100 ml) d. Experimental concentration is the maximum concentration used- this maybe N/A Note: If your Tissue is not included in the dropdown list for the "Agents," Select "Other Tissue, Blood, or Body Fluids." This will bring up a conditional "Other" box where you can type in the tissue that you are using. Note: For any uncharacterized tissues/blood/body fluids, the Risk Group and Biosafety Level should be RG2/BSL-2
Primary Cells or Cell Lines	**Question 1**- Make sure that all items are answered for each item a. Primary cells/cell lines type name and type of agent b. Agent RG and BSL c. Maximum quantity is the maximum that will be handled (e.g. 100 ml) d. Experimental concentration is the maximum concentration used- this maybe N/A Note: If your cells/cell line is not included in the dropdown list for the "Agents," Select "Other Primary Cells or Cell Lines." This will bring up a conditional "Other" box where you can type in the cells/cell lines that you are using. Note: For any uncharacterized cells/cell lines, the Risk Group and Biosafety Level should be RG2/BSL-2
Bacteria, Yeasts, Fungi, or Parasites	**Question 1:** Make sure that all items are answered for each item a. Agent type name and type of agent b. Agent RG and BSL c. Maximum quantity is the maximum that will be handled (e.g. 100 ml) d. Experimental concentration is the maximum concentration used- (e.g. 1X10E6/ml) Please provide product information sheets if available in "Supporting Documents"
Viruses or Prions	**Question 1 :** Make sure that all items are answered for each item a. Agent type name and type of agent b. Agent RG and BSL c. Maximum quantity is the maximum that will be handled (e.g. 100 ml) d. Experimental concentration is the maximum concentration used- (e.g. PFU,)

	e. Viral vector parent viruses need to be listed in this section  Viruses or Prions 1. * Identify viruses or prions by strain and source: Type Agent / Other / RG / BSL / Strain / Source / Max Qty / Storage / Usage / ECX / Animal / Human / rDNA View Prion Other Virus or Prions / Adenovirus / RG-2 / BSL-2 / Ad5Rb; Ad5E2F / Dr. Chellappan / 20 ml / [redacted] / 1 x 10 E12 vector genome/ml / yes / no / yes View Virus Lentivirus / RG-2 / BSL-2 / pMD2G, psPAX2, pLenti-pGKluciferase-blast and pL-CRISP.gRNA.SFFV.GFPR / Dr. Yang, Addgene / 20 ml / 1 x 10E12 / yes / no / yes View Virus Retrovirus / RG-2 / BSL-2 / pSM2zADAM10; pRS-APP; pRS-caspase3; pRS-caspase7 / Open Biosystems; Origene; Dr. Yang / 20 ml / 1 x 10E12 / yes / no / yes Please provide product information sheets for viruses or viral vectors if available in "Supporting Documents"

Biohazards	**Question 1:** This is a table that pulls all of the data from the previous section and displays it here.
	Question 2:
	For each agent listed provide the disease or potential adverse effect.
	• For bacteria, viruses Please include the following for each agent:
	  • Infectious dose and/or the LD50;
	  • Availability of treatment or prophylaxis/vaccine;
	  • Known drug or vaccine resistance;
	  • Symptoms/disease which may result from exposure
	This information may be found from the vendor where it is purchased or check the Material Safety Data Sheets (MSDS) for Infectious Agents and the BMBL for this information.
	• For lentviral and retroviral vectors: exposure to retroviral and lentivitral vectors may theoretically lead to insertional mutagenesis. Therefore, please add a statement that although extremely unlikely there is a theoretical possibility of retroviral and lentiviral vectors causing insertional mutagenesis.
	• If there is no risk make a statement as such

Recombinant or Synthetic Nucleic Acids Usage	**Question 1:** Selects the NIH Guidelines category that you research falls under. NIH Guidelines
Recombinant or Synthetic Nucleic Acid Work Description	**Question 1:** List all vectors (non-viral and/or viral) in this section. This should include the viral vector type, vector name (i.e. pLenti-CMV-Hygroviral, pLKO.1, etc.) **Question 2:** List all of the genes, inserts, gene products, etc. **Question 3:** Describe gene activity for each of the genes (e.g. Cre Recombinase-Derived from the P1 bacteriophage, it catalyses the site specific recombination event between two DNA recognition sites (LoxP sites) **Question 4:** For administration of transduced cell lines, describe the assay system/test that will be used to show that these cells are free from viral particles for animals to be

	housed in ABSL-1. If no assay is described or are being tested, animals will be housed in ABSL-2.
Human Gene Transfer/Human Clinical Trial: Approval	The NIH Guidelines have been updated 04/25/2019. This is no longer required pre the guidelines.
Human Gene Transfer/Human Clinical Trial: Materials	The NIH Guidelines have been updated 04/25/2019. The Informed consent is no longer reviewed by the IBC.
Animals	**Question 4:** Is there is an exposure risk to research personnel/animal care staff animal due to administration of agent to the animals? Check the appropriate route of exposure. Consider the following: a. If experiments involve research animals does the agent cause disease in animals/humans b. Is there possibility of transmission from animals to humans c. Can the agent be shed by the animal **Question 5:** Indicate the duration of animal housing at ABSL-2. The Help text provides that guidance for how long animals should be housed at ABSL-2 is dependent on what is administered to them. **Help Text:** For ABSL-2 practices please follow Comparative Medicine SOP #408. Time period recommended for ABSL-2 housing if using the following: ▪ Transduced cell lines verified by assay to be free of viral particles administered to animals - ABSL-1. ▪ Transduced cell lines not verified by assay to be free of viral particles administered to animals - ABSL-2 for duration of study. ▪ Direct adenovirus or adeno-associated viral vector administration to animals - ABSL-2 for 72 hours. ▪ Direct administration of other viral vectors (e.g. Lentivirus, retrovirus) that are co-administered with human cells to the animals - ABSL-2 for the duration of the study. ▪ Direct administration of other viral vectors (e.g. Lentivirus, retrovirus) that are not co-administered with human cells to the animals - ABSL-2 for 7 days. ▪ Administration of uncharacterized primary human explants to animals (e.g. human tumors - ABSL-2 for the duration of the study. ▪ Administration of infectious agents (bacteria/viruses)- ABSL-2 for the duration of the study.
Risk Group and Containment Practices	**Question 1:** This is the highest RG for the whole protocol **Question 2:** Ensure that the experimental procedures that are selected here are described in the Biosafety Summary Q2.

	Question 3: This should include any special practices/procedures to contain aerosol/splashes. If you will be centrifuging at BSL-2, provide a statement that the sealed centrifuge rotors/safety cups will be loaded/unloaded in BSC **Question 4:** This should include any safety equipment that is described in your procedures. • If centrifuging at BSL-2, be sure to select "Centrifuge with safety cups or sealed rotor heads." • If a chemical fume hood will be used, ensure that its use is described in Biosafety Summary Q2. **Question 5:** This is the highest BSL/ABSL for the whole project
Exposure Assessment and Protective Equipment	**Question 1:** Describe your exposure management/response plan. This should include both the immediate response and the reporting of a potential exposure. Consider the following: **Immediate Response:** The exposed site must be washed immediately for 10 minutes with copious amounts of water ▪ Remove any contaminated clothing ▪ If needle-stick, cut, animal bite or scratch, wash with soap and water after allowing the wound to bleed freely. Apply an appropriate skin disinfectant if applicable. ▪ If mucous membrane (eyes, nose, mouth) flush with water at the nearest faucet or eye wash station for at least 15 minutes. ▪ If skin contact (intact or non-intact) wash with soap and water. Apply an appropriate skin disinfectant if applicable. ▪ Seek medical attention, no matter how seemingly insignificant the injury may seem. Reporting: **All personnel:** For medical emergencies, call 911. Notify Biosafety officer (813) 974-0954 (After hours (813) 469-1625) or Biosafety manager (813) 974-5091 (After hours (813) 842-7020) or biosafety@usf.edu the same day as the potential exposure if involving infectious agents/recombinant or synthetic nucleic acid molecules about the lab accident/potential exposure and the organisms involved. **USF Employee/Volunteer (work-related)::** The supervisor (with the employee), immediately contact workers compensation at (800) 455-2079. In case of emergency, call as soon as practicable. Complete the Supervisor's Incident/Injury Report and forward to Environmental Health and Safety within 24 hours. Proceed to approved medical care facility for initial care. Contact Medical Health Administration Health (Employee Health) office at (813) 974-3163 or pager (813) 216-0153.

	USF Students (non-employee): Proceed to Student Health Services 813-974-2331 OR personal insurance health care provider **Reporting for Moffitt Personnel** 1. Moffitt Incidents Website per Moffitt Work Related Injury policy EH-13. 2. Notify the Biosafety Officer at (813) 974-0954 or after hours at (813) 469-1625. List if there any special items specific to your protocol/agent. This may include: a. Any pre- and post-exposure prophylaxis or immunizations for your protocol. b. Any special treatments c. Any contact that may be at greater risk d. Anyone that would be at a greater/unacceptable risk (e.g. Zika and pregnant females) from the agent Is there possibility of transmission from humans to animals **Question 2:** Select the appropriate Personal Protective Equipment that will be worn/used by the research staff for working on this protocol. Note: For BSL-2 practices, the recommended PPE is a lab coat or gown, gloves and eye protection if there is a risk of splashing. If additional PPE will be worn, include when it will be worn in Biosafety Summary Q2. **Question 3:** This is the required PPE to be worn by animal care staff. This should be consistent with the ABSL described in the protocol. **Question 4:** Select based on the agents used. If the protocol includes the use of blood/blood products or ucharacterized human cells, please select "General Vaccine(s) (Hepatitis B, Tetanus, etc.). Note: All personnel should be offered the Hepatitis B vaccine. Please have personnel contact the appropriate occupational health office (Moffitt (Marie.Massaro@moffitt.org), USF Medical Health Administration (mha@health.usf.edu) or USF EH&S (ehs@usf.edu)) for information.
Waste Management	**Question 1:** Describe appropriate processes for both solid and liquid waste specific to your laboratory. Be sure to include the contact time for inactivation. (e.g. "Biohazardous liquid waste will be inactivated with a **final** concentration of 10% bleach for at least 30min.") **Question 2:** Describe the spill procedures that will be followed. This should include both reporting and spill cleanup. Effective disinfectants for inactivation of the pathogen on surfaces, equipment and in spill situations? **Consider the following:** **Biosafety Level 2 (BL2) Spill** • Notify others in the laboratory regarding the spill • Close door, and post with a warning sign. • Remove contaminated clothing, turning exposed areas inward, and place in a biohazard bag. • Wash all exposed skin with soap and water. • Inform Supervisor and/or Lab director and USF Biosafety Officer (974-0954)/Biosafety Manager (974-5091) **Clean-up of BL2 Spill**

	• Allow aerosols to disperse and or settle for at least 30 minutes before reentering the laboratory (if spill outside cabinet). Assemble clean-up materials (disinfectant, paper towels, biohazard bags, and forceps). • Put on protective clothing (lab coat, facemasks/face protection, utility gloves, and booties if necessary). • Cover the area with disinfectant-soaked towels, and then carefully pour disinfectant around the spill. Avoid enlarging the contaminated area. Use more concentrated disinfectant as it is diluted by the spill. Allow at least a 20 minute contact time. • Pick up any sharp objects with forceps, tongs or autoclavable dust pan and brush and discard in a sharps container. • Clean up the disinfectant and spill using mechanical means, such as an autoclavable room and dustpan, since there may be sharps under the paper towels, and place the materials into a sharps container. • Smaller pieces of glass may be collected with cotton or paper towels held with forceps. If no sharps were involved in the spill discard the materials into an autoclave bag. • Wipe surrounding areas (where the spill may have splashed) with disinfectant. • Spray the area with 10% household bleach solution and allow to air-dry (or wipe down with disinfectant-soaked towels after a 20-minute contact time). • Place all contaminated paper towels and any contaminated protective clothing into a biohazard bag and autoclave. • Wash hands and exposed skin areas with soap and water.
Shipping and Transport	**Question 1:** If your biohazards(s) will be stored in and used in separate rooms, this should be marked "Yes" and a description provided. (E.g. "The viral vector will be stored in MDC 123 and taken to MDC 456 for use") **Question 2:** • Will you be shipping any materials to others (e.g., researchers at other universities, etc.) Is so, select "Yes." If you will only be receiving biohazardous materials this is "No." • If "yes," personnel shipping the biohazardous materials must have taken shipping training. Please list their name and date of training. • Training is offered by our office. (https://docs.google.com/forms/d/e/1FAIpQLSdpTsMSGvXu_X19XvgBqYLQVU1yiAJ6Q5mZx2uHTqKsP7C33A/viewform)
Supporting Documents	• Moffitt requires that you must get approval to use replication deficient viral vectors outside of designated viral vector rooms. You must contact Moffitt Safety for this form (RESEARCH FACILITY APPROVAL FOR REGULATED OR HIGH RISK ACTIVITIES). A copy of the approved form must be provided prior to using the viral vectors in the open lab space. • Documents such as permits, disinfectant information, etc. can be uploaded here.