Using DocuSign and Phone Consent for UCI IRB Approved Informed Consent Processes

During the declared national and statewide emergency in response to the COVID-19 pandemic, the UCI IRB is broadly allowing the use of DocuSign as well as phone consent with voice recording to document informed consent for:

1. **Critical Research**, as determined by the Dean or research unit director, involving human participants, and

2. **Non-critical human research** carried out from the homes of study team members.

About DocuSign – Use DocuSign for electronic consent when a subject has access to their own computer, tablet or smart phone. For security reasons, they subjects should not use public or shared devices for signing e-informed consents. For information about DocuSign, please visit: [https://docusign.uci.edu/](https://docusign.uci.edu/)

About Phone Consent and Audio Recordings – For those researchers where DocuSign may not be an option. If written consent is required, this process can occur over the phone, and should include an audio recording to document the consent process. Remember that all expectations of informed consent documentation still apply (45 CFR 46.117 and 21 CFR 50.27), in particular, please be sure to provide a copy of the consent to the subject to keep either by mail, email or fax. Please review and/or use this [sample script template](https://docusign.uci.edu/) when developing a script for your study.

Important Things to Remember – Please discuss the use of DocuSign (because UCI’s licensed version is not compliant with 21 CFR Part 11) or phone consent with your sponsor/s and (as applicable) the IRB of Record prior to implementing. Please do not submit a prospective modification to the IRB requesting DocuSign. Rather, make the change, log it in the study record and update the IRB protocol at the next necessary modification.

Whether using DocuSign, phone consent or written consent, Lead Researchers must ensure there is a system to verify the subject’s identity and facilitate the subject’s understanding of the information presented to them. To help ensure the highest quality of clinical data, please review this resource on how paper and electronic source data meet ALCOA elements. Consider using RedCap to store consent documents and electronic recordings.

Federal Regulations - Before getting started with any electronic consent process, researchers and their teams should review the joint FDA/OHRP guidance on using electronic consent in FDA-regulated research: [Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers](https://docusign.uci.edu/). In addition, please refer to the [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](https://docusign.uci.edu/).

HIPAA- For studies involving protected health information where the UCI IRB has required HIPAA research authorization be obtained, electronic consent may also be used. Refer to [Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency](https://docusign.uci.edu/) and [FAQs on telehealth remote communications](https://docusign.uci.edu/) for more information.