

# UDC Updates

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Newsletter for the Universal Data Collection Project

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## NOTE:

To avoid unexpected delays, please install and test your CDC ID software before your HTC initiates UDC.

With the initiation of UDC, CDC has received many questions about the details of the project. To address commonly asked questions, the Hematologic Diseases Branch of CDC will publish a periodic newsletter to disseminate information regarding UDC to all centers. If your center has questions, problems, or suggestions regarding any aspect of UDC, please forward these issues to your regional coordinator. Your regional coordinator will help you work through any problems and will forward all suggestions or problems to CDC. Common problems will be addressed in this newsletter.

## Informed Consent

To safeguard patients' rights as participants in research studies, we would like to clarify several issues regarding the informed consent form.

### Is the consent form returned to CDC?

Signed consent forms are not returned to CDC. Instead, each HTC keeps the signed consent forms. A copy of the signed consent form should be given to each patient upon participation.

The patient's CDC ID number must be on the signed consent form. Be sure to make the patient aware that this is their participant identification number.

Therefore, a patient must sign a new consent form each year prior to participation.

This does not mean the participant has to sign a new consent form every time they have blood drawn or data collected for UDC. For example, if a participant has blood collected a second time to confirm unexpected test results, a new consent form does not need to be signed. A second consent form will be signed only if the patient participates in UDC the following year.

### Must the patient sign a consent form every year?

Participation in UDC one year does not obligate a patient to participate in successive years.

## CDC ID Software

The CDC ID software is designed to generate the same ID number when the same first and last names are entered. However, the software will not allow you to type in a number to give you that patient's name. Because the software is sensitive to spelling and name abbreviations and because various staff members may be generating CDC ID numbers for

patients, your HTC must keep a record with participants' exact names and CDC ID numbers.

CDC identifies patients only by their CDC ID number, so test results will be returned with the CDC ID numbers as identifiers. Your HTC must have a mechanism by which CDC ID numbers can be matched with patient names.

## More Corrections to the Procedures Manual

Those centers who have already received procedures manuals have also received a packet of pages with updates and corrections to the UDC HTC Procedures Manual. However, additional items need to be changed. Replacement pages for these will be included in your UDC supply kit, but you may wish to mark the changes in your manuals now:

p. 21, "Appendix H" should read "Appendix I"

p. 27, "Appendix J" should read "Appendix H"

pp. 63 & 67, references to the example of the FedEx airbill should send you to page 73

pp. 77 & 78, dated 1/19/98, "Serum Bank Holiday Schedule" and Hepatitis Lab Holiday should read "1998", not "1997."