

In This Issue

- Form FDA 1572
- Translation & Interpretation Services for Non-English speaking participants
- Education Update

Quick Links

- [University Hospitals](#)
- [Center For Clinical Research](#)
- [Office of Research Compliance](#)
- [UHCMC IRB](#)
- [UHCMC Grants and Contracts](#)
- [William T Dahms Clinical Research Unit](#)
- [Clinical Trial Listing](#)



Questions, Comments, Suggestion?

If you have questions, comments or suggestions about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Education Updates!

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Contact Us

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Form FDA 1572

The Form FDA 1572, also referred to as the [Statement of Investigator](#), is an agreement signed by the investigator to provide certain information to the sponsor and assure he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic conducted under 21 CFR Part 312 (Investigational New Drug Applications or IND regulations).

An investigator is fully responsible for fulfilling all of the obligations of the investigator as identified in the Federal Regulations. By signing the form, the investigator affirms he or she is qualified to conduct the study and represents the investigator's commitment to follow the FDA regulations. Investigators should complete the form accurately and be aware that making a willfully false statement to the sponsor or to the agency (FDA) is a criminal offense.

Who should be listed as a sub-investigator on the 1572?

An important section on the Form FDA 1572 is section number 6, which lists names of sub-investigators who will be assisting the investigator in conducting the research. The purpose of this section is to capture information about individuals who, as part of an investigative team, will be assisting the investigator and who are significantly involved in the design and conduct of the research (i.e., the research would not go forward without their contribution). These individuals should be listed on Form FDA 1572.

Example

If a research coordinator, nurse, resident, fellow, or other hospital staff are performing critical study functions and collecting and evaluating study data, these individuals should be included in this section of the 1572.

Additional guidance on the completion of the Statement of Investigator form (Form FDA 1572) is summarized in a recently published document: *Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions – Statement of Investigator (Form FDA 1572)* (<http://www.fda.gov/oc/gcp/draft.html>). The most recent version of the 1572 is available [here](#).

Obtaining translation and interpretation services for inclusion of non-English speaking subjects: Use of institutional approved vendors

Investigators who wish to enroll research subjects who do not speak English must comply with UHCMC IRB policy and Federal Regulations pertaining to human subject protections. These regulations include presentation of any study information to the research subject in the subject's native language.

There are many ways to obtain these services including through the use of outside vendors. If an outside vendor is used, please note that only UH-approved translation/interpretation services may be utilized. Some current service providers include [CyraCom International](#) and [Transperfect Translations](#). For information about additional approved vendors, or to request approval of a new service, please contact the UH Department of Purchasing. Any cost incurred from obtaining these services is the investigator's responsibility.

Education Update

August 11, 2009 | Noon | Lerner Tower 2060

Research Administrator's Forum: Accessing Clinical Services When Conducting Research
Presented by *Rich Buchta*, (Clinical Manager), from the ECG Department and *Claudia Kraly, BS, CNMT, RT(R)*, (Operations Manager), from Radiology.

[Click here to register for this or other education sessions offered.](#)