1 PURPOSE

1.1 To increase the efficiency of internal and external transactions that require authorization, the West Virginia University Office of Human Research Protections (WVU OHRP) may require that the WVU research community and research administration use electronic and digital signatures to conduct certain transactions that previously required handwritten or “wet” signatures and approvals on paper documents. This procedure establishes the scope by which WVU OHRP differentiates transactions for which digital and electronic signatures are required and recognized.

1.2 Digital Signature - Legally-binding digital signature delivered by a software solution that includes the following attributes: digital certificate, signing algorithm, identity-based confirmation, auditable attributes (name, date), validation of the certificate delivered by a digital signature solution.

1.3 Electronic Signature – A typed name or other representation of a signature not delivered by a digital signature solution with the capabilities listed above (i.e., cut\pasted signatures such as a cut\pasted signature or picture of a signature). For most internal authorizations, electronic signatures provide a suitable means of acknowledgment but cannot ensure that the individual is who they say they are. WVU and its affiliates provide policies regarding employee guidelines and associated discipline in the event of fraud, misrepresentation, or misuse of institutional resources.

1.4 The WVU+kc Protocol Management system is an acceptable form of electronic signature for Principal Investigators and other authorized staff who submit human subjects research-related forms and information to WVU OHRP for review and approval.

1.5 SCOPE:

- This procedure applies to the internal\external documents listed below and can apply to other internal and external documents as determined by institutional management or the IRB Chairs.

- This procedure does not apply to Consent and Assent forms used during the conduct of research requiring research participant or legal, authorized representative signatures. Refer to WVU Informed Consent policies for more information.
2 RESPONSIBILITY

2.1 WVU staff engaging in the oversight or conduct of human subjects research conducted under the auspices of WVU are responsible for ensuring appropriate authorization of documents according to regulatory and institutional policy.

2.2 WVU OHRP is responsible for ensuring that documents related to the human research protections program are authorized appropriately and according to regulatory and institutional policy.

2.3 WVU staff are required to report suspect or fraudulent activity related to document signatures immediately to the WVU OHRP Director.

3 PROCEDURES

To the fullest extent permitted by law, WVU OHRP accepts digital and electronic signatures as legally binding and equivalent to handwritten or "wet" signatures to signify an agreement or authorization when the procedures listed below are followed:

3.1 INTERNAL DOCUMENTS:

The electronic signature methodology applied to documents for internal authorization for online forms:

3.1.1 The following items are included in WVU OHRP internal online forms and are accepted as the document preparers signature:

- A checkbox with the associated text: By checking this box, I agree that I understand the contents of the document, and I am aware of the consequences of executing this document. I agree to the terms and conditions presented in this document.

- The typed name of the authorized employee with the date (If the software permits, a signature can be inserted in the place of the typed name).

- The following text will be included at the end of the document: Notice: WVU Office of Human Research Protections accepts this acknowledgment and the typed name of the individual as an authorized electronic signature under the WVU Human Research Protections SOP 046 –Digital and Electronic Signatures.
3.2 INTERNAL DOCUMENTS that do not permit a typed name in the signature box (paper forms), forms that must be routed for multiple approvals, and in situations where a written or “wet” signature cannot be obtained:

3.2.1 Complete the form, type your name, and the date in the signature box.
3.2.2 Email the attached form to IRB@mail.wvu.edu or the appropriate WVU OHRP staff member.
3.2.3 Include the following text in the email: “I authorize the contents of the attached form,” and type your name.

3.3 Internal documents within the scope of this procedure:

- IRB Meeting Confidentiality Form
- CITI Program Admin Confidentiality Form
- WVU OHRP Information Access Request Form

3.4 EXTERNAL DOCUMENTS:

3.4.1 A WVU OHRP approved digital signature solution will be used to obtain authorization for the external forms listed below and other documents as directed by institutional management or the IRB Chairs.

3.5 External documents within the scope of this procedure:

- Approval in Principle Letter
- IAA Non-WVU IRB of Record
- IAA WVU IRB of Record
- Collaborative Research Letter of Permission Form

3.6 It is a violation of this procedure for an individual to sign on behalf of another individual unless authority was explicitly granted by that individual and notice was sent to WVU OHRP via email from the individual granting permission.
4 REFERENCES

WVU Institutional Policy

WVU Human Research Protection Policy Letter (2.13.19)

Federal Law\Regulations

Electronic Signature in Global and National Commerce Act (ESIGN)

West Virginia Law

Uniform Electronic Transactions Act (UETA) State Law