New Jersey Institute of Technology
Institutional Biosafety Committee (IBC)
Attachment 1
To be completed for Human Gene Transfer Research

For questions regarding human subjects board (IRB) review requirements please contact the IRB

Complete this IBC Attachment ***ONLY*** if the research involves the administration of recombinant or synthetic nucleic acid molecules into human subjects

- Complete the IBC Application and Attachment 1 and provide both documents for IBC review.
- These documents may be emailed to the IBC at IBC@njit.edu.
- In order that applications are processed in time for monthly IBC meetings, the web-posted deadline dates apply

1. Are recombinant or synthetic nucleic acid materials prepared or reconstituted at a location other than the administration site? (Mark "X" for Yes/No in un-shaded box) • **If "Yes", address precautions regarding transportation of the materials between the locations**	Yes	☐	No	☐
2. Are recombinant or synthetic nucleic acid materials produced or manufactured at the University of Pittsburgh or an affiliate facility? (Mark "X" for Yes/No in un-shaded box) • **If "Yes", provide the location and name of the facility**	Yes	☐	No	☐
3. Has FDA and IND information been submitted to the IBC Office with this application? (Mark "X" for Yes/No in un-shaded box) • **If "Yes" Provide the IND#**	Yes	☐	No	☐
4. Is the IND holder affiliated with UPMC or the University of Pittsburgh?	Yes	☐	No	☐
5. Is the goal of this research study to induce or enhance immune response in the study subjects? (Mark "X" for Yes/No in un-shaded box) • **If "Yes" describe the expected response**	Yes	☐	No	☐
6. Provide the dosage groups, route of administration and volume/concentration per dose				
7. Describe pre-production verification of the nucleic acid molecular structure. Include a restriction analysis diagram and pertinent sequence data. It is acceptable to reference the specific pages in supporting documents, as applicable				

8. Describe post-production verification of the nucleic acid molecular structure (release criteria). It is acceptable to reference the specific pages in supporting documents, as applicable	
9. Describe pre-release testing methods of analysis of the recombinant or synthetic nucleic acid product. It is acceptable to reference the specific pages in supporting documents, if applicable	
10. What is the nature of the pre-clinical study data? Provide references to published data, and site the specific pages in supporting documents, if applicable	
11. Address any specific precautions to be taken by staff personnel assisting in this research	