**WCG IBC Services SUBMISSION FORM**

 **Site-level IBC Review of Clinical Research**

Use this form to request initial review of a specific clinical study by your Institution’s WCG-administered IBC.

If WCG does not already administer an IBC on behalf of your Institution, submission of a separate form to establish the IBC is required ([IBC Registration Form](https://www.wcgclinical.com/irb-resources/ibc-forms/)).

For Institutions with an existing IBC administered by WCG, only this form is required for this review to be initiated.

WCG IBC Services only accepts documents submitted electronically via email attachment to IBCServices@wcgclinical.com.

SUBMISSION REQUIREMENTS

The following study-specific documents are required for review (may be provided by the Sponsor or CRO):

[ ]  Protocol

[ ]  Investigator’s Brochure

[ ]  Pharmacy Manual or equivalent

The following site-specific documents must be provided with this form (unless already on-file; see Section 5):

[ ]  Site map(s) or floor plan(s) showing all research areas to be used

[ ]  Full resume or curriculum vitae (CV) of the Principal Investigator *(current within the last 3 years; must include publications and/or clinical research experience)*

**1. PROTOCOL**

Sponsor Name:  Sponsor Protocol #

If known, NCT Number (ClinicalTrials.gov):

Has this protocol ever been reviewed by another IBC on behalf of this Institution?[ ]  Yes\* [ ]  No

*\*If yes, please explain:*

Do you have a target enrollment date or eligible patients identified for the study? [ ]  Yes\* [ ]  No

*\*If yes, provide the date and/or explain:*

If known, please provide the name of the WCG-administered IBC for which this submission is being made*:*

**2. PRINCIPAL INVESTIGATOR**

Name:

Phone:  Email:

Degree(s):  Specialty:

Are staff who prepare and administer the study agent qualified to do so under local and state laws?

[ ]  Yes [ ]  No\* *\*If no, please explain:*

**3. PRIMARY STUDY CONTACT**

The Primary Study Contact is the person responsible for IBC review preparation who will serve as the main point of contact between WCG and your site after the submission is made.

Name:  Job Title:

Phone:  Email:

**List up to three additional site contacts to include on IBC review meeting invitations and/or copy on emails related to the preparation of site-specific documents required for IBC review:**

Name:  Email:  [ ]  Invite to Meetings [ ]  Copy on Emails

Name:  Email:  [ ]  Invite to Meetings [ ]  Copy on Emails

Name:  Email:  [ ]  Invite to Meetings [ ]  Copy on Emails

**4. RESEARCH LOCATION(S)**

**List all locations where study agent receiving/shipping, storage, preparation, and/or dosing will occur.**

**Main Location**

Facility Name:

Address:

City: State:  Zip code:

Country:

Type of Facility: [ ]  Outpatient medical office [ ]  Hospital [ ]  Other *(specify)*:

**What study agent-related activities will occur at this location?**

[ ]  Receiving or shipping [ ]  Storage [ ]  Preparation [ ]  Dosing

[ ]  Other *(specify)*:

**Additional Location**

Facility Name:

Address:

City: State:  Zip code:

Country:

Type of Facility: [ ]  Outpatient medical office [ ]  Hospital [ ]  Other *(specify)*:

**What study agent-related activities will occur at this location?**

[ ]  Receiving or shipping [ ]  Storage [ ]  Preparation [ ]  Dosing

[ ]  Other *(specify)*:

**Additional Location**

Facility Name:

Address:

City: State:  Zip code:

Country:

Type of Facility: [ ]  Outpatient medical office [ ]  Hospital [ ]  Other *(specify)*:

**What study agent-related activities will occur at this location?**

[ ]  Receiving or shipping [ ]  Storage [ ]  Preparation [ ]  Dosing

[ ]  Other *(specify)*:

**To list other locations where study agent-related activities will occur, attach additional sheets as needed.**

**5. SITE-SPECIFIC INFORMATION NEEDED FOR IBC REVIEW**

**Provide the information and documents requested below.**

**If this study will use facilities and research practices covered by site documents already on file with WCG for an IBC-approved study, provide the approved Principal Investigator’s name and the sponsor protocol number below, and proceed to Section 6. The information and documents listed below do not need to be provided again.**

Principal Investigator: Sponsor Protocol Number:

1. **The study agent will be prepared in/on:**

[ ] a biosafety cabinet (provide current certification report)

[ ] a compounding aseptic containment isolator/glovebox (provide current certification report)

[ ] a countertop

1. **List the disinfecting agent(s) that will be used to decontaminate work surfaces after study activities. Check all that apply:**

[ ] 10% bleach solution

[ ] Commercial disinfecting wipes (list brand and type):

[ ] Commercial disinfecting solution (list brand and type):

[ ] Other:

1. **Provide the specific room names/numbers that will be used for the following activities. These names should match the annotations on site maps:**
	1. Study agent storage (example: IP Freezer Room):
	2. Study agent preparation (example: Pharmacy Clean Room):
	3. Study agent dosing (example: Exam Rooms 1-10):
	4. Biohazardous waste storage (example: First Floor Soiled Utility Room):
2. **Attach site map(s) that show the locations listed above.** Label the map(s) similar to the sample at the end of this form, indicating each room or area that will be used for the study and any handwashing sinks and eyewashes present in those areas. Site maps may be floor plans, architectural renderings, evacuation routes, or graphical representations of the research areas to be used for the study.
3. **If available, attach photographs of the locations listed above.** Photos are required for IBC review, but can be provided with your submission or after it has been made. A WCG IBC photo template is available to download and use from [our website](https://www.wcgclinical.com/irb-resources/ibc-forms/). If you are not using the WCG template, be sure to include a label or description for each photo. Photos should capture any sinks, eyewashes, sharps containers, biohazardous waste bins, disinfectants, and/or biosafety cabinets present in the research areas to be used for the study.

**6. ADDITIONAL CONTACT INFORMATION**

**Sponsor:**

Company Name:

Contact Name:

Phone:  Email:

**CRO (Contract Research Organization):** *if applicable*

Company Name:

Contact Name:

Phone:  Email:

**SMO (Site Management Organization):** *if applicable*

Company Name:

Contact Name:

Phone:  Email:

**Institutional Review Board:**

[ ]  WCG IRB [ ]  Other *(specify below)*:

Other IRB Name:

Contact Name:

Phone:  Email:

**7. BILLING INFORMATION FOR THIS PROTOCOL**

**This submission constitutes a request from the Principal Investigator for IBC review of the research. WCG IBC Services will bill third parties (e.g., Sponsor or CRO) directly only when we are authorized to do so; otherwise, payment responsibility remains with the Institution. WCG IBC Services bills for each protocol separately following each IBC review meeting that is held.**

Party to be billed\* (e.g. Sponsor or CRO):

Address:  Mail Stop/Cost Center:

City:  State:  Zip code:

Country:

Phone:  Email:

“ATTENTION”:

Describe any special billing instructions: (for example reference numbers, purchase order number or tracking number)

**8. PERSON COMPLETING THIS FORM**

Name and Job Title: Date:

Phone:  Email:

**9. PRINCIPAL INVESTIGATOR ACKNOWLEDGEMENT**

Per the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), Principal Investigators are responsible for complying with the NIH Guidelines during the conduct of recombinant or synthetic nucleic acid molecule research.

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

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 subsequent changes in the research to the IBC for review and approval or disapproval.

Signature of Principal Investigator or Authorized Delegate\* Date

\*As an Authorized Delegate, I confirm that I have the authority to sign on behalf of the Principal Investigator.

**10. RESEARCH OPPORTUNITIES**

WCG IBC Services is sometimes asked to suggest investigators for multicenter studies. Please notify WCG IBC Services if you would like not to be included in multicenter study investigator suggestions.

**11. SAMPLE SITE MAP**

