IBC SERVICES SUBMISSION REQUIREMENTS
Part B: Review of Protocol

Use this checklist to assemble your request for your local IBC to review a specific protocol.

Submission of a separate form (Part A: Institution Information) is required for IBC Services to establish your local IBC. Both forms (Part A and Part B) are required before this review can be initiated.

For sites with an existing IBC, administered by 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 ibcs@wcgclinical.com.

PART B: PROTOCOL REQUIREMENTS

☐ IBC Services Submission Form Part B: Protocol Information
☐ Full Curriculum Vitae (CV) for PI (including publications and research experience)
☐ Informed Consent Form (draft acceptable)

Following Documents may be provided by the study sponsor or delegate:

☐ Protocol
☐ Investigator’s Brochure
☐ Responses to Appendix M-I-A of the NIH Guidelines (if applicable)

Please select one of the following and provide applicable documentation:

☐ Submitting to IBC and IRB for Initial Study Review to NIH OSP
☐ Study Registered with NIH OSP or reviewed by RAC
☐ Study Exempt from NIH OSP Registration or RAC review
**PART B: PROTOCOL INFORMATION**

**B1. PROTOCOL INFORMATION**

<table>
<thead>
<tr>
<th>Sponsor Protocol #</th>
<th>NIH OSP Registration #</th>
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Has this protocol been registered with NIH OSP?  
**Yes**  
**No**  

Has the protocol been granted a vaccine exemption under Appendix M-VI-A?  
**Yes**  
**No**  

*If yes, please attach copy of the vaccine exemption correspondence received from NIH OBA.*

Has this protocol ever been reviewed by another IBC on behalf of this institution?  
**Yes**  
**No**  

*If yes, please explain:*

Date the IND application for this protocol went into effect:  
**Pending**  

Please ask your sponsor; this relates to compliance with annual NIH reporting requirements.

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

*If yes, date:  
explain:*

**B2. PRINCIPAL INVESTIGATOR INFORMATION**

Name:  
Address:  
City:  
State:  
Zip code:  
Phone:  
Email:  
Principal Investigator’s Degree:  
Specialty:  
Are staff who prepare and administer the investigational 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 primary contact for IBC review.

PI Representative Name:  
Title:  
Address:  
City:  
State:  
Zip code:  
Phone:  
Email:  

**B4. RESEARCH LOCATION(S)**

List all facilities where study agent will be present and where subjects receive required post-dosing care.

Main Site, Name:  
Address:  

same as PI address or:
IBC SERVICES SUBMISSION FORM
PART B: PROTOCOL INFORMATION

Address: ____________________________________________
City: __________________________ State: ____________ Zip code: ________________
Phone: __________________________ Email: _______________________

**Type of facility:** □ Outpatient medical office  □ Hospital  □ Other (specify): ________________

**What study activities will be done at this site?**
□ agent receiving or shipping  □ agent storage  □ agent preparation  □ dosing
□ specimen collection  □ other subject medical care or follow-up
□ Other (specify): ________________

**Additional Site:**
Address: ____________________________________________
City: __________________________ State: ____________ Zip code: ________________
Phone: __________________________ Email: _______________________

**Type of facility:** □ Outpatient medical office  □ Hospital  □ Other (specify): ________________

**What study activities will be done at this site?**
□ agent receiving or shipping  □ agent storage  □ agent preparation  □ dosing
□ specimen collection  □ other subject medical care or follow-up
□ Other (specify): ________________

**To list more sites, please attach additional sheets.**
B5. ADDITIONAL CONTACT INFORMATION

**Sponsor:**

Name: ________________________________
Address: ________________________________
City: ______________________ State: _______ Zip code: ____________
Country: ______________________________
Contact Name: __________________________
Phone: _____________ Email: ______________
Medical Monitor: __________________________
Phone: _____________ Email: ______________

Has the sponsor ever received any NIH support for rDNA research?  [ ] Yes  [ ] No  [ ] Don’t Know

**CRO (agent for the sponsor): if applicable**

Company Name: ________________________________
Address: ________________________________
City: ______________________ State: _______ Zip code: ____________
Country: ______________________________
Contact Name: __________________________
Phone: _____________ Email: ______________

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

Company Name: ________________________________
Address: ________________________________
City: ______________________ State: _______ Zip code: ____________
Country: ______________________________
Contact Name: __________________________
Phone: _____________ Email: ______________

**Institutional Review Board:**

IRB Name: ________________________________
Address: ________________________________
City: ______________________ State: _______ Zip code: ____________
Country: ______________________________
Primary 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 upon IBC meeting and then annually until study closure is accepted.

Party to be billed*: ________________________________

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 Title of Person Completing This Form ________________________________

Phone __________________ Date __________________

Sponsor Protocol # ____________________________ OBA/RAC Protocol # ____________________________
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 DNA 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. Evaluate and address all aspects of the Appendix M and RAC recommendations;
3. Be adequately trained in good microbiological techniques;
4. Be responsible for training the staff, supervising their activities, and overseeing biosafety procedures for their research;
5. Instruct and train the research staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents;
6. Inform the research staff of the reasons and provisions for any precautionary medical practices advised or requested;
7. Supervise the safety performance of the research staff to ensure that the required safety practices and techniques are employed;
8. Make available to all research staff descriptions of the potential biohazards and the precautions to be taken;
9. Correct work errors and conditions that may result in the release of recombinant DNA materials;
10. Ensure the integrity of the physical and biological containment of recombinant materials;
11. Comply with shipping requirements for rDNA molecules;
12. Comply with reporting requirements for human gene transfer experiments conducted in compliance with the NIH Guidelines (see Appendix M-I-C, Reporting Requirements);
13. 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;
14. Report any new information bearing on the NIH Guidelines to the IBC and to the NIH;
15. Remain in communication with the IBC throughout the conduct of the project;
16. Adhere to IBC approved emergency plans for handling accidental spills and personnel contamination;
17. Submit any subsequent changes in the research to the IBC for review and approval or disapproval.

I further acknowledge that I will submit all additional rDNA research (including non-NIH-funded research) for IBC review before initiation of any study-related activities (for sites within the US).

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.**