



## Site Submission Form

Sponsor: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

**Instructions:** Please complete all sections as you would like the information to appear on all documents. For assistance in completing the Site Submission Form, please contact Harrison IRB at 740 845 0814.

1. Principal Investigator Information					
a. Principal Investigator Name					
Site Name (if applicable)					
Address					
City		State		Zip Code	
Phone		Fax			
Email					
Website					
b. Site Contact for IRB Regulatory Documents					
Name					
Title					
Phone					
Email					
c. Site Contact for Submission and Study-related Questions					
Site Contact:					
Contact Phone:					

2. Site Activities/Information
<p>a. Please select the activities that will be performed at the primary site.</p> <p> <input type="checkbox"/> (A) Administrative/No Subject Contact                    <input type="checkbox"/> (B) Consent Process                    <input type="checkbox"/> (C) Regulatory Activities  <input type="checkbox"/> (D) Study Related Procedures                    <input type="checkbox"/> (E) Study Visits                    <input type="checkbox"/> (F) Other: _____             </p>
<p>b. Please provide an overview of the procedures that will be taken at your site to ensure that the study data is kept confidential: _____</p> <p>_____</p> <p>_____</p>
<p>c. Please provide an overview of the provisions to protect the privacy interests of subjects: _____</p> <p>_____</p> <p>_____</p>

3. Additional Forms for Submission (if applicable)
<p>a. Will additional sites be used throughout the conduct of this research?    <input type="checkbox"/> Yes    <input type="checkbox"/> No                  (If yes, please complete the Additional Site Form)</p>
<p>b. Are any of the sites located at an institution that has its own IRB?    <input type="checkbox"/> Yes    <input type="checkbox"/> No</p>
<p>c. Will any procedures for this project be conducted in an institution with an IRB that requires notification or oversight for the procedure?    <input type="checkbox"/> Yes    <input type="checkbox"/> No                  (If you answered <b>yes</b> to questions b or c, please submit the Waiver of Jurisdiction Form)</p>

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#### 4. Emergency Precautions

a. Is the primary research site equipped to handle emergencies?  Yes  No

b. How close is the nearest emergency facility? \_\_\_\_\_

c. What is the name of this facility? \_\_\_\_\_

#### 5. Research Staff (as listed on the FDA Form 1572) –

a. Name of Research Staff	Title of Research Staff	Activities/Responsibilities for this study *

b.  The Principal Investigator verifies that the research staff has received human subjects protection training and have been trained for their proper roles and responsibilities relating to the conduct of research for this study.

\*(A) PI Designee (B) Administrative Only (C) Consent Process (D) Regulatory Activities  
(E) Study Related Procedures (F) Interpretation for Non-English Speaking Subjects (G) Other

#### 6. Informed Consent Form (ICF)

a.  Please select this checkbox if you will be submitting site-specific information for review  
**Please note that prior authorization from the sponsor may also be required.**

b. Please list the numbers as they should appear in the ICF:

Office Phone: \_\_\_\_\_ After hours number: \_\_\_\_\_

#### 7. Informed Consent Process

a. Harrison IRB requires an overview of your site's process for obtaining consent and authorization. You may attach your site's SOP or instructions providing detailed information which must address the bulleted list below **OR** provide the details to the questions answered below:

- The person(s) who will conduct the consent interview.
- The person(s) who will provide consent or permission.
- Any waiting period between informing the prospective subject and obtaining consent.
- Steps taken to minimize the possibility of coercion or undue influence.
- The language(s) to be used by those obtaining consent.
- The language(s) understood by the prospective subject or the legally authorized representative.
- The information to be communicated to the prospective subject or the legally authorized representative.

Attached is a copy of your site's SOP or instructions for obtaining consent and authorization.  
(The information provided as an attachment must cover all of the items in the bulleted list above).

Please provide a detailed account for obtaining consent and assent (if applicable) authorization at your site. \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

b. Who will conduct the consent interview with the prospective subject? (Check all that apply).

Principal Investigator  Sub-Investigator

Research Coordinator  Other (specify): \_\_\_\_\_

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**7. Informed Consent Process (continued)**

c. Who will provide consent or permission to participate in the research?

- Subject  
 Parent

- Subject's Legally Authorized Representative\*  
 Other (specify): \_\_\_\_\_

**\*Harrison IRB requires that a legally authorized representative be appointed through a legal process and prior approval must be obtained by Harrison IRB prior to the use of a Legally Authorized Representative.**

d. Our site will ensure that the subject or the subject's Legally Authorized Representative will sign and date the consent document.  I agree.

Our site will ensure that the subject or the subject's Legally Authorized Representative will receive a copy of the signed document for his/her records  I agree.

e. If you will allow the Subject's Legally Authorized Representative (LAR) to provide consent to participate in the research, how do you determine which individuals meet the criteria for being a LAR under your state and local law? \_\_\_\_\_

\_\_\_\_\_  NA

f. Describe how you will verify that the person is qualified to sign on behalf of the prospective subject:

\_\_\_\_\_  
\_\_\_\_\_  NA

g. The potential participant must have adequate time to consider whether to consent to participate in the research. How will you ensure there is sufficient time for the subject to consent?

- Subjects will be permitted to take the document home with them to discuss with friends and family members  
 There will be a waiting period of \_\_\_\_\_ hours for subjects to consider their decision to participate.

h. Describe the steps your site will take to minimize the potential for coercion or undue influence (select all that apply):

- Subjects will be informed that if they choose not to participate, their decision will not have any effect on receiving their normal medical care.  
 Payment to the subjects and potential benefits must not be overemphasized when reviewing the consent document.  
 It is clearly explained to the subject that participation is voluntary.

If the Investigator is the subject's physician, please identify how the site will minimize the potential for coercion or undue influence (select all that apply):

- the difference between the research and standard of care are explained, and/OR  
 another authorized representative (i.e., sub-Investigator or research coordinator) at the site will conduct the consent process

i. The consent process will take place:

- in a private room  in a waiting room  in an open ward  
 in a group setting  in a group setting and followed up in a private room  
 in an emergency setting (please explain): \_\_\_\_\_

\_\_\_\_\_  other (please explain): \_\_\_\_\_

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### 7. Informed Consent Process (continued)

j. The site will communicate information to the subject or the subject's LAR in a language that is understandable to the subject or representative.  I confirm.

- The information will not include exculpatory language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights.
- The information will not include exculpatory language through which the subject or the subject's representative releases or appears to release the investigator, sponsor, the organization or its agents from liability or negligence.

### 8. Translations

a. Do you plan to enroll non-English speaking subjects into this study?  Yes  No

b. Please list the language(s) for translation, if needed: \_\_\_\_\_

The site confirms that a qualified translator is available to discuss the research study, the contents of the informed consent documents and can answer any questions the subject may have regarding the study.

### 9. Community Attitude

a. Please describe the attitude (positive and negative) towards research in the community from which your site will be recruiting subjects: \_\_\_\_\_

b. Has there been any recent media focus on research in your community?  Yes  No  
If yes, please explain: \_\_\_\_\_

### 10. Compensation

a.  We will not be providing compensation to participants in this research study.

b.  We will be providing monetary compensation to participants in this research study.

The dollar amount per visit: \$ \_\_\_\_\_

Number of paid visits: \_\_\_\_\_

Total amount at completion of study: \$ \_\_\_\_\_

c. If compensation is not equally prorated, please provide a detailed description of your compensation plan: \_\_\_\_\_

d. Payments will be made  at the end of the study  at the end of each visit

other: \_\_\_\_\_

e.  Other payment: Please provide a description for non-monetary payment to subjects: \_\_\_\_\_

### 11. State Laws

a. Are there any state or local laws that impact research at your site?  Yes  No  Unknown

If yes, please explain: \_\_\_\_\_

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**12. Conflict of Interest**

a. All individuals involved in the design, conduct or reporting of the research protocol are to disclose the following financial interest:

i. Do you or your immediate family have any of the following:

- Ownership interest, stock options, or other financial interest related to the research (unless it meets the following three tests):
  - Does not exceed \$50,000 when aggregated for the immediate family
  - Publically traded on a stock exchange
  - No arrangement has been entered into where the value of the ownership interests will be affected by the outcome of the research.
- Compensation related to the research (unless it meets the following two tests):
  - Does not exceed \$25,000 in the past year when aggregated for the immediate family
  - No arrangement has been entered into where the amount of compensation will be affected by the outcome of the research including, but not limited to, a patent or trademark, copyright or licensing agreement.
- Proprietary interest related to the research including, but not limited to, a patent, trademark, copyright, or licensing agreement.

b. If you have any of the above, describe the financial interest and any steps planned to prevent the financial interest from interfering with the design, conduct or reporting of the research, including interfering with the protection of participants.

None of the individuals involved in the design, conduct or reporting of this research protocol have a financial interest that requires reporting.

Yes, one or more of the individuals involved in the design, conduct or reporting of this research protocol must report a financial interest.

Name of individual: \_\_\_\_\_ Position with Company \_\_\_\_\_  
 Name of individual: \_\_\_\_\_ Position with Company \_\_\_\_\_  
 Name of individual: \_\_\_\_\_ Position with Company \_\_\_\_\_  
 Please explain: \_\_\_\_\_  
 \_\_\_\_\_

**13. Research Population - approximate demographic population for your community**

Gender:	Origin:
_____ %: Male	_____ %: Caucasian      _____ %: African Descent      _____ %: Asian
_____ %: Female	_____ %: Middle Eastern      _____ %: Pacific Islander      _____ %: Hispanic
Age:	_____ %: Native American      _____ %: Other
_____ %: 0-17	
_____ %: 18 – 64	
_____ %: 65+ yrs.	

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14. Subject Recruitment	
a. How many subjects do you plan to enroll in this study? _____	
b. Indicate all recruitment methods used for this study:	
<input type="checkbox"/> Advertisements*	<input type="checkbox"/> Private Practice <input type="checkbox"/> Referrals <input type="checkbox"/> Previous/Extension Study
<input type="checkbox"/> Chart/Database Review <input type="checkbox"/> Screening Script* <input type="checkbox"/> Internet* <input type="checkbox"/> Other: _____	
*Please submit with the Advertisement Submission Form for review and approval prior to use.	
Please note the number of material submitted at this time by your site for review: _____ <input type="checkbox"/> NA	
c. Will your site recruit <b>vulnerable subjects</b> to participate in this study? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please check all that apply and answer the questions following your selection:	
<input type="checkbox"/> Children	<input type="checkbox"/> Cognitively Impaired <input type="checkbox"/> Impoverished or Unemployed <input type="checkbox"/> Prisoners
<input type="checkbox"/> Illiterate	<input type="checkbox"/> Pregnant Women <input type="checkbox"/> Non-English Speaking <input type="checkbox"/> Students
<input type="checkbox"/> Inpatient	<input type="checkbox"/> Nursing Home Patients <input type="checkbox"/> Hearing or Visually Impaired
<input type="checkbox"/> Wards of the State	<input type="checkbox"/> Other: _____
d. Harrison IRB requires an overview of your site's process for ensuring additional measures are taken at your site when recruiting vulnerable subjects. You may attach your site's SOP or instructions <b>OR</b> provide the details in the space below.	
<input type="checkbox"/> Attached is a copy of your site's SOP or written instructions for ensuring additional protections are taken when enrolling vulnerable subjects.	
<input type="checkbox"/> Overview of sites additional protections for vulnerable subjects: _____	
_____	
_____	

15. Current Studies and PI's Research Experience	
a. Number of years the PI has been conducting clinical research	_____ years <input type="checkbox"/> new to research
b. Number of studies currently supervised by the PI	_____
c. Number of research personnel currently supervised by the PI	_____
d. Number of research sites currently supervised by the PI	_____
e. Number (approximate) of subjects currently supervised by the PI	_____
f. Number (average) of studies per coordinator at a given time	_____
g. Please list any training you have received applicable to conduct this research:	
<input type="checkbox"/> Industry-based Training	<input type="checkbox"/> CITI Research Training <input type="checkbox"/> Sponsor Protocol Training
<input type="checkbox"/> Other:	_____

16. Previous IRB Review for this Study	
a. To the best of your knowledge, has this study been submitted to another IRB? <input type="checkbox"/> No <input type="checkbox"/> Yes	
If yes, please describe the outcome below: _____	

17. FDA Audit Documentation	
<b>If any of the questions below are answered "Yes", please provide supporting documentation.</b>	
a. Are there any pending or on-going legal, regulatory or professional actions or restrictions related to the practice of medicine or research at the site?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b. Has the site been audited by the FDA in the last 5 years?	<input type="checkbox"/> Yes <input type="checkbox"/> No
c. Has the Principal Investigator been audited by the FDA in the last 5 years?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d. Has the Principal Investigator ever had his/her license revoked or suspended?	<input type="checkbox"/> Yes <input type="checkbox"/> No
e. Has the Principal Investigator had any other professional sanctions?	<input type="checkbox"/> Yes <input type="checkbox"/> No

PI: \_\_\_\_\_ Protocol Number: \_\_\_\_\_

As Principal Investigator, it is my responsibility to:

- Comply with all federal, state and local regulations regarding the conduct of research;
- Comply with the requirements for reporting by Harrison IRB;
- Conduct the research of this study as outlined in the approved study plan and notify Harrison IRB of any changes in the research prior to implementing these changes, except where necessary to eliminate apparent, immediate harm to human subjects;
- Supervise all testing of the investigation product and/or device involving human subjects; and
- Ensure prompt reporting of all serious adverse events and protocol deviations as required by Harrison IRB; and,
- Obtain informed consent from subjects prior to performing any study procedures for the research.

PI Name: \_\_\_\_\_

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Attachments

Please verify that you have all required attachments to this form, as applicable, before submitting for IRB review. Bolded items are required by Harrison IRB.

- Site Submission Form signed by the Principal Investigator**
- FDA Form 1572**
- Principal Investigator's CV, including research experience**
- Copy of Principal Investigator's Medical License**
- Additional Site Form, if performing study-related activities at another site
- Harrison IRB Waiver of Jurisdiction Form
- SOP or Written Instructions for Consent and/or Assent process, if applicable
- Additional information attached regarding you state's laws regarding research, if applicable
- Site-specific recruitment materials with authorization from the Sponsor
- Additional information describing additional measures to protect vulnerable populations, if applicable
- FDA Audit Information
- Other documentation: \_\_\_\_\_

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Harrison IRB will accept your submission by fax or overnight delivery to the following location:

Harrison IRB  
16B South Main Street  
London, Ohio 43140  
Phone: 740 845 0814  
Fax: 740 421 4014