

## **Would you ever need to re-consent a research participant?**

Informed consent is a process that involves dynamic and continuing exchange of information throughout the study. Regulations require that participants be informed when there is new information that might affect his/her willingness to continue participation. Many times, re-consent with a current or revised consent form is used to communicate new information to study participants or to ensure that consent remains legally valid.

### Re-consent Reasons

Re-consenting may be required for various reasons including but not limited to cases where:

- the study protocol/procedure has been modified;
- new safety information exists;
- new alternative treatment becomes available;
- a pediatric participant reaches adulthood (18 years old);
- original consent or process was not properly executed (e.g. participants were consented by individuals not listed on the study personnel list or not HSP trained or using invalid form);
- consent form template language is updated;
- potential for consent capacity to fluctuate;
- a substantial period of time has elapsed; or
- any other changes as required by the IRB or sponsoring agency.

### Re-consent Form and Process

The IRB reviews both the revised consent form and the proposed process. Use the IRB approved revised form for enrollment of future participants. Typically, all **active participants** must also be re-consented with the revised form (unless the investigator and IRB agree that the change does not impact current active participants).

### No Changes in Consent Form at time of Continuation Review

The consent form is among documents submitted to the IRB for Continuation Review which occurs within a specified time period following the initial approval (usually on a yearly basis). At the time of continuation review, if approved, the IRB stamps the informed consent for the given period of time again, usually 1 year. Once the continuation review is approved and the consent is stamped by the IRB, use the updated stamped consent form for enrollment of future study participants. However, unless there is an IRB directive specific to the protocol dictating otherwise, if **no** changes are made to the consent, **active participants** do not have to re-sign the updated consent form.

Some of the material in this guidance was adapted from Cornell Medical College Office of Clinical Trial Administration

University of Kentucky

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