Tips and Resources for Implementing Electronic Consent at UM

Accessibility Issues

Although this training discusses eConsent and options such as SignNow, REDCap and Zoom to assist with this process, there are some accessibility issues using SignNow (and other applications) for individuals with certain medical conditions or disabilities. Research teams in all specialties should consider all options available when creating/amending IRB applications regarding consenting participants.

Some participants may have trouble physically using the technology. For example, if participants will not have use of their upper extremities, and are expected to sign a consent document (or e-consent) this would not be possible using certain applications (e.g. SignNow). Other participants may have trouble with decisional capacity and require a legally authorized representative (LAR) who may or may not be in the same physical location as the participant. Therefore, it is important for study teams to work with the IRB to have alternative processes in place to allow for accessible informed consent.

Alternatives to the standard practice of consenting participants could include:
- Reading the IRB approved consent document or comprehensive consent script to the participants
- Study team members documenting the process took place with no signature from the participant
- Having a group call with the participant and LAR where both can view the informed consent document but sending the copy to be signed to the LAR

Introduction to Electronic Consent

- [Introduction to Electronic Consent online module](#)

- This online module was designed to be a general introduction to electronic informed consent (eConsent) available to study team members across the country. Because of this we want to provide additional information specific to UM.

- Some key messages from the module and how they apply at UM:

* eConsent uses new tools and technology but the conversational skills and purpose of the consent remain unchanged. If you would like to learn more about this topic you can sign up for the training [Conducting and Obtaining Valid Informed Consent](#).

* eConsent procedures and materials need to be IRB reviewed. In eResearch, you can get the latest approved versions of your informed consent document and any supplementary materials in the documents tab. Always make sure you check you are using the latest version before you start a consent conversation.

* eConsent is more than just getting the signature on the form. Make sure you are still assessing whether your participants understand what they are consenting to. There are a number of ways to do this depending on what is best for your study and participant population but using a video technology platform like Zoom may give you a chance to pick up on non-verbal cues as you could in-person.

* The recommended technology to get the informed consent signature at U-M is SignNow but REDCap is also an option especially if you are already utilizing REDCap as a tool in your study that team members are familiar with.

* Whatever technology you are going to use make sure you practice on it before you start a consent conversation and know not only how it works but how to troubleshoot if you or your potential participants have technical glitches.

Resources

IRBMED:

* In the guidance section, search for electronic systems for more information on eConsent.

* Includes U-MIC videos walking through Sign Now technology

* Even if IRBMED is not your IRB of record, they are still a valuable resource for learning more about eConsent.

MICHR Clinical Research Management Team

* Offers a free consultation through Study Management Mentoring service

* CRM can provide assistance with setting up eConsent using the following technology platforms:

        *SignNow

        *REDCap access and training