

## Initial Protocol Submission Form

### **Submission Instructions**

Protocol Submissions should be made through the Total IRB Web Portal, iROC. Contact [jenny.gidley@totalirb.com](mailto:jenny.gidley@totalirb.com) for access to portal. In the event electronic submissions are not possible, submissions should be faxed to 888-433-7802 or mailed to:

Total IRB  
Attn: IRB Administration  
9650 Strickland Road  
Suite 103-147  
Raleigh, NC 27615

Submitter must notify Total IRB via email at [jenny.gidley@totalirb.com](mailto:jenny.gidley@totalirb.com) on the day hard copy documents are sent for submission.

### **Submission Checklist**

The following items should be included with initial study submission. Board review cannot be scheduled until all items are received

- Initial Protocol Submission Form
- Protocol
- Informed Consent Form
- Investigator Brochure
- Any other materials that will involve subjects (e.g. subject diaries, advertisements, questionnaires, etc.)

### **Informed Consent Forms**

Total IRB suggests that the Sponsor provide a template consent form for use at all sites in a multi-center study. In the event that a site requests changes to the template consent form, the Sponsor will be notified and required to approve site requested changes prior to Total IRB review.

### **Approval Notices**

Note that Total IRB's Web Portal, iROC, is the primary means that Sponsors, CROs and Sites will receive approval notices and acknowledgements. Unless arranged in advance, approval correspondence will not be mailed to Sponsors, CROs or sites.

## I. BASIC STUDY INFORMATION

Protocol Number:	
Protocol Title:	
Protocol Version Date:	
Sponsor:	
CRO (if applicable):	

1. Will an independent data safety monitoring committee oversee the research?  Yes\*  No

\*If Yes, please indicate who Total IRB may contact to obtain information about the findings of the committee:

Name:	
Company:	
Title:	
Email:	
Phone Number:	

2. Is this protocol similar to one previously reviewed by Total IRB?  Yes\*  No

\*If Yes:

- Please list protocol numbers(s):
- Please note relationship with other studies (e.g. sister study, extension, same study program, etc.):

3. Has this protocol been disapproved, terminated, deferred, tabled, or declined for review by another IRB prior to submission to Total IRB?  Yes\*  No

\*If Yes, list the name of the IRB(s), and the outcome of the review(s) on a separate page; Include copies of correspondence from IRB(s).

<b>II. STUDY CONTACT INFORMATION</b>	
<b>A. Sponsor Contact:</b> Sponsor agrees to access study approval documents, make secure electronic submissions and view study startup reports online via the Total IRB Web Portal	Agree <input type="checkbox"/>
Name:	Title:
Company:	
Address:	
City:	State/Province:
Zip/Postal Code:	Country:
Phone:	Fax:
<b>B. CRO Contact</b>	
Should contact have access to all study documents?  *If Yes, agree to access study approval documents, make secure electronic submissions and view study startup reports online via the Total IRB Web Portal?	<input type="checkbox"/> Yes* <input type="checkbox"/> No  <input type="checkbox"/> Agree
Name:	Title:
Company:	
Address:	
City:	State/Province:
Zip/Postal Code:	Country:
Phone:	Fax:
<b>C. Medical Monitor/Scientific Advisory Contact:</b> (For protocol, consent form and safety issues)	

## II. STUDY CONTACT INFORMATION

Should contact have access to all study documents?

\*If Yes, agree to access study approval documents, make secure electronic submissions and view study startup reports online via the Total IRB Web Portal?

Yes\*    No

Agree

Name:

Title:

Company:

Address:

City:

State/Province:

Zip/Postal Code:

Country:

Phone:

Fax:

Which contact should be the primary contact for Total IRB phone calls, correspondence and questions?

Sponsor       CRO       Medical Monitor

### D. Electronic Invoices for Services Should be Sent to:

Name:

Title:

Company:

Address:

City:

State/Province:

Zip/Postal Code:

Country:

Phone:

Fax:

III. TIMELINE INFORMATION	
1. When will we receive the first site submission?	
a. How many total sites will be involved in the study?	
b. How many sites will be utilizing Total IRB as their IRB?	
2. By when do you intend for all Total IRB sites to be approved?	
3. When is first subject first visit expected?	
4. When is last subject last visit expected?	
5. When is the investigator meeting scheduled?	
6. What is the expected number of enrolled subjects for the entire protocol?	
Additional info regarding timelines or study startup that Total IRB should know:	

IV. PROTOCOL AND CONSENT INFORMATION
<p>1. Is this study funded or supported (in whole or part) by a US federal department or agency?  <input type="checkbox"/> Yes*      <input type="checkbox"/> No</p> <p>*If Yes, a federally funded addendum is required . Contact Total IRB at 866-569-1785 to make this request.</p> <p><b><u>Check one of the following:</u></b></p> <p><input type="checkbox"/> Drug Study with sites in US – complete question 2 below</p> <p><input type="checkbox"/> Device Study – skip question 2 below  <i>(If your study involves a device either as an investigational product or as part of the study, please complete and submit Total IRB's Device Supplemental Submission Form)</i></p> <p><input type="checkbox"/> Other (please specify):</p>

#### IV. PROTOCOL AND CONSENT INFORMATION

2. Drug Study (*\*fields noted with an asterisk require a response*)

\*IND#:

If not available, please explain or note N/A if not applicable:

If this study is being conducted under an IND, please check which of the following apply to this protocol:

The IND number is active and research can be initiated immediately upon Board approval.

The IND application relating to this study was received by the FDA less than 30 days ago.  
(*Total IRB will not process approval documents until receiving written confirmation that the IND is active*)

Please note IND application date (if less than 30 days ago):

\*Phase I  II  III  IV  Other:

\*Drug Name:

\*Medical Indication:

3. This study will be conducted at (check all that apply):

Hospital

Surgery Center

Nursing Home

University

Public Health Clinic

Research Facility

Hospice

Free-standing Psychiatric Facility

Facility owned by or affiliated with a hospital or university

Private Practice (specify specialty):

Other (specify):

4. Please indicate whether the protocol design requires the enrollment of any of the vulnerable populations listed below. Check all that apply:

Pediatric Subjects/Minors

Pregnant Women/Fetuses

Handicapped

Mentally Disabled individuals (includes all cognitively impaired populations)

Economically Disadvantaged individuals

Educationally Disadvantaged individuals

Non-English speaking individuals

Illiterate individuals

Other (specify)

None

#### IV. PROTOCOL AND CONSENT INFORMATION

5. What is the age range of participants?:

*An assent form may be required for minors subjects ages 7 and older. Note the age of majority in Alabama and Nebraska is 19; 21 in Puerto Rico.*

Is possible (for non-pediatric studies) that your protocol will allow enrollment of participants under 21?

Yes  No

6. Please provide subject payment information. If subjects are to be paid, state specifically for which visits subjects will receive payment and when such payment will be made; for example, "payment will be made within one month after the last study visit". Please be as specific as possible to minimize confusion.

Subjects will not be paid

OR

Provide a statement for the consent form explaining the payment plan (amounts, visits not paid, when payment will be made). If there are different payment plans for separate populations or for additional sub-studies, detail those as well:

7. Is pharmacogenetic sampling a part of this study?  Yes\*  No

\*If yes, will a pharmacogenetic consent form be required?  Yes  No

#### V. STUDY REQUESTS

##### 1. Consent Form

Please note any particular issues, requests or concerns about this study's consent form:

##### 2. Translations

Would you like Total IRB to arrange for the translation of the consent form?  Yes\*  No

\*If yes, for which language(s)? (*translation fee applies*)

Spanish Other(s):

## V. STUDY REQUESTS

When would you like the translation process to begin?

- After consent form negotiations are complete (*Standard Translation Service*)  
 After the first site request is received (*May delay translations by up to 4-6 weeks*)

*If sponsor provides already translated study materials, Total IRB must receive a copy of translated documents, including certification of translation certificate. Total IRB will require a QC check before board review (administrative fee applies)*

### 3. Other Consent Issues

Informed Consent Waivers:

Will a Waiver of Documentation of informed Consent be necessary?  Yes\*  No

\*If yes, please also complete and submit the Informed Consent Waiver Form

### 4. Model Recruitment Materials

Recruitment materials should be submitted with the initial submission packets to allow for faster, easier, and more cost effective processing. There are no additional charges for the review of recruitment materials that are included with the initial submission packet. Materials received after initial submission will be subject to additional review and distribution charges.

Do you require prior Sponsor approval of investigator/site generated recruitment materials?

- Yes\*  No

\*If yes, Total IRB will require investigators obtain written Sponsor approval prior to Board review. To facilitate faster processing, please make sites aware that Sponsor approval is required.

Are recruitment materials or subject materials attached?  Yes\*  No

\*If yes, check all that are attached:

- |  |                                       |                                       |
|--|---------------------------------------|---------------------------------------|
| <input type="checkbox"/> Newspaper                   | <input type="checkbox"/> Letter       | <input type="checkbox"/> Posting      |
| <input type="checkbox"/> Brochure                    | <input type="checkbox"/> Internet     | <input type="checkbox"/> Phone Screen |
| <input type="checkbox"/> Newsletter                  | <input type="checkbox"/> **Television | <input type="checkbox"/> **Radio      |
| <input type="checkbox"/> Public Service Announcement |                                       |                                       |

*\*\*Recordings will not be viewed without scripts. Submit scripts prior to recording. Any Total IRB required modifications to the advertisement must be included in final version of recording. Sponsor must submit final recording to Board.*

## V. STUDY REQUESTS

Have any of these or similar recruitment materials been previously approved by Total IRB for this protocol or other protocols?  Yes\*  No

\*If Yes, please attach a copy of the previously approved items(s). Total IRB administrative support will provide the Board with information about the previous Board review, so that the previous decision of the Board can be taken into account when the materials are reviewed.

### 5. Site Submission

- Principal Investigators will make initial site submissions for Board review directly to Total IRB
- The Sponsor/CRO will make initial site submissions for Board review on behalf of Principal Investigators. \*Under this selection, any submission received directly from a site will be held pending Sponsor/CRO approval.

## VI. SAFETY REPORTING

### 1. Submission and Acknowledgement of Study-wide Safety Information and Unanticipated Problems

Typically Investigators are required to report all appropriate safety information to Total IRB. For a multi-site study, however, the Sponsor/CRO can assume responsibility for reporting protocol-level safety information and unanticipated problems (e.g. IND Safety Reports, DSMB report summaries, FDA Public Health Advisories, new or updated study product safety information).

#### **Please choose how you would like these reports to be submitted to Total IRB:**

- Investigators will be responsible for submitting to Total IRB all protocol-level safety information and unanticipated problems. Are IRB stamped acknowledgments to the submitting Investigator required?  Yes\*  No

*\*If Yes, administrative fee applies to acknowledgements.*

- Sponsor/CRO assumes responsibility for submitting to Total IRB protocol-level safety information and unanticipated problems on behalf of Investigators

- Sponsor/CRO wishes to have Total IRB provide a formal safety acknowledgement letter to each Investigator who has approved/active status at the time the safety information is reviewed. I understand that for this service, Total IRB will impose its standard charge for delivering study-wide safety acknowledgements

OR

## VI. SAFETY REPORTING

- Sponsor/CRO agrees to assume responsibility for distributing Total IRB's acknowledgement letter to Investigators.

*Note that Investigators in either case will be responsible for submitting site-level safety information and unanticipated problems to Total IRB.*

### 2. Submission and Acknowledgement of Investigator Brochures, Package Inserts or Medical Device Product Information

The Sponsor/CRO is expected to submit to Total IRB on behalf of Investigators any revisions to the Investigator's Brochure, package insert or medical device product information and a summary of changes. **Please select one of the following two options:**

- Sponsor/CRO wishes to have Total IRB provide a formal acknowledgement letter to each Investigator who has approved/active status at the time the safety information is reviewed. I understand that for this service, Total IRB will impose its standard charge for delivering study-wide safety acknowledgements
- Sponsor/CRO agrees to assume responsibility for distributing Total IRB's acknowledgement letter to Investigators

## VII. TOTAL IRB WEB PORTAL (iROC)

The Total IRB Web Portal (iROC) is a password-protected area of our web site that offers customers a range of online tools: secure electronic submissions, posted approval documents, access to previous submissions and access to all site level documents.

The Sponsor and CRO contacts noted in this questionnaire (see section 2) automatically receive access to iROC. Customers may request additional protocol-level accounts in the spaces below. Investigative sites may request portal accounts separately. All users will be asked to read and accept Total IRB's Terms of Use the first time they log on to the Portal. *To request additional users at a later date, please visit [www.totalirb.com](http://www.totalirb.com) or contact IRB administration for instructions.*

I request access to protocol and site information on Total IRB's Web Portal for the following individual(s):

First Name:	
Last Name:	
Title:	

<b>VII. TOTAL IRB WEB PORTAL (iROC)</b>	
Phone Number:	
Company Name:	
	<input type="checkbox"/> Sponsor <input type="checkbox"/> Other (please specify) <input type="checkbox"/> CRO                                      Relationship to study:
Corporate Email Address:	
First Name:	
Last Name:	
Title:	
Phone Number:	
Company Name:	
	<input type="checkbox"/> Sponsor <input type="checkbox"/> Other (please specify) <input type="checkbox"/> CRO                                      Relationship to study:
Corporate Email Address:	

<b>VIII. SHIPPING</b>	
<p>The Total IRB Web Portal, iROC, is the primary method for Sponsor/CRO and site personnel to access approval documents. However, if required, Total IRB can ship approval documents to Investigators via US Priority Mail. Total IRB can also ship via alternative carriers and bill the Sponsor/CRO carrier account as indicated below.</p> <p><b><i>Shipping Preference to Investigators:</i></b></p>	
<input type="checkbox"/> Total IRB Standard: approvals posted to Web Portal (iROC)	No Shipping Charges
<input type="checkbox"/> Total IRB Upgrade: hard copy approvals sent via US Priority Mail	No Shipping Charges
<p>If alternate carrier is required indicate carrier and your carrier billing account number below.</p>	

<b>VIII. SHIPPING</b>	
<input type="checkbox"/> UPS 2-day, plus iROC	Sponsor/CRO Billing Account Number:
<input type="checkbox"/> UPS Next Day, plus iROC	Sponsor/CRO Billing Account Number:
<input type="checkbox"/> FedEx Priority Overnight, plus iROC	Sponsor/CRO Billing Account Number:
<input type="checkbox"/> FedEx Standard, plus iROC	Sponsor/CRO Billing Account Number:

<b>IX. PERSON COMPLETING FORM</b>	
<p>On behalf of the Sponsor/CRO, I am requesting Total IRB review the information submitted. I certify that I have reviewed all responses provided on this submission form and all responses are true and accurate. Sponsor/CRO understands that Total IRB will conduct its review in compliance with the applicable laws, ethical standards and Total IRB policies. I understand that Total IRB has the right to conduct a site visit at any time with proper notification. On behalf of the Sponsor/CRO, I agree to promptly report any information that becomes available that may affect the safety of subjects, subject's willingness to participate, or the IRB's approval to continue the study.</p>	
<hr/>	
<b>Form Completed By ( Printed Name)</b>	<b>Date</b>
<hr/>	
<b>Title, Company</b>	
<hr/>	
<b>Phone:</b>	<b>Email:</b>