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## Questions, Comments, Suggestion?

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

## Contact Us

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216.844.5576  
**E-mail us!**

## Informed Consent Documentation Initiative: Compliance

Informed Consent **documentation** in addition to documentation of the **process** of informed consent are critical steps in ensuring the protection of human research participants. The Center for Clinical Research and Technology and the UH Department of Compliance and Ethics have developed a new initiative to improve compliance with informed consent documentation requirements. The Informed Consent Documentation Initiative (ICDI) will be launched throughout the UHCMC research community in June.

The ICDI involves the use of a Consent Documentation template that will assist researchers in their compliance with the numerous requirements including the UHCMC IRB Policy, DHHS, FDA and JCAHO. The Consent Documentation template, developed by the Center for Clinical Research and Technology, will be distributed to all departments conducting research at UHCMC for use in the research record. The template is designed to ensure compliance with the regulations regarding the documentation of the consent process (i.e. narrative of the process) and that copies of the informed consent document are maintained in appropriate locations such as the research records and UH medical records. ([IRB Policy](#), [Informed Consent](#))

ICDI training sessions will be scheduled in May 2008 to introduce the template to research staff as well as understand effective use of the template. Beginning in June 2008, UHCMC research staff will begin implementation of ICDI template. The Office of Research Compliance will organize a systematic process for researchers to summarize compliance with the template and periodic reports to be submitted to the Office of Research Compliance.

## Signature Blocks on Consent and Assent Documents

All signature blocks on informed consent documents and assent documents should be updated if you are enrolling patients. Please reference the [Consent Language](#) template for the appropriate signature blocks. These changes should be submitted to the IRB for review and approval. They can be submitted as an Amendment prior to continuing review or at Continuing Review. If there are any questions regarding the signature block, please contact the IRB Administration Office at 216.844.1529 or the Office of Research Compliance at 216-844-5524.

## Helpful Note: Version Dates on Consent and Assent Documents

Please ensure that all consent and assent documents contain a study specific version date. This version date must be located in the bottom left corner of the informed consent and assent documents. This date must be changed every time revisions are made to the text of the document to differentiate the text from previously approved versions. The intention of this requirement is help researchers ensure that valid documents are being used.

## IRB Website Updates

Several of the IRB's policies and forms have been updated. Please be sure to review the IRB website periodically to ensure you are complying with current requirements and using the most recent versions of the forms and templates. Submissions that do not meet these requirements may be returned and review times will be delayed.