West Virginia University is committed to conducting research with the highest regard for the welfare of human subjects while upholding and adhering to the principles of The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research. The first principle presented in Belmont stresses that research participants are autonomous individuals, meaning that participants should be treated as independent people, capable of making a fully informed decision. Researchers are obligated to clearly inform participants about the research study and data being recorded although it lacks definite guidance on how this information should be presented.

Since electronic media are becoming more advanced and common in the research setting, this guidance is intended to help guide WVU investigators on how to integrate electronic informed consent processes into their research. For the purposes of this guidance, electronic informed consent refers to using electronic systems and processes that may employ multiple electronic media (i.e. text, graphics, audio and video, etc.) to convey information related to the study.

Consent Procedures in Protocol

The investigator is responsible for ensuring that informed consent is obtained prior to a participant completing study related procedures; this can be done either in person or electronically. If any or all the consent process takes place electronically and is not personally witnessed by study personnel, the electronic system must include a method to ensure that the person electronically signing the informed consent is the subject who will be participating in the research study or is the subject’s legally authorized representative (LAR).

Note: OHRP recognizes that it may not be possible or necessary for all types of research covered by 45 CFR part 46 to verify that the person signing the informed consent is the subject or the subject’s LAR who will be participating in the research study. OHRP encourages investigators to apply a risk-based approach to the consideration of subject identity. For example, social behavioral minimal risk research will not typically warrant such verification. In addition, informed consent may be waived for minimal risk research meeting the requirements at 45 CFR 46.116(d).

If using an electronic informed consent process, a clear description of the electronic media, confidentiality protections, and timing of the consent process should all be included in the IRB submission. The informed consent process should include all required and additional information, as applicable, per the Office for Human Subjects Protections (OHRP) or Food & Drug Administration (FDA) regulations for the conduct of human subject research. For more information and guidance on how to implement electronic consent processes into research, please consult the Use of Electronic Informed Consent: Questions and Answers.

Electronic Signature

The Revised Common Rule (2018) permits participant informed consent to be documented using electronic methods; however, subjects must be provided with a version of the consent from that they can retain. The copy provided to the research participant may be either physical or electronic (i.e. email).
The consent process, method of obtaining documentation of consent (electronic signature), and the method in which a copy of the agreed upon consent document is provided to the participant should all be clearly outlined in the approved IRB protocol.

**Note:** Communicating with research participants via email may be a convenient way to send consent and study related material for both the researcher and participant; however, there are risks involved, particularly when communicating health related information. Participants should be made aware of the risks involved and prospectively agree to communicate in this manner.

**Electronic Signature vs Waiver of Documentation**

Researchers should be aware of the difference between obtaining informed consent using electronic methods and requesting a waiver of the requirement to document informed consent. There are a few ways in which an electronic signature might be documented. Some examples include:

When a consent procedure will not include a physical or electronic signature, a waiver of the requirement to obtain written documentation of the consent process should be requested in the submitted IRB protocol. A Waiver of Documentation is normally requested whenever participants are asked to complete minimal risk online survey and they are asked to only select “yes or no” to continue with the survey or obtaining verbal consent using a telephone script.

**Note:** Obtaining HIPAA Authorization under a Waiver of Documentation is not permitted; either a physical signature or an electronic signature must be obtained.

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**Commented [J6]:** Should this procedure/policy dive into secure systems, etc? Such as secure programs for signatures? It seems HSC has a requirement for e-signatures ([https://its.hsc.wvu.edu/computer-support/adobe-sign-e-signature/](https://its.hsc.wvu.edu/computer-support/adobe-sign-e-signature/)). If so, I believe you should consult with Amanda Griffith at IT Security.

**Commented [J7]:** Should be discussed among the Chairs, legal, ITS to see what is available to be used and secure.