



Site Submission Form

Each question must be answered completely. Do not skip any sections. If a question does not apply, write not applicable (N/A). The site/Principal Investigator cannot be reviewed by the Board until this questionnaire and all supporting documents are received.

I. STUDY INFORMATION	
Principal Investigator:	
Protocol Number:	
Protocol Title:	
Sponsor name and/or Funding Agency:	

II. CONTACT INFORMATION		
PRINCIPAL INVESTIGATOR (PI):		
Name:	Title:	
Company:		
MAILING ADDRESS: (should match Box 1 of Form FDA 1572)		
Address:		
City:	State:	Zip / Postal code:
Phone:	Fax:	
Email:		
PHYSICAL ADDRESS: (if different than above)		
Address:		
City:	State:	Zip / Postal code:

II. CONTACT INFORMATION

PRIMARY CONTACT FOR TOTAL IRB:

This will be the primary contact for the board to communicate regarding this study (for example follow-up on incomplete answers on this form, request for additional information, etc.).

Name:	Title :
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Company:

Address:

City:	State:	Zip / Postal code:
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Phone:	Fax
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Email:

IS SITE/PI AFFILIATED WITH A SITE MANAGEMENT ORGANIZATION (SMO)?
 Yes (complete information below) No

SMO Contact Person:	Title:
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Company:

Address:

City:	State:	Zip / Postal Code:
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Phone:	Fax:
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Email:

COMMUNICATION FROM TOTAL IRB:

Total IRB's web portal, iROC, is the standard way to receive study documents (e.g. approvals, Informed Consent Documents, continuing review notices, etc.)

Yes, agree to access all notices and documents from Total IRB on iROC Web Portal. This service is free of charge.

- No, must also receive hard copy of all study documents via mail. If mail is required, indicate vendor:
- US Postal Service regular mail (no additional charge)
 - FedEx (Provide account number):
 - UPS (Provide account number):
 - Other (Specify carrier and account number):

II. CONTACT INFORMATION			
ELECTRONIC INVOICES FOR SERVICES SHOULD BE SENT TO:			
<input type="checkbox"/> Bill Sponsor/CRO (indicate n/a in boxes below)		<input type="checkbox"/> Bill Site/SMO (complete information below)	
Billing Contact Person:		Title:	
Company:			
Address:			
City:	State:	Zip / Postal code:	
Phone:		Fax:	
Email:			

III. INVESTIGATOR INFORMATION																																							
<i>Attach a <u>CV and a license</u> for the Principal Investigator. CVs and licenses for sub-investigators do not need to be submitted.</i>																																							
<p>1. If this PI will conduct research involving an investigational drug in the state of Massachusetts, provide a copy of the Massachusetts Research Registration under which the research will be conducted.</p> <p>Registration number: <input type="checkbox"/> N/A</p>																																							
<p>2. Sub-investigators: <input type="checkbox"/> None OR <input type="checkbox"/> Listed below</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%; text-align: left; padding: 5px;">Name</th> <th style="width: 25%; text-align: left; padding: 5px;">Education</th> <th style="width: 25%; text-align: left; padding: 5px;">Research Training</th> <th style="width: 25%; text-align: left; padding: 5px;">Other Qualifications</th> </tr> </thead> <tbody> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> <tr><td>_____</td><td>_____</td><td>_____</td><td>_____</td></tr> </tbody> </table> <p style="padding: 5px;"><i>Please attach additional page(s) if necessary.</i></p>				Name	Education	Research Training	Other Qualifications	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____	_____
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III. INVESTIGATOR INFORMATION

3. Has the PI or any sub-investigator ever been disciplined by a medical/licensing board, or been convicted of a misdemeanor or felony that relates to the practice of medicine? Yes* No

*If Yes, attach a summary of the event and resolution.

4. Has the PI or any sub-investigator ever been disciplined/sanctioned by the FDA, OHRP or by an IRB? This would include issuing a reprimand, restricting the ability to conduct research or placing other conditions upon investigator. Yes* No

*If Yes, attach a summary of the event and resolution.

5. Has the PI ever been audited by the FDA, OHRP, or other regulatory agency, received a Warning Letter, a FDA 483, or other notice? Yes* No

*If Yes, attach a summary of the event and resolution.

6. Has the PI ever had a Sponsor or IRB impose any sanctions or restrictions on him/her, or terminate or suspend the approval of a study for any reason? Yes* No

*If Yes, attach a summary of the event and resolution.

7. Is any action or investigation currently pending from any licensing board, federal agency or court of law concerning the professional conduct of the principal investigator in his/her capacity as a research investigator or as a clinician? Yes* No

*If Yes, attach a summary of the event and when resolution is expected.

8. Does the PI or any sub-investigator, or immediate family of PI or any sub-investigator have a significant financial interest in this study?

Yes, one or more of the following are true (check all that apply and provide a detailed explanation):

Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded);

Has a financial interest in the research with value that exceeds \$10,000 other than payments for conducting the trial as outlined in the clinical trials agreement;

III. INVESTIGATOR INFORMATION

- Has a financial interest in the research with value that exceeds 5% ownership;
- Has received or will receive compensation with value that may be affected by the outcome of the study;
- Has a proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement;
- Has received or will receive payments other than payment for the conduct of clinical research from the sponsor that exceed \$10,000 in the last 365 days;
- Is an employee of the agency or company sponsoring the research;
- Is on the board of directors of the sponsor;
- Has a financial interest that requires disclosure to the sponsor or funding source; or
- Has any other financial interest that the investigator believes may interfere with his or her ability to protect subjects.

No, none of the above is true.

9. Indicate the human research subject protection training that the PI has completed within the past 3 years (check all that apply):

- None (site cannot be approved for research until training is completed)
- OHRP Training modules
- NIH Human Research Participant Training
- Certified Clinical Investigator (CCI) through DIA
- Completion of the Collaborative IRB Training Initiative (CITI)
- Academic/medical center's institutional human subject protection training requirements satisfied
- Clinical Research Professional (CRP) through SOCRA
- Certified Clinical Trial Investigator through ACRP
- Other: (specify)

10. Has the PI confirmed that sub-investigators and other research staff have been trained and are aware of their obligations for human research subject protection regulations? No* Yes

*If No, state how this will be addressed:

11. Number of studies conducted by the PI in the last year (can be approximated):

- 0 studies* 1 - 5 studies 6 - 10 studies > 10 studies

*If the PI has not conducted any studies in the last year, provide a brief description of the PI's

III. INVESTIGATOR INFORMATION

qualifications to be the PI for this study:

12. How many studies is the PI currently conducting (either as PI or sub-investigator)?

0 studies 1 - 5 studies 6 - 10 studies > 10 studies*

*If the PI is currently conducting more than 10 studies, provide a brief description of the resources in place to ensure that the PI has sufficient time to conduct and complete the research:

13. Describe any additional resources available at your site that will assist with the conduct of this study (example information: number studies per study coordinator, # of study coordinators at site, % of PI time devoted to clinical research, pharmacists available, other personnel involved in study, etc.) :

IV. SITE INFORMATION

List the main location where subjects will be screened, enrolled, treated and followed:

Location:

Address:

City:

State:

Zip / Postal code:

1. What type of facility is the primary location?

- Research Dedicated Facility
- Private Practice
- Hospital*
- Other (specify):

* If research will be conducted in a hospital, a letter from the hospital's institutional official allowing the conduct of the research is required. attached not applicable

2. Will subjects be screened, enrolled, treated, followed, or otherwise seen at any additional locations?

Yes* No

*If Yes, attach an Additional Location Form.

IV. SITE INFORMATION

3. Is there a local IRB with jurisdiction over the primary location where research will be conducted for this study? Yes* No

* If Yes, attach a waiver of jurisdiction from local IRB and letter from institutional official allowing the conduct of research at the site.

4. Are there state or local laws governing research that impose obligations greater than those imposed by the federal regulations? Yes* No

*If Yes, attach a description and copies of applicable laws.

5. What category applies to the primary location?

- Urban
 Suburban
 Rural
 Other (specify):

6. What is the community attitude toward research conducted at this facility?

- Neutral
 Positive (explain):
 Negative (explain):

7. How close is your site to the nearest emergency facility?

- Less than 1 mile
 Between 1 and 5 miles
 Between 6 and 10 miles
 More than 10 miles

8. Check the on-site emergency equipment available at your site (check all that apply):

- Crash cart Defibrillator Oxygen Emergency Medications
 CPR certified staff Other:
 None (attach documentation explaining how medical emergencies are handled at your site)

V. SUBJECT INFORMATION & INFORMED CONSENT

<p>1. How many subjects do you anticipate enrolling at this site?</p>	<p>Screened: Screen Failures: Randomized:</p>
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2. Check any of the following methods that the PI will use to recruit subjects for this study:

- Advertising (*All recruitment materials must be approved by IRB before use*)
- From a database for which subjects have given prior permission to be contacted for research studies
- From Personal Contact (e.g., patients, students)
- Referrals (*Offering or accepting payment for referring patients to research studies [finder's fee] is NOT allowed*)
- Other (specify):

NOTE for HIPAA compliance, you may need an authorization from the subject or a waiver of authorization before you can use or disclose identifiable health information for research screening or recruitment purposes. This may affect your ability to recruit subjects into this study.

3. Are recruitment materials or subject materials attached? Yes* No

*If Yes, check all that are attached:

- Newspaper Flyer Letter (from Dr. to subject)
- Brochure Web Site Public Service Announcement
- Video (*recordings will not be reviewed without scripts*)**
- Audio (*recordings will not be reviewed without scripts*)**
- Telephone screening script
- Other:

Note that Total IRB requires written sponsor permission for all site advertisements prior to review. Attach permission along with copy of recruitment materials.

***To avoid unnecessary additional production costs due to re-work, it is strongly recommended that you seek IRB pre-approval of scripts before producing the recordings. Any Board-required modifications to the material must be reflected in the final version of the recording.*

VULNERABLE POPULATIONS

4. Will you enroll any subjects that are not English Speaking? Yes* No

V. SUBJECT INFORMATION & INFORMED CONSENT

*If Yes, answer the following questions:

Will you follow the expected safeguards noted below? Yes No*

- Subject will be provided with informed consent and other documentation in native language
- Site (or interpreter) has ability to communicate with subject in native language
- Investigator will provide adequate opportunity for the subject to ask questions and comprehend information presented

*If No, attach a letter of explanation

What language (other than English) do you need the Consent Form translated?

- Spanish
 Other (specify):

5. Will you enroll children/minors in this study? Yes* No

*If Yes, answer the following questions:

- Do you have experience with pediatric subjects? No Yes
- Under your state and local law, what is the age of consent:
- Under your state and local law, who is authorized to consent on behalf of minors for general medical care ("Guardians")?:
- Will you follow the expected safeguards noted below? Yes No*
 - Parental permission and assent will be obtained as required by IRB.
 - Site will ensure that outside parties (parent/guardian) are not unduly influencing subject to participate.
 - Site will verify any state law restrictions on the use and authority of guardians in research by consulting with legal counsel.
 - If emancipated minors are enrolled without parental permission, the site will contact IRB to obtain appropriate consent process and further consideration of appropriate safeguards.
 - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information presented.

*If No, attach a letter of explanation.

6. Will you enroll illiterate or educationally disadvantaged subjects (other than young children) in this study? Yes* No

V. SUBJECT INFORMATION & INFORMED CONSENT

*If Yes, answer the following question:

Will you follow the expected safeguards noted below? Yes No*

- A witness not involved with the research will be present during the consent process to attest to the accuracy of the presentation and the apparent understanding of the prospective subject.
- The prospective subject will be asked to “make their mark.”

*If No, attach a letter of explanation.

7. Will you enroll adults with diminished decision-making capacity in this study? Yes* No

*If Yes, answer the following questions:

- Under your state and local law, who is authorized to consent on behalf of a prospective subject to his or her participation in the procedures involved in research (“Legally Authorized Representative”)?
- Will you follow the expected safeguards noted below? Yes No*
 - The prospective subject will not participate in the study unless she/he provides assent.
 - Consent will be obtained from a legally authorized representative (LAR) when appropriate.
 - If surrogate consent is required from LARs, the site will verify any state-law restrictions on the use of LARs in research by consulting with local legal counsel.
 - Investigator will provide adequate opportunity for the subject to ask questions and comprehend information presented.

*If No, attach a letter of explanation.

8. Will you enroll economically disadvantaged subjects in this study? Yes* No

*If Yes, answer the following question:

Will you follow the expected safeguards noted below? Yes No*

- Set compensation and other inducements at a level that is not coercive.
- Prorate compensation.

*If No, attach a letter of explanation.

V. SUBJECT INFORMATION & INFORMED CONSENT

9. Will you enroll pregnant women in this study? Yes* No

*If Yes, answer the following question:

Will you follow the expected safeguards noted below? Yes No*

- Discuss possible risks to the woman and fetus during the consent process.

*If No, attach a letter of explanation.

10. Will you enroll Sponsor or site employees or their family members? Yes* No

*If Yes, answer the following question.

Will you follow the expected safeguards noted below? Yes No*

- Investigator/site staff will ensure and explain that participation does not affect subject's position.

*If No, attach a letter of explanation.

11. Will you enroll subjects in this study from any additional vulnerable population groups (e.g. prisoners, physically handicapped)? Yes* No

*If Yes, indicate which population and how site will provide additional protections for this group:

INFORMED CONSENT

12. Will you use the model informed consent form developed by the Sponsor and/or the IRB? Note consent will be customized with site specific contact information and reimbursement if applicable.

Yes No*

*If No, the following is required. Check each box to indicate information is attached:

- Attached is an electronic copy of the informed consent form with changes tracked from the template informed consent form for this study
- Written documentation of sponsor approval
- Rationale for each requested change

V. SUBJECT INFORMATION & INFORMED CONSENT

13. Who will discuss the study and obtain consent from study subjects? Check all that apply:

- Principal Investigator Sub-Investigator(s)
 Study Coordinator Others (specify):

14. How will you be sure the participant will have enough time to consider whether to consent and understands the information? *(please check all that apply)*

- Participants will be allowed to take consent form home prior to signing
 Participants will be allowed as much time as is necessary to consider the decision
 All study procedures and risks are explained without using medical jargon
 Participants will be allowed as much time as is necessary for questions and answers
 Other (please describe):

15. Provide 24-hour phone number to be listed in Informed Consent Document:

16. Will subjects be paid for their participation? This includes reimbursement for parking, bus fare, etc.

- Yes* No

*If Yes, answer the following questions:

- a. Per visit payment amount: \$_____ (Payment must be prorated by visit)
b. Maximum total payment for each subject: \$_____
c. When will subjects be paid? Every Visit End of Study Other (specify):

17. Describe the procedures for documentation of informed consent, including any procedures for obtaining assent for minors, using witnesses, translators and document storage:

18. Describe the circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable populations:

19. PRIVACY FOR SUBJECTS

“Privacy” refers to a person’s interest in controlling the access, timing, extent, and circumstances of sharing private information to others. Check each box below to confirm that your site will use the following practices to safeguard subject privacy:

- Subjects consented in a private setting away from the public

V. SUBJECT INFORMATION & INFORMED CONSENT

- Study related assessments and procedures will be conducted in a private setting
- Site will only collect information from participant that is necessary for the research

If any of the 3 boxes above were not checked, a letter of explanation must be attached.

20. CONFIDENTIALITY

Confidentiality refers to how a subject's private information will be managed and used. It is a means of protecting that information from unauthorized disclosure.

Note: It is the Principal Investigator's responsibility to ensure that research activities conducted at all locations are HIPAA compliant for any location considered a "covered entity".

Check each box below to confirm how your site will use the following practices to safeguard subject confidentiality:

- Paper study records will be kept in a secure location accessible only to study staff.
- Electronic study records will be protected with electronic safeguards (e.g., computer passwords, access privileges, firewalls, etc.).
- Participant identifying information will be protected from improper use and disclosure.
- Confidentiality agreements will be required of study staff.
- The site will not use collected information for purposes other than the research purposes the participant has specifically consented to and authorized.
- Other (specify):

Will your site require a partial waiver of authorization in order to screen for this study (if your site is a covered entity)? Yes* No

*If Yes, provide rationale for this need:

VI. PRINCIPAL INVESTIGATOR AGREEMENT

As Principal Investigator I am responsible for the conduct of this research study at my site. I agree to uphold ethical standards and practices in research and conduct this study in accordance with applicable regulations. I further certify by checking each box below that: *(Note: All boxes must be checked for application to be processed)*

- I will conduct this study according to the approved protocol and in accordance with ICH/GCP Guidelines, 21CFR Parts 50, 56, 312, and 812; Title 45 Part 46 and Title 45 Parts 160-164 and any additional conditions required by the FDA or Total IRB;
- My research staff and I have reviewed the Belmont Report. We understand and will uphold the three principles of research ethics set forth in the report: respect for persons, beneficence and justice;
- I will not initiate subject related activities prior to receiving the Total IRB approval letter and approved informed consent form;
- I will conduct the study in accordance with the Board-approved protocol and will not intentionally implement a change to the protocol without prior written approval from the IRB, except when necessary to eliminate an apparent immediate hazard to a subject;
- I will report changes to the protocol without prior IRB approval to eliminate an apparent immediate hazard to subjects within 24 hours of implementation;
- Either I or someone under my supervision will explain the informed consent document(s) to each prospective subject (or legally authorized representative, guardian, individual authorized to provide surrogate consent, as applicable) before obtaining his or her signature on the current, IRB approved consent document(s) and before conducting any study-related procedures;
- I have reviewed the relevant safety documents for the study product(s) (e.g., Investigator's Brochure, device manual, package insert) and am familiar with the potential risks and side effects of the study product(s);
- The research staff assisting in the conduct of this study at this site are informed of their obligations relating to the protection of human research subjects;
- The research site is adequately equipped to manage emergencies or problems that may occur during the course of this study;
- I will make myself available to discuss concerns and complaints with the subject, subject's representative, sponsor/CRO, and Total IRB during and after the conduct of the research study;
- I will notify Total IRB in writing when the study is closed at my site.

I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above.

Entering your name below also indicates an acknowledgment and agreement that: correspondence and notifications from Total IRB may be generated and signed in electronic form; you may print out such electronic documents in hard copy; any such printouts accurately reflect the electronic original. All such printouts shall be treated in all ways as originals. An electronic, photostatic or facsimile copy of this document is as valid as the original and shall be conclusive evidence of execution of the original by the undersigned.

Printed Name of Principal Investigator

Date

VII. CHECKLIST AND SIGNATURE

Please include the following attachments, as applicable to your submission:

Required

- Form FDA 1572
- CV and license for Principal Investigator

As Applicable

- Recruitment Materials (and sponsor written approval)
- Copy of Massachusetts Research Registration (see section III)
- Explanation of any disciplinary or criminal history (see section III)
- FDA or OHRP audit documentation (see section III)
- Description of any financial conflict of interest (see section III)
- Additional Site Location form (see section IV)
- Letter from Institutional Official allowing research to occur (see section IV)
- Local IRB Jurisdiction Waiver (see section IV)
- Copy of any applicable state or local laws governing research (see section IV)
- Site SOPs/additional documentation for handling a medical emergency (see section IV)

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Form Completed By

Date

Title, Company

Phone:

Email: