IBC - IBC Research Application **Protocol ID:** IBC-2021-01290 (Johnson, Christina)
Protocol Title: Sample protocol on how to enter administration of gene modified cells into animals

Amendment
Personnel Information
Storage
Locations
Protocol Information
Sec.1 - Summary
Sec.2 - Research Act...
Sec.3 - Recombinant ...
Sec.4 - Viral Vectors
Sec.5 - Microorganisms
Sec.6 - Biological T...
Sec.7 - Human Subjects
Sec.8 - Animal Research
Sec.9 - Community
Sec.10 - Dual use
Sec.11 - SOPs
Funding
Attachments
Attestation
Return Notes
Manager Notes
Print View
Event History

Sec.1 ... Sec.2 ... Sec.3 ... Sec.4 ... Sec.5 ... Sec.6 ... Sec.7 ... Sec.8 ... Sec.9 ...
Sec.10... Sec.11...

For guidance, see **Help** in top right corner of this window.

Summary

Items marked with red stars (*) are required by the system to construct the protocol.

Official Project Title *
Sample protocol on how to enter administration of gene modified cells into animals

Lay Summary
Please provide the committee with a brief explanation of the proposed project. Use language that is understandable to those with general knowledge of biology, and define all abbreviations and acronyms. Do not attach grant applications (typically <350 words).

Two examples are given. Luciferase is an example for a plasmid. GFP is an example for an integrating viral vector.

Technical Summary
Describe the activities involving recombinant/synthetic nucleic acid molecules, biological toxins, and/or infectious agents proposed in this application. Explain how the use of the agent(s) will further the goals of this research.

EXAMPLE 1
A plasmid expressing the luciferase reporter gene will be expanded using molecular grade E. coli. The plasmid will be transfected into cell lines. Cells are administered to rats.
1. Section 3. Complete and check tissue culture for 8d.
2. Section 3. Clone the gene entry in section 3 and in question 2, change III-D4b from no to yes. Change question 8d from tissue culture to “Directly into OTHER species, or indirectly into ANY species” and complete text box with information of cell line species.
3. Section 8. Complete 8.2. Answer question 1 with "other" (mouse or rat will not work) and specify the species of cell line that will be used since it determines housing level. In question 2 check the gene(s) that will be administered to animals and then proceed to complete section 8. Administration BSL is usually ABSL2. Housing level is ABSL1 for rodent cells and ABSL2 for human cells.

EXAMPLE 2
A plasmid expressing the GFP reporter gene will be expanded using molecular grade E. coli. The plasmid will be transfected into packaging cells to generate lentiviral particles that are then used to transduce cell lines. Cells will be administered to mice.
1. Section 3. Complete. For question 2 check III-D1a and III-D4b with yes. Check tissue culture for 8d
2. Section 4 – List viral vectors used - Complete one entry with question 14 being answered as “tissue culture” since the plasmid will need to be expanded in the packaging cell line to generate viral particles. Needles are not involved at this step, so there should be no injection risk.
3. Section 4 – List viral vectors used - Clone the “tissue culture” entry. Change question 4 to “Directly into OTHER species, or indirectly into ANY species” and add information into text box. Needles are usually used to inject cells into animals so there is an injection risk.
4. Section 8. Complete 8.2. Answer question 1 with "other" (mouse or rat will not work) and specify the species of cell line that will be used since it determines housing level. In question 2 check the viral vector(s) that will be administered to animals and then proceed to complete section 8. Administration BSL is usually ABSL2. Housing level is ABSL1 for rodent cells and ABSL2 for human cells.

Sec.1 ... Sec.2 ... Sec.3 ... Sec.4 ... Sec.5 ... Sec.6 ... Sec.7 ... Sec.8 ... Sec.9 ...
Sec.10... Sec.11...