

In This Issue

- Documentation of the Informed Consent Process
- New UHC IRB Procedure: Advertisements to Receive an Approval Stamp
- Helpful Tip : When to File an Informed Consent Document in a Patient's Medical Records.

Quick Links

[UHHS](#)

[Center For Clinical Research](#)

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[UHC IRB](#)

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Documentation of the Informed Consent Process:

One of the criteria for the approval of research is that the Institutional Review Board of University Hospitals of Cleveland (UHC IRB) must determine that informed consent will be documented in writing unless the documentation can be waived in accordance with the Federal regulations (DHHS [45 CFR 46.117](#)) and FDA ([21 CFR 50.27](#))). The UHC IRB requires a written consent document, containing the required elements under [45 CFR 46.116](#) and [21 CFR 50.25](#), as part of the informed consent process.

Participants are required to sign and print their name, and to date the consent form, unless the IRB has approved a waiver or alteration of informed consent, or a waiver of the documentation of informed consent (see UHC IRB Policy [Informed Consent](#)).

The person obtaining informed consent must be certified in human subjects protections at UHC and Case, be listed with the IRB in the current approved protocol, and sign and date the consent form.

In addition, the Principal Investigator (PI) must confirm subject eligibility and verify that consent was obtained appropriately by signing and dating the informed consent document within 30 days. A co-investigator can only confirm subject eligibility, and consent verification, if this process has been described in the protocol and approved by the UHC IRB.

Corrective action plan:

If a co-investigator has signed a consent form in place of the PI, and the approved informed consent process in the protocol does not allow for such, the PI must resign and date the consent form. In addition, the incident must be documented in the regulatory binder and participant research file, with a clear indication that the minor protocol deviation has been corrected.

New UHC IRB Procedure: Advertisements to Receive an Approval Stamp

Advertising materials are part of the recruitment process and must be approved by the UHC IRB. UHC IRB approval is required for all television, radio, videotape or print advertisements, posters, flyers, handouts, e-mail solicitations, Internet websites, and other recruitment methods and materials intended for the recruitment of prospective research participants to a research protocol. Those communications which, are intended to be seen or heard by health professionals only, such as letters to physicians, do not require IRB approval.

Effective July 31, 2006, **all approved advertisements will have an official IRB stamp**, indicating the specified protocol for which it has been approved and the effective date. Previously approved advertisements can be re-submitted for stamping at the time of continuing review or be included with a subsequent amendment. If you have any questions, please do not hesitate to contact UHC IRB office staff or the UHC Office of Research Compliance staff.

Helpful Tip: When to File an Informed Consent Document in a Patient's Medical Records.

A copy of the consent form (signed and dated) must be filed in the patient's medical record for all treatment or intervention studies. Documentation of the informed consent process should be also recorded in the medical record (see UHC IRB Policies [Informed Consent](#) and [Protocol Submission Requirements](#)).