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Subject: **UAB Policy on Electronic Informed Consent**

POLICY STATEMENT

It is UAB policy that Electronic Informed Consent (eIC) may be used as an option to satisfy the regulatory requirements for documenting informed Consent for non-exempt human subjects' research, provided that proper documentation, verification, and adherence to applicable regulations takes place. An investigator will seek informed consent in accordance with federal regulations at 45 CFR §46.116 and, if applicable, 21 CFR 50.20, §§50.25 and any applicable regulations of the sponsor (e.g. DOE GUI338, DoD GUI339, DOJ/NIJ and BOP GUI341). The IRB may grant a waiver of informed consent in accordance with §§46.116(c), 46.116(d) and, if applicable, 21 CFR §§50.23(d), 50.23(e), 50.24 and HHS waiver for emergency research at 61 FR 51531, or any applicable regulations of the sponsor. Also, an investigator will document informed consent in accordance with 45 CFR §46.117 and, if applicable, 21 CFR §50.27 or other applicable regulations of the sponsor unless the IRB waives documentation of informed consent in accordance with 45 CFR §46.117, and, if applicable, 21 CFR §56.109 (c), (d) or other regulations of the sponsor. The principal investigator is responsible for ensuring informed consent is obtained from each participant before study participation.

This policy applies to non-exempt human subjects' research conducted at UAB or by UAB-associated entities. In this document, "participant" refers to participants over the age of 18, their LAR, or the parent or legal guardian of a child.

Background:

Electronic Informed Consent (eIC) refers to the use of electronic systems and processes to obtain and document informed consent; these systems may employ multiple electronic media, including text messaging, email, graphics, audio, video, podcasts, passive and interactive websites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

Electronic signatures (eSignature) refer to the use of an eIC platform or process to document the informed consent.

<u>Method to send and receive the eIC</u>
The copy of the informed consent form provided to the participant can be paper or electronic (i.e., be provided on an electronic storage device, via email, etc.). If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained,

and information should be accessible until study completion (if a paper version is provided, it should contain the necessary content from any hyperlinks)

The investigator should submit to the IRB copies of all forms (electronic and paper forms) and informational materials, including links to any videos and Web-based presentations, which the participant will receive and view during the eIC process

The protocol must include a plan for providing copies of the consent to participants or justify why this is not possible. HHS and FDA regulations require that the person signing the informed consent be given a copy of the informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)) unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c).

Requirements for the eIC conversation & Identity Verification

The eIC process may take place on-site or remotely and may employ both traditional consent processes and eIC processes. For consent that will be obtained remotely, the investigator should address identify verification of participants and participants' ability to access the appropriate technology to complete the electronic consent process.

Unless appropriately waived, non-exempt research will require a consent interaction. The informed consent process involves a discussion, where an investigator reviews the consent form with the participant who is then given the opportunity to ask questions or get clarification as needed. When conducting the consent interaction electronically (phone or videoconference), verify the following:

- That the participant is in a private place and has enough time for the process
- The form the participant received is the currently approved version
- That all the pages of the consent were received
- That the participant can read all the pages of the consent.

Signature requirement

When conducting eIC, there are a number of ways in which an eSignature might be documented. Some examples include:

- Attaching a scanned handwritten signature or using an eSignature service such as AdobeSign or DocuSign;
- Typing one's name with an accompanying check box and statement noting an intent to affix a legal signature (e.g., "By checking this box and typing my name below, I am electronically signing this consent form"); or
- Signing with a stylus or finger in an electronic document.

The investigator cannot delegate his/her responsibility for obtaining informed consent from participants to the electronic system.

The presentation of the eIC and consenting process should include:

- An easy process for the participants to navigate.
- Allow the participant to move forward or backward within the consent and to stop and continue later.
- Providing participants with instructions to download or print a copy of the eIC.
- Informing participants of approximate time needed to complete the process and what information will be presented to them.
- Sufficient opportunity for the participant to consider whether to participate, which includes the opportunity to ask questions.
- When appropriate, an option for participants to use paper-based consent documents, if preferred.
- When appropriate, a description of whether research staff will be available to assist participants in the eIC technology.

The IRB should review:

- Any optional questions or methods used to gauge participant comprehension of key study elements.
- The usability of the eIC materials to ensure that they are easy to navigate.
- The contents of any hyperlinks used to convey study-related information.

<u>Other considerations</u>

The electronic consent form must contain the same information as the ICF approved by the UAB IRB, including document approval and version date in the final version the participants will see. A copy of the electronic consent form should be included with the submission, if available.

Regulated Under HIPAA (45 CFR 164):

Method to send and receive the eIC

UAB is a hybrid HIPAA covered entity with covered and non-covered components. An email in conjunction with any indication of treatment or diagnosis sent from a HIPAA-covered component (e.g., the School of Medicine) constitutes a disclosure of Protected Health Information, or PHI because email address is one of the 18 HIPAA identifiers. Sending a copy of the consent that contains information suggesting treatment or diagnosis, via email from a UAB clinical area or another covered component falls under the aegis of HIPAA.

To send a copy of the consent form that contains treatment or diagnosis information from a HIPAA covered component to a prospective research participant for review prior to consent, the email leaving UAB must be encrypted. UABMC email addresses can be encrypted; however, if participants respond, the response email is not automatically encrypted. Therefore, the email should contain instructions on how to contact the PI for questions and specifically caution against replying to the email without encrypting.

The UAB Medicine email system addresses end in uabmc.edu. The UAB Medicine email system is the only email system approved for PHI. Additionally, the UAB Medicine email system provides encryption capabilities for emails containing PHI or other restricted/sensitive information going to email accounts outside the uabmc.edu system, which includes emails to uab.edu email addresses. However, encryption is not automatic. If you must send an email with PHI outside the uabmc.edu email system, then you must encrypt the email by one of the following methods:

- Type “[encrypt]” anywhere in the subject line OR
- Select the “Send Securely--Encryption” button, above the regular “Send” button to send the email.

Investigators may contact the Information Technology/Enterprise Information Security's Risk Management & Compliance Team at DSO-RiskMgt@uab.edu to ensure the planned use of emails is appropriate.

Another option would be to post a copy of the consent form on a secure online location (e.g., secure website, REDCap, etc.) and email a link to the participant, ensuring that the email does not contain any indication of treatment or diagnosis in the subject line or body of the email. Emails sent from REDCap and AdobeSign are considered secure for HIPAA purposes.

Alternatively, for in-person consent, the consent may be presented to the participant, via a touch-screen-enabled device.

Requirements for the eIC conversation & Identity Verification

If the consent process occurs in-person, verification of the identity of the person is straight-forward. Verifying identity in other aspects of the eIC can be more challenging. When the consent interaction is conducted virtually, the person conducting the interaction must verify

the identity of the participant signing the consent. This may include verification of state-issued identification or another valid form of photo identification during a meeting on a videoconferencing platform

Those that plan to use videoconference to meet with participants, discuss PHI, or for any other reason requiring HIPAA compliance, must use a HIPAA-compliant platform. The IRB application must specifically state that the platform being used is a HIPAA-compliant version.

HIPAA-compliant platforms generally do NOT allow:

- Recording
- Private chat
- Chat logs
- File transfer
- Detailed Call/Meeting Reports

Signature requirement

A valid electronic signature for documentation of informed consent and HIPAA authorization could be the participant's typed name or it could even be as simple as a check mark or an X or any other symbol in a box on a form. Any method is valid, provided that the mark or symbol is "logically associated" with the individual making that mark. To associate the individual to the mark, the subject could type their name or even an assigned unique ID number.

REDCap, Qualtrics, AdobeSign, and DocuSign are all systems that are compatible with HIPAA regulations for documented informed consent and authorization. Other considerations

HIPAA regulations do not currently address eSignatures or electronic authorization.

Regulated Under FDA (21 CFR 50 and 56):

Method to send and receive the eIC

Although FDA regulations do not place restrictions on how informed consent forms are distributed, it is presumed that any FDA-regulated clinical investigation is also subject to HIPAA regulations. Distribution of informed consent forms for FDA-regulated clinical investigations should use the same precaution as outlined above for studies regulated under 45 CFR 164. Similarly, FDA regulations do not require that the participant's copy include a signature. The FDA recommends that a copy of the signed informed consent form that includes the date when the consent was signed be provided to the subject. However, the AdobeSign process provides access to a final version of the fully signed informed consent to all users on the route.

Requirements for the eIC conversation & Identity Verification

- Identity verification is a critical step for ensuring compliance with the FDA Part 11 requirements for electronic signatures. The eIC process for FDA regulated clinical investigations may use the same identify verification methods as outlined above for studies regulated under 45 CFR 164.

Signature requirement

For clinical investigations governed by FDA regulations, eIC must comply with the requirements of 21 CFR 11. Currently, the only Part 11 compliant, fully validated electronic platform supported by UAB is AdobeSign.

An alternative method of obtaining an eSignature for informed consent is by having participants 'sign' their consent electronically by typing their name and date and utilizing a 'Signature' field, which uses a stylus, mouse, or finger to "write" their signature on the form.

Other considerations

Prior to utilizing AdobeSign for FDA-regulated research, investigators must undergo Part 11-compliance training with UAB IT Business Services. This training includes how to ensure use of appropriate settings to ensure compliance. It also includes the options for identify verification of the participant, as required by 21 CFR 11. In order to initiate the Part-11 compliance training, users may submit a ticket to UAB IT Business Services.

If the study is conducted or supported by HHS and involves an FDA-regulated product, the study may be subject to all three regulations: the Common Rule, FDA, and HIPAA. Where the regulations differ, the regulations that offer the greater protection to human participants should be followed.

For further guidance on the use of eIC for FDA-regulated research, see the Use of Electronic Informed Consent Questions and Answers.

Non-FDA/non-HIPAA Regulated (45 CFR 46 Subpart A):

Method to send and receive the eIC

The use of email and text are acceptable methods of providing a review copy of the consent form for non-FDA/non-HIPAA regulated research. In these cases, the researcher must inform the participant of the inherent risks of sending sensitive data in this manner. This may be done verbally or in person, and the process must be described in the research application.

Requirements for the eIC conversation & Identity Verification

The informed consent interaction may take place on the phone, in person, or on a video-conferencing platform such as Skype or Zoom.

For non-FDA/non-HIPAA regulated research, the HHS regulations acknowledge that it may not always be possible to verify that the person signing the informed consent is the study subject and therefore encourages a risk-based approach to the consideration of subject identity. For example, for minimal risk research, if the consent form was mailed, emailed, or faxed directly to the individual, it may be sufficient verification if the signed informed consent form is sent back to the study team via the same method; however, if the research involves risks greater than that encountered in everyday life, a higher level of scrutiny may be required when verifying identity.

Signature requirement

Participants who were mailed or emailed a consent form or given a consent form in person to take home for review may use any of the above methods. In addition, participants may email or text a clear copy of the signature page of the current, IRB-approved ICF.

Other considerations

Non-exempt studies that are not regulated by HIPAA or FDA may still require a higher level of privacy and confidentiality measures due to sensitivity of data or applicability of other regulations (e.g., FERPA, GDPR).