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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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## E-mail us!

## Update to UHCMC IRB policies, forms and templates: Assent

A number of UHCMC IRB Policies and Procedures and submission documents have been revised as part of the ongoing quality improvement of the UHCMC Human Research Protection Program. The following is a summary of changes that have occurred relative to the UHCMC IRB Policy [Assent from Children in Research Studies](#):

- **Definitions were revised;**
- **Revisions were made to clarify parental permission procedures for research involving children; and consent of minors in research;**
- **Revisions were made to clarify that the Federal regulations require the permission of the parents (i.e., both) unless the IRB determines that one parent is appropriate; and**
- **Minor revisions were made to clarify the IRB requirements for research involving children under 45 CFR 46.407 (Subpart D); Assent requirements; Waiver of Assent; Alteration/Waiver of parental permission; and special considerations for the inclusion of Emancipated minors.**

In addition to the revisions made to the Policy, the **signature blocks** in the [Consent Form Template](#) have also been revised to address the 3<sup>rd</sup> item listed above.

Please ensure that all submissions use the most recent version of all submission forms (e.g., protocol submission forms, consent templates, HIPAA Authorization language, etc.) if the protocol involves obtaining parental permission and assent from minors. All forms/checklists and templates are available on-line ([Forms & Templates](#)).

An **education session** regarding Assent, inclusion of children in research and obtaining parental permission will be held **Wednesday, December 5, 2007 from 10-11:00 AM** in the Center for Clinical Research, Lakeside 1400. A total of three (3) Continuing Research Education Credits (CRECs) will be awarded. Please register at: <http://ora.ra.cwru.edu/research/orc/education/onlinecalendar.cfm>

## Inclusion of Children in Research

Inclusion of children in research requires additional ethical and regulatory considerations as they are considered a "vulnerable population" according to the Office of Human Research Protections (OHRP) regulations. When children are involved in research, Federal regulations require the permission of the parent(s) or guardian before a child can be enrolled in research. Regulations also require that assent be obtained from the child unless the requirement is waived by the IRB or is not required under applicable regulations.

Assent must be considered seriously by all researchers who include children as subjects of research. Per UHCMC IRB policy, an investigator who wishes to include children as participants must propose an **assent plan** in the research protocol. If the investigator believes that assent is not appropriate for the child population being studied, appropriate justification must also be provided in the protocol. **Requests for waivers of assent** must be specifically requested and subsequently approved by the IRB. Investigators must also describe the additional safeguards in place to protect the rights and welfare of the children.

The child should be given an explanation (written or verbal) of the proposed research procedures in a vocabulary and language that is appropriate to the child's age, experience, maturity, and medical condition. This explanation should include a discussion of any discomforts and inconveniences the child may experience if he or she agrees to participate in the study. If a child is asked for assent and refuses, the child's parent(s) or guardian may not override the child's decision.

The UHCMC IRB Policy [Assent from Children in Research Studies](#) requires that investigators document assent by using the [current IRB approved and stamped assent form](#) in order to obtain valid written assent as with obtaining informed consent.