

**Human Research Protections Program
Medical College of Wisconsin and Froedtert Memorial Lutheran Hospital**



September 20, 2012

To Whom It May Concern:

Re: Enrollment of Subjects during "delay gaps" of available approval documents

The IRB recognizes that since "approval dates" and "effective dates" for continuing reviews are defined in FDA guidance (*Guidance for IRBs, Clinical Investigators, and Sponsors -- IRB Continuing Review after Clinical Investigation Approval* (February 2012)), and since it will often take the IRB office a few days to make a newly effective consent document available to the investigator via eBridge, there will sometimes be brief delay gaps (no more than two or three days) between approval "effective date" and the availability of a new consent document to an investigator.

The IRB recognizes too that occasionally an investigator may find it necessary to enroll a new subject during this "delay gap," rather than waiting a few more days to use the newly effective consent documents.

For these reasons, the IRB will allow an investigator to use the most recent approved consent document version (instead of a newly effective consent document that is not yet available), as long as the expiration date for the most recently approved version has not been reached.

To use the most recently approved version instead of the newly effective version, the investigator must satisfy the following three criteria:

- The investigator must document (in study files) why it was necessary to enroll the subject during the delay gap, rather than waiting a few more days;
- The expiration date associated with the most recent approved consent document version must not have been reached; and
- If there are any content changes between the most recent approved and the newly effective consent document (even a single word), the investigator must solicit the subject's informed consent and documents that using the newly effective consent document at the first available opportunity.

If an investigator feels the need to enroll a new subject during the delay gap between "effective date" and the availability of a new consent document, but the expiration date for the most

recent approved consent document has been reached, then the investigator has no choice but to wait for the newly effective consent document to be available.

Sincerely,

A handwritten signature in black ink, appearing to read 'David Clark', written in a cursive style.

David Clark, PhD

Director, Human Research Protections Program,

Medical College of Wisconsin and Froedtert Memorial Lutheran Hospital

How should the investigator enroll a new subject during the time gap between the IRB's approval date of the Continuing Progress Report and actual receipt of the corresponding new, stamped consent document?

FDA Guidance (*Guidance for IRBs, Clinical Investigators, and Sponsors -- IRB Continuing Review after Clinical Investigation Approval* (February 2012)) discusses this issue at length.

In this guidance, the FDA defines the IRB "approval date" for a Continuing Progress Report means, and explains why the "approval date" must often predate the availability of a new consent form by days or weeks.

In this guidance, the FDA defined the IRB "effective date" for a Continuing Progress Report means, and explains why there is often a gap of days or weeks between the approval and effective dates.

There will always be a short delay between the "effective date" and when the new consent form is available to the investigator – because "effective date" is defined by IRB review actions, and there are steps that IRB office staff must take to make any new consent document available to the investigator.

Therefore, investigators must be prepared for brief delay gaps between the "effective date" and the availability of a new consent document – of two to three days.

- If an investigator feels the need to enroll a new subject during the delay gap between "effective date" and the availability of a new consent document, s/he should use the most recent approved consent document version, as long as the expiration date for that version has not been reached. A new MCW IRB policy (draft attached) permits this option as long as these three criteria are satisfied:
 - The investigator documents why it was necessary to enroll the subject during the delay gap, rather than waiting a few more days;
 - The expiration date associated with the most recent approved consent document version has not been reached; and
 - If there are any content changes between the most recent approved and the newly effective consent document (even a single word), the investigator once again solicits the subject's informed consent and documents that using the newly effective consent document at the first opportunity.

- If an investigator feels the need to enroll a new subject during the delay gap between "effective date" and the availability of a new consent document, but the expiration date for the most recent approved consent document has been reached, then the investigator has no choice but to wait for the newly effective consent document to be available.