



Site Submission Form Completion Guidelines

These guidelines have been prepared to assist you with the completion of Harrison IRB's Site Submission Form. Please answer all of the questions in the Site Submission Form to minimize any delay in processing your site's submission. Harrison IRB has also provided these guidelines on its website under the "Sites" tab. If you have any additional questions regarding the completion of the Site Submission Form, please do not hesitate to contact Harrison IRB at (740) 845-0814.

1. Principal Investigator Information

Please provide the contact information for the Principal Investigator and site as you would like for the information to appear on all IRB-related documents.

- Principal Investigator Name is the name listed on the FDA Form 1572.
- Site Name is the site information listed on the FDA Form 1572.
- Primary Contact for IRB Communication is the person who will be receiving site correspondence such as approval documents, notices, etc. and would be available to answer any questions we may have regarding the Site Submission Form.

2. Site Activities/Information

- Please note all actions that will be taken at the site to ensure privacy and confidentiality of subject records and study data and activities that will be conducted at the primary site.

3. Additional Forms for Submission (if applicable)

- The additional site form must be completed if study activities will be conducted at other facilities. The site(s) must also be listed in Section 3 of the FDA Form 1572.
- The IRB Waiver of Jurisdiction only applies to those sites that have their own IRB (usually a hospital or university).

4. Emergency Precautions

- Please complete the information related to emergency measures taken at your site. You are only required to provide the name of the nearest

emergency facility. Additional contact information (address or phone) regarding the nearest facility is not required.

5. Research Staff

- Please list all research staff (also noted on the FDA Form 1572) and list their responsibilities.
- Research staff training is required if there are personnel listed on the FDA Form 1572 that will be assisting in the research study. Please confirm if training has been completed.

6. Informed Consent Form (ICF)

- Please provide site specific changes (other than site contact information and stipend) by noting the changes on the hard copy of the template informed consent form or by tracked changes to the Word document if it has been provided to your site. Sponsor approval for these changes must be provided at the time of submission.
- Please list the phone numbers that will be listed on the informed consent form for subjects to contact you during normal office hours and after hours in the case of an emergency.
 - You may note that the after hours number is the “same” as the office number, but if there is no number listed for the after hours number, we will be required to contact you to confirm that subjects will be able to reach someone during an emergency.

7. Informed Consent Process

- Please provide a **thorough** account of how you will recruit subjects (as provided as bullet points on the Site Submission Form), provide study information to the subjects, consent subjects and any ongoing activities at your site to ensure informed consent of subjects. Please note that you may provide your site’s standard operating procedure (SOP) or written instructions as an attachment to the Site Submission Form. For more information regarding informed consent please visit the FDA’s website: <http://www.fda.gov/oc/ohrt/irbs/informedconsent.html> or call Harrison IRB at (740) 845-0814 if you have any questions.
- All questions in this section must be completed thoroughly.

8. Translations

Harrison IRB will translate the template informed consent document at the Sponsor’s request. If the Sponsor authorizes the translation of study materials, the site will be provided with a document that is populated with the site’s specific contact information and stipend. Please note that if your site requires additional changes to the informed consent form and requests

translation of the consent, Harrison IRB must receive approval from the Sponsor prior to translating the document and sending it to your site.

9. Community Attitude

- For this section, please refer to the following question:
What is the response when you approach potential subjects to participate in research? This question is typically targeted to understand the community's attitude towards research for certain therapeutic areas that may be controversial or may have recently received negative or positive press attention

10. Compensation

- Stipend information will be incorporated into the Informed Consent Document for your site and must be as accurate as possible.
 - Dollar Amount Per Visit....: The amount per visit "times" the number of visits must equal the total amount paid. There are occasions when the site may not reimburse for a study visit (i.e., Screening Visit), so this must be documented. Please provide as much detail as possible to minimize IRB site queries.
 - Payment will be made: It is important that the sites complete this section as well because the information is listed on the ICF.

11. State Laws

- It is the responsibility of the Primary Investigator to know your state's laws as they pertain to clinical research. For example, the state of California requires additional documentation from sites participating in clinical research. Please visit the Harrison IRB website at www.harrisonirb.com for further information or call our office at (740) 845-0814.
- Harrison IRB has an affiliation agreement with the Department of Health in Massachusetts which allows us to review Massachusetts sites. We are also required to audit Massachusetts sites within 30 days of receiving their application if they have not been audited by the IRB within one year. Please note that this is not a "for cause" audit, but rather a state requirement.

12. Conflict of Interest

- Harrison IRB provides a link on its website to direct Investigators to the FDA website with guidelines for "Financial Disclosure by Clinical Investigators. This information is helpful if you have any questions regarding the "Conflict of Interest" section in our Site Submission Form.
 - Immediate family members is defined as spouse and each dependent child

- Financial and non-financial criteria may be reviewed by Harrison IRB to determine Conflict of Interest. Examples include:
- Financial interest in the research with value that cannot be readily determined
- A financial interest in the research with value that exceeds a specified monetary threshold
- Has received or will receive compensation with value that may be affected by the outcome of the study
- A proprietary interest in the research, such as a patent, trademark, copyright or licensing agreement
- Has received or will receive payments from sponsor that exceed a specified monetary threshold in a specified period of time
- Being an executive or director of the agency or company sponsoring the research
- A financial interest that requires disclosure to the sponsor or funding source
- Has any other financial interest that the investigator believes may interfere with his or her ability to protect participants.
- Changes to financial conflict of interest must be reported to Harrison IRB within 10 business days of the conflict by submitting the Site Information Change Request Form available on the website.

13. Research Population

- Provides information to Harrison IRB to understand the diversity of the demographic population for your community.

14. Subject Recruitment

- This section of the Site Submission Form allows you to provide additional information regarding the number of subjects you intend to recruit, as well as provide additional measures to ensure vulnerable populations are protected.
- At this time you may also submit recruitment materials for your review. Prior authorization from the Sponsor must be provided in writing before Harrison IRB will approve the advertisements and/or additional study materials. For FDA information regarding the subject recruitment, please visit Harrison IRB's website at www.harrisonirb.com.

15. Current Studies and PI's Research Experience

- We use this information in conjunction with "Research Staff Training" to determine the experience of the site.

16. Previous IRB Review for this Study

- The FDA requires that Investigator and/or Sponsors disclose prior review of research by another IRB. For more information, please visit the Harrison IRB website at www.harrisonirb.com.

17. FDA Audit Documentation

- Please complete this section and provide additional documentation of past FDA audits that were conducted at your site in the last 5 years.

Signature and Attachments

- The PI must sign and date the Site Submission Form to validate the application.
- Attachments: This is a beneficial checklist for the site to ensure you have submitted all of the documents to complete the IRB application.

Thank you for submitting your application to Harrison IRB! We look forward to working with you!