**WCG IBC Services**

**Change in Principal Investigator Form**

Use this checklist to assemble your request to change the Principal Investigator of an existing, IBC-approved study.

IBC Services will only accept documents submitted electronically via email attachment to IBCServices@wcgclinical.com.

REQUIREMENTS: CHANGE IN PRINCIPAL INVESTIGATOR

[ ]  IBC Services Change in Principal Investigator Form

[ ]  Full curriculum vitae for the incoming PI *(must include all relevant publications and clinical trial experience; abbreviated CVs will not be accepted)*

[ ]  Documentation that the study Sponsor is aware of the change (*e.g.* *email, letter or similar from the Sponsor, CRO, or IRB*)

**WCG IBC Services**

**Change in Principal Investigator Form**

**1. CURRENT STUDY INFORMATION**

Institution Name:

Sponsor Protocol Number:

Current Principal Investigator:

**2. NEW PRINCIPAL INVESTIGATOR INFORMATION**

Name:

Address:

City: State:  Zip code:

Phone:  Email:

Degree:  Specialty:

**3. NEW PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT**

“On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines\* in the conduct of recombinant or synthetic nucleic acid molecule research.” [NIH Guidelines Section IV-B-7]

As Principal Investigator, I agree to adhere to the NIH Guidelines and acknowledge that under the NIH Guidelines I am responsible to:

1. Not initiate or modify clinical gene transfer research until all requirements of the NIH Guidelines are met;
2. Be adequately trained in good microbiological techniques;
3. Be responsible for training the staff, supervising their activities, and overseeing biosafety procedures for their research;
4. Instruct and train the research staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
5. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested;
6. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed;
7. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken;
8. Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid molecules;
9. Ensure the integrity of the physical and biological containment of recombinant materials;
10. Comply with shipping requirements for recombinant or synthetic nucleic acid molecules;
11. Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the IBC, NIH, and other appropriate authorities (where applicable) within the timeframe as set forth in the NIH Guidelines;
12. Report any new information bearing on the NIH Guidelines to the IBC and to the NIH;
13. Remain in communication with the IBC throughout the conduct of the project;
14. Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination;
15. Submit any changes in the research to the IBC for review and approval or disapproval prior to implementing the changes.

Signature of Principal Investigator Date

\**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, or as revised or substituted.