**WCG ibc sERVICES sUBMISSION fORM**

**Study-level IBC Submission by Sponsor/CRO**

**INSTRUCTIONS**

The purpose of this form is to allow a clinical trial sponsor or CRO to make a central/study-level submission of protocol documents to IBC Services on behalf of participating sites. The use of this form is optional.

Please note that in order to secure IBC approval, each site must first establish an IBC with WCG, and each investigator must separately sign and submit a separate form for [Site-level IBC Review of Clinical Research](https://www.wcgclinical.com/irb-resources/ibc-forms/). To request information about how investigators should request IBC approval please contact IBC Services at IBCServices@wcgclinical.com.

**The following documents are required for IBC review:**

1. Protocol
2. Investigator’s Brochure
3. Pharmacy Manual and/or Product Preparation and Administration Instructions (if available)

Draft versions may be submitted, but final versions of the Protocol and Investigator’s Brochure will be required prior to IBC approval. Subsequent versions will be treated as amendments/changes in research as applicable.

Sponsors are welcome to submit additional documentation regarding the investigational product and research plan if relevant to biosafety. Study subject-facing documents, such as the Informed Consent Form, are not required for IBC review.

Please complete this form and submit along with the required sponsor documents to IBCServices@wcgclinical.com.

**1. PROTOCOL INFORMATION**

Sponsor Protocol #:

Protocol Title:

ClinicalTrials.gov Identifier, if available:

Alternative identifiers, if applicable.

Site number estimates (for planning purposes only; estimates do not represent a commitment by the submitter):

* Expected total number of dosing sites:
* Number of dosing sites expected to use WCG IBC services:

Duration of product administration (IBC oversight may often be closed after last dose):

* For approximately how many years will product dosing occur at each site?

**2. CONTACT INFORMATION**

**Sponsor:**

Company Name:

Primary Contact Name:

Phone:  Email:

Additional Contact Name:

Phone:  Email:

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

Company Name:

Primary Contact Name:

Phone:  Email:

Additional Contact Name:

Phone:  Email:

**3. BILLING PREFERENCE FOR THIS PROTOCOL**

The cost of IBC Services should be invoiced as follows:

[ ]  Billing plan is not yet decided.

[ ]  WCG should invoice each investigator individually.

[ ]  WCG should invoice sponsor or CRO according to billing instructions below:

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)

**4. PERSON COMPLETING THIS FORM**

Name and Job Title: Date:

Phone:  Email: