**IBC Services SUBMISSION REQUIREMENTS**

**Part B: Review of Protocol**

Use this checklist to assemble your request for your Institution’s IBC to review a specific protocol.

If WCG IBC Services does not already administer an IBC on behalf of your Institution, submission of a separate form (IBC Services Submission Form Part A) is required.

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

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

PART B: PROTOCOL REQUIREMENTS

The following documents must be provided with this Submission Part B:

[ ]  Full Curriculum Vitae (CV) for the Principal Investigator *(current within the last 3 years and must include publications and/or clinical research experience)*

[ ]  Completed site-specific protocol information sheet (*see Appendix A, page 7*)

The following documents are required for review (may be provided by the study sponsor or delegate):

[ ]  Protocol

[ ]  Investigator’s Brochure

[ ]  Pharmacy Manual or equivalent *(if available)*

**B1. PROTOCOL INFORMATION**

Sponsor Protocol #

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

*\*If yes, please explain:*

Do you have a specific calendar requirement for opening enrollment? [ ]  Yes\* [ ]  No

*\*If yes, date:*        *explain:*

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

**B2. PRINCIPAL INVESTIGATOR INFORMATION**

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:*

**B3. STUDY PRIMARY CONTACT INFORMATION**

*The Primary Contact/Study Coordinator is the person designated as the person responsible for IBC review preparation.*

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

**B4. 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.**

**B5. ADDITIONAL CONTACT INFORMATION**

**Sponsor:**

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:

**B6. BILLING INFORMATION FOR THIS PROTOCOL**

NOTE:   This Part B submission constitutes a request from the Principal Investigator for IBC review of the research. 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. 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)

**B7. PERSON COMPLETING THIS FORM**

Name and Job Title: Date:

Phone:  Email:

**B8. 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 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 subsequent changes in the research to the IBC for review and approval or disapproval.

Signature of Principal Investigator Date

**B9. RESEARCH OPPORTUNITIES**

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

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

**APPENDIX A: SITE-SPECIFIC INFORMATION NEEDED FOR IBC REVIEW OF A NEW PROTOCOL**

**Overview:** Institutional biosafety committees are tasked with reviewing site-specific facilities, practices, and policies in place at Institutions conducting clinical trial research involving recombinant/synthetic nucleic acids. As such, IBCs require various site-specific documents and information for review.

**Instructions:** Provide answers to the questions below. While you may not currently have all of the information requested, providing as many details as you can will allow IBC Services to complete additional site-specific documents on your behalf and will accelerate IBC approval of the trial at your site.

**Institution:**

**Protocol Number:**

**Person Completing this Appendix:**       **Email:**       **Phone:**

1. **Where do you plan on preparing the study agent? Check one:**

[ ] In a biosafety cabinet (provide most recent certification report)

[ ] In a compounding aseptic containment isolator/glovebox (provide most recent certification report)

[ ] On a countertop

[ ] Unknown/to be determined

1. **What disinfecting agent(s) will be used to clean 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:

[ ] Unknown/to be determined

1. **Where will the following activities occur? Be as specific as possible; if unknown, note “TBD”:**
	1. Study agent storage (example: IP Freezer Room):
	2. Study agent preparation (example: Pharmacy):
	3. Study agent dosing (example: Exam Rooms 1-10):
	4. Biohazardous waste storage (example: First Floor Soiled Utility Room):
2. **If available, attach site map(s) (e.g. floor plan, evacuation map) that show the locations listed above. Label the map(s) similar to the example below. If you need help labeling your map, a member of our staff will assist you after we receive your submission.**

