

## In This Issue

- New Guidelines: Enrollment of Subjects with Decisional Impairment
- Formatting Documents

## Quick Links

[University Hospitals Center For Clinical Research](#)  
[Office of Research Compliance](#)  
[UHCMC IRB](#)  
[UHCMC Grants and Contracts](#)



## 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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## New Guidelines: Enrollment of Subjects with Decisional Impairment in Research

The IRB of University Hospitals Case Medical Center (UHCMC) has implemented revised guidelines for informed consent with subjects whose decision-making capacity is impaired. The new guidelines address current requirements of Federal and State regulations and applicable laws as well as UHCMC Clinical policies for persons with decisional impairment that clarify the individuals who may act as a legally authorized representative.

The following overview provides a summary of the changes and references the relevant UHCMC IRB Policies that are impacted:

- The UHCMC IRB has clarified the term Legally Authorized Representative (LAR) to be an individual, judicial or other entity authorized under applicable law to consent (provide permission) on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- Documentation of the status of the LAR appointment is required in both in the subject's medical record and research file. An explanation must be included in the IRB protocol regarding the LAR consent process.
- The signature block on the consent form template and tutorial has been revised to accommodate the signature of a LAR, including when a **next of kin** is used.
- Specific criteria need to be met in order for a waiver of informed consent to be approved by the IRB.
- The use of a surrogate must not be used as an alternative to informed consent.

Under this new approach, a LAR may now include:

- a person properly appointed by an advanced directive (such as a living will or declaration); or
- a durable power of attorney for health care/ certain court appointed guardians; or
- a **next of kin** when **neither** of the above exist; and **only** under certain limited circumstances approved by the IRB, (see IRB policy [Decisionally Impaired Research Subjects](#))

In all circumstances, the investigator is responsible for determining a person's status as a LAR. In doing so, the validity and scope of the LAR must be carefully evaluated to determine whether the LAR has been granted the authority to make decisions regarding procedures involved in the research.

One education session regarding the enrollment of subjects with decisional impairment in research was held on September 5, 2007 from 10-11:00 AM, and a second education session will be held on September 17, 2007 from 12-1:00 PM in the Center for Clinical Research, Lakeside 1400. Please **register at:**

<http://ora.ra.cwru.edu/research/orc/education/onlinecalendar.cfm>

## Formatting Informed Consent, Assent and HIPAA documents

One of the common findings observed during the monitoring process is a lack of sufficient space at the bottom margin of the consent and assent forms, and HIPAA authorization document for the IRB and Research Privacy Board (RPB) approval stamps. Therefore, by not providing sufficient space, the IRB Administrative Office must to place the approval stamp in other areas on the document, such as the left hand margin or squeezed at the bottom of the document. When this occurs, the research teams are subsequently not ensuring that the stamp is entirely present on photocopied versions or are removing the approval date when hole-punching the document. Therefore, in order assist the research community to ensure that the stamp is present and complete, the IRB Administration Office will permit the consent and assent templates to be altered such that the area in the top right hand corners of the documents can be designated as the IRB approval stamp area. Please contact the IRB Administration Office with any questions (216-844-1529.)

In addition to issues with the placement of the IRB/RPB approval stamps, version dates are often missing. Please be advised that the current consent and assent templates have an IRB version date at the bottom left hand corners of the forms. The protocol specific version date should be placed above or below the IRB version date.