

**INFORMATION SHEET FOR REGISTERING INVESTIGATOR-INITIATED
CLINICAL TRIALS AND REPORTING RESULTS ON
WWW.CLINICALTRIALS.GOV**

For new and ongoing investigator-initiated clinical trials as of January 25, 2008 that prospectively assign subjects to one or more health-related interventions to evaluate the effects on health outcomes, the Principal Investigator (PI) responsible for initiating, conducting and coordinating the overall study is responsible for registration.

An “ongoing” trial has enrolled one or more subjects and the final subject has not been examined or received an intervention for the purpose of collecting data on the primary outcome. “Health-related” interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcome include any biomedical or health-related measures obtained in subjects, including pharmacokinetic measures and adverse events.

Who should register an applicable investigator-initiated clinical trial?

The Principal Investigator (PI) of the applicable clinical trial has the responsibility of determining whether or not a trial should be registered and completing and maintaining the information on the registration site. The PI is responsible for ensuring that the trial is registered, information is complete, accurate and updated. This includes reviewing the listing and making necessary changes at least annually or more frequently if changes occur including enrollment status. In addition, “basic results” must be reported within 1 year of the study completion (defined as data collection for the pre-specified primary outcome).

Penalties for Failure to Register

There are penalties for responsible parties who fail to register applicable clinical trials or who submit false or misleading information. Civil monetary penalties are allowed under FDA regulations. Civil penalties for investigator sponsors can range up to \$10,000/day (FDAAA Law). For federally-funded trials, the penalties could include withholding or recovery of grant funds.

Timing of Registration at ClinicalTrials.Gov

For new clinical trials submission requirements are triggered by enrollment. The PI or sponsor must submit required information **no later than 21 days** after the first participant is enrolled.

For ongoing clinical trials already registered, new information must be posted. A trial that was enrolling subjects as of September 27, 2007 (even one which does not involve a “serious or life-threatening disease or condition”) must be registered and updated at least annually.

What are the requirements for updating clinical trial registrations?

- Unless there have been no changes, registration information must be updated no less than once every 12 months.
- If recruitment status changes, the registration must be updated within 30 days.
- If the trial is complete (whether concluded or terminated prior to conclusion), registration must be updated within 30 days.

Requirements for posting basic study results:

The PI of the applicable investigator-initiated clinical trial is responsible for posting basic study results at the conclusion of the study. The following items must be posted on the site:

- **DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PATIENT SAMPLE** – A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients

who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

- PRIMARY AND SECONDARY OUTCOMES – The primary and secondary outcome measures, as stated in FDAAA Section 801, and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.
- POINT OF CONTACT – A point of contact for scientific information about the clinical trial results.

Detailed instructions for submission of “Basic Results” may be obtained on the clinicaltrials.gov Protocol Registration System website at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

How do I register my study on Clinicaltrials.gov?

Go to the <http://clinicaltrials.gov/> website and click the link under “Investigator Instructions” then click on the link [PRIS Information Page](http://prsinfo.clinicaltrials.gov/) that takes you to <http://prsinfo.clinicaltrials.gov/>.

1. Under Account Application Process, follow the instructions for “Individual Accounts.” Main Line Health does not have an organization account. The Study PI is the responsible official for initial registration and for keeping the listing updated.
2. On the page titled “Getting a PRS Individual Account”, answer the questions listed. **NOTE: Question 6** asks whether your organization already is registered with the PRS. The answer to this question is “No” – and we do not have a PRS administrator. Proceed to apply for an individual account.
3. On the page titled “Individual Account Information” enter the requested information. When entering information, use the information in the table below in specified fields:

| For MLH Employees | | For Non-MLH Employees | |
|---|---|---|---|
| Field Name | Response | Field Name | Response |
| Organization Name | Enter PI’s name. DO NOT ENTER MAIN LINE HEALTH The sponsoring organization is the entity with primary responsibility for initiating and conducting the trial(s) to be registered. As the PI of an investigator-initiated study, the PI is the sponsoring organization. | Organization Name | Enter PI’s name or employer/practice name. DO NOT ENTER MAIN LINE HEALTH The sponsoring organization is the entity with primary responsibility for initiating and conducting the trial(s) to be registered. As the PI of an investigator-initiated study, the PI is the sponsoring organization. |
| Organization Address | Enter PI address | Organization Address | Enter PI address |
| Organization Abbreviations and Acronyms | Leave Blank or enter applicable PI/practice acronyms. DO NOT ENTER MAIN LINE HEALTH or MLH | Organization Abbreviations and Acronyms | Enter applicable PI, employer/practice acronyms. DO NOT ENTER MAIN LINE HEALTH or MLH |
| Official Representative | Enter PI name | Official Representative | Enter PI name |
| Affiliation | Enter “MAIN LINE HEALTH” | Affiliation | Enter applicable affiliations. May include “MAIN LINE HEALTH” |
| Regulatory Authority | <i>For studies involving FDA-regulated product: enter: “FDA”</i> <i>For studies with no FDA regulated products enter: “Main Line Hospitals IRB”</i> | Regulatory Authority | <i>For studies involving FDA-regulated products enter: “FDA”</i> <i>For studies with no FDA regulated products enter: “Main Line Hospitals IRB”</i> |
| Regulatory Authority Address | <i>For studies involving FDA-regulated products enter:</i> 10903 New Hampshire Avenue Silver Spring, MD 20993 <i>For studies with no FDA regulated products enter:</i> Main Line Hospitals IRB 100 Lancaster Avenue Wynnewood, PA 19096 | Regulatory Authority Address | <i>For studies involving FDA-regulated products enter:</i> 10903 New Hampshire Avenue Silver Spring, MD 20993 <i>For studies with no FDA regulated products enter:</i> Main Line Hospitals IRB 100 Lancaster Avenue Wynnewood, PA 19096 |

What do I need to know to register the trial and how long will it take?

It will take ~ 1 hour to register a trial and it is recommended to have the protocol and informed consent on hand. To complete the protocol template, begin from the “Main Menu” page, go to “Protocol Record” and select “Create.” You can copy and paste information from the protocol into the data fields. A list of all the variables to be completed can be found at <http://prsinfo.clinicaltrials.gov/definitions.html>. **DO NOT GUESS - You must look up the variables and provide the necessary information in the prescribed format.**

When creating the “Protocol Record” consider the following:

1. It is suggested that you enter your MLH IRB file number assigned by the IRB as your “unique protocol ID”
2. Enter “Main Line Hospitals IRB” as the IRB “board name”.
3. Enter “Anne Marie Hobson, 484-476-2692, hobsona@mlhs.org” as the IRB “board contact”.

DO NOT SUBMIT AN INCOMPLETE or INACCURATE RECORD – Fines can be levied if the record is not complete and accurate within the required timeframe.

Useful Links:

<http://prsinfo.clinicaltrials.gov/>

FAQs: <http://prsinfo.clinicaltrials.gov/faq.html>

How do I register my trial and report results?: <http://prsinfo.clinicaltrials.gov/registering.pdf>

Helpful Hints: <http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf>