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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

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## Informed Consent Language Template

The University Hospitals Case Medical Center (UHCMC) Standard Research Consent Language Template was revised recently in accordance with changes to the Informed Consent policies (See [Informed Consent policy](#), [Decisional Impairment policy](#) and [Assent policy](#)). The revised guidelines address current requirements of Federal and State regulations; clarify the individuals who may act as a legally authorized representative (LAR); and documentation of LAR. In addition, the modifications specific to the template include the following sections:

- Signature blocks for adults and children
- Disclosure of Study Records
- Contact Information

The signature block for adults was revised to address consent from a legally authorized representative (including approved next of kin). **Inclusion of the LAR signature portion is only for studies that intend to enroll subjects who do not have the capacity to provide informed consent** (this must be consistent with the research protocol and inclusion must be approved by the IRB).

The signature blocks for children includes two selections: one pertains to permission from both parents, unless the other parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child; and the other pertains to obtaining permission from one parent when approved by the IRB. (See [IRB Templates, Consent Language; Consent Language and Tutorial; Consent Language for International Studies](#)).

The above referenced revisions must be incorporated into the consent and/or assent document either prior to Continuing Review or at the time of Continuing Review for all studies open to enrollment. In order to prevent the delay of approvals, please be certain to comply with the UHCMC IRB requirements by using the current version of the Consent Language Template.

## Office of Research Compliance and Education Introduces Responsible Conduct of Research Education Seminars and Workshops

The Center for Clinical Research has introduced a series of education seminars and workshops to the UHCMC research community as part of our commitment to promote research integrity. The sessions, available to all researchers and their staff, focus on a variety of topics including the IRB, Adverse Event Reporting, Grants & Contracts, and UHCMC Human Research Protection Program (HRPP) policy updates. Registration for the sessions is available [online](#) and the majority of the sessions offer Continuing Research Education Credits (CRECs). The Office of Research Compliance and Education has developed this program based on input from the research community and the types of observations made during the monitoring visits conducted by the Compliance team.

We appreciate the enthusiastic response from the research community during the launch of the education seminars and encourage all research staff to attend as many of the sessions as possible. Your suggestions and recommendations for future topics are welcome. In the future, we hope to offer future education sessions that can be individualized for your department or research team. If you are interested in offering an education programs in your department, please contact Carol Fedor, ND, CCRC, Clinical Research Manager, at (216) 844-5524 or [carol.fedor@uhhospitals.org](mailto:carol.fedor@uhhospitals.org)