UCI Health

Compliance and Privacy Office

COVID-19: Supplemental guidance related to remote clinical research at UCI Health subject to Medicare, HIPAA, or FDA regulations (May 19, 2020)

This guidance document is effective immediately and remains subject to change as federal, state, and institutional regulations are updated in response to the COVID-19 public health emergency.

The UCI Health Research Compliance Program works to ensure that policies, procedures, programs and educational activities are developed to satisfy federal, state and institutional regulations governing the conduct of research.
This interim guidance provides UCI Health clinical research considerations during the declared national and statewide emergency in response to the COVID-19 pandemic. This guidance complements the continuing updates on the UCI Office of Research (OR) Research Continuity website, the UCI Health Telehealth Resource Center, and the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.

Remote Research Visits

The Principal Investigator, or designated Sub-Investigator, must make the determination if a remote visit is acceptable or if an in-person visit is necessary. The use of remote visits for research should be discussed with the sponsor and reviewing IRB, as applicable, prior to implementation.

The Office for Civil Rights (OCR) has provided a notice to allow covered health care providers to use popular applications that allow for video chats without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules related to the good faith provision of remote visits during the COVID-19 nationwide public health emergency.

Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks, and providers should enable all available encryption and privacy modes when using such applications.

Allowed applications:

- Zoom for Healthcare – highly preferred method
- Skype for Business / Microsoft Team – next preferred method
- Apple FaceTime, Facebook Messenger video chat, Google Hangouts video

Applications NOT ALLOWED:

- Public facing applications
  Facebook Live, Twitch, TikTok, etc.

Important considerations for remote research visits

- Documentation should capture *specific* information, such as the reason for any contingency measures implemented.
  - For example, “due to COVID-19” is not sufficient documentation for the implementation of such alternative processes. Rather, the specific limitation imposed by COVID-19 leading to the alternative process should be documented.
- The investigator, or designated study personnel, should be trained on how to conduct real-time remote visits.
- Procedures should be in place to maintain patient privacy, as would be done for a clinical visit.

- Both the investigator and the participant should confirm their respective identities with one another before engaging in real-time remote visits, in accordance with an identity verification plan developed by the sponsor.
- *Specific* documentation of the remote research visit should be completed, similar to how it would be done for in-person visits, including:
    - Date and time of the real-time remote visit
    - Location of the participant
    - Location of the investigator, or designated study personnel, conducting the remote visit
- The FDA does not consider these interactions as electronic records and are not subject to 21 CFR Part 11.

Remote Research Consent:

- A complete informed consent process must be conducted for participant enrollment, unless previously waived by the IRB. When accessing, creating, using or disclosing PHI a signed HIPAA authorization form is required.
- Allowances for remote consent should be discussed with the sponsor and the reviewing IRB, as applicable, prior to implementation.
- Obtaining research consent and HIPAA authorization are allowed through these acceptable remote methods, along with *specific* documentation of the consent process:
    - Phone call
    - EPIC remote visits
    - Mail through USPS, UPS, FedEx, etc.
    - Fax
    - Email through UCI HS [ucsecure] method
    - DocuSign
- The research participant or their legally authorized representative (LAR) must sign and date the informed consent form before the investigator may conduct any study-related procedures involving the participant. Where it is not feasible for investigators to receive the signed consent form prior to beginning study-related procedures, the investigators should have the participant/LAR confirm verbally during the consent interview that the participant/LAR has signed and dated the form. The case history for each participant must document that informed consent was obtained prior to participation in the study.
- HIPAA compliant practices must be used when emailing or faxing documents that may contain PHI when paired with a signature (e.g. diagnoses).
- For FDA-regulated studies, if any or all of the consent process takes place remotely and is not personally witnessed by study personnel, the electronic system, such as DocuSign, must include a method of identity verification. The FDA also allows two acceptable options (attestation or photograph), as outlined in the specific guidance for the conduct of clinical trials during the COVID-19 pandemic.
- Use of a witness during the informed consent process should follow UCI IRB Policy for the Role of a Witness and/or Participant Advocate

Use of DocuSign for Electronic Signatures:

- **Security** – For security reasons, research participant/LAR should not use publicly available devices for e-signing research informed consents and HIPAA Authorization forms. The participant or LAR should utilize a privately-owned device to which they have regular access and use.

- **Limited Use** – The UCI licensed version of DocuSign has not been evaluated for 21 CFR Part 11 compliance. The use of the current UCI licensed version of DocuSign for FDA-regulated studies is only approved for limited use until further notice and may be subject to further FDA Guidance.
- UCI will temporarily accept electronic signatures on the Form 700U, with the understanding that the wet-ink signed forms will be submitted in the future.
- Essential and Source Documents – In accordance with ICH Good Clinical Practice (GCP), all clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation, and verification, irrespective of the type of media used.

Additional Considerations for FDA-regulated Research:

UCI is broadly allowing the use of electronic records and signatures during the COVID-19 public health emergency. Acceptable electronic records and signatures must be discussed with the study sponsor and the reviewing IRB, as applicable.

- For EPIC remote visits, researchers may rely on this statement for UCI Health's EPIC system compliance with 21 CFR Part 11, as applicable.
- If a researcher needs to deviate from the requirements of Part 11 due to COVID-19, it should be well documented and available to the FDA in the future.

Documentation Requirements for Informed Consent

- All expectations of informed consent documentation still apply, according to 45 CFR 46.117 and 21 CFR 50.27. Particularly, the person signing the consent form must receive a copy of the consent form.
- **Need** – Document the *specific* need to obtain remote consent during the COVID-19 public health emergency.
- **Verification of Identity** – When using DocuSign, research personnel must ensure there is a standard process to verify the identity of the individual who signs the documents. Document *both* the verification of identity and the process.
- **Informed Consent Conversation** – Document that the informed consent conversation occurred, the method by which it occurred (e.g. telephone call, remote visit), and the participant's understanding of the information presented to them.
  Verification of Signature – A research participant/LAR may e-sign the consent and HIPAA authorization *during* the informed consent conversation; this process should be documented in the research record. If the consent and HIPAA are signed *after* the informed consent conversation ended, the researcher must follow up with the research participant/LAR to provide an opportunity to ask questions. Verification of identity and confirmation that the consent and HIPAA remain in effect should be documented.
- **If the participant's signed consent document cannot be collected, a copy of the informed consent document signed by the investigator and impartial witness should be placed in the source documents, with a notation by the investigator of how the consent was obtained. For the research participant/LAR signature, the FDA considers two acceptable options:**
  - A dated attestation by the witness who participated in the call and by the investigator that the patient confirmed that they agreed to participate in the study and signed the informed consent.
  - A photograph of the informed consent document with attestation by the person entering the photograph into the study record that states how that photograph was obtained and that it is a photograph of the informed consent signed by the patient.

- Changes necessary to eliminate apparent immediate hazards to research participants (e.g., to limit exposure to COVID-19) may be implemented prior to IRB approval in accordance with §46.108 (a)(3)(iii) and 21 CFR 56.108(a)(4). Protocol changes should be documented and must be submitted to the IRB at the next modification. Protocol deviations should be documented using standard processes and submitted to the IRB accordingly.

Does the 1572 need to be updated for COVID-related changes?

- In accordance with the 21 CFR 312.53(c)) and FDA guidance, there are two instances when it is necessary for an investigator to complete and sign a new 1572:
    - An investigator participating in a new protocol is added to the IND.
    - A new investigator is added to the study.

Health Information Management (HIM):

- Remote research consents and HIPAA Authorizations must continue to be emailed to HIMEDCOScan@hs.uci.edu, per the standard operating process.
- For telephone consents requiring a witness and conducted in accordance with FDA's guidance and UCI Health Informed Consent policy, email the following documents to HIMEDCOScan@hs.uci.edu:
    - Informed consent document(s) signed by the investigator and impartial witness.
    - The dated attestation by the witness and investigator confirming participant/LAR agreed to participate and that participant/LAR signed the informed consent **OR** the photograph of the participant/LAR-signed informed consent document with attestation of how the photograph was obtained and that the photograph is the consent form signed by the participant/LAR.
    - Research HIPAA Authorization
- Along with the documentation requirements for informed consent, Investigators may use this language to document the verbal consent process on the consent form: "Read consent to patient on xx/xx/xxxx and in the presence of (witness) the patient agreed."
- Audio or video recordings should not be submitted to HIM, as they are not considered part of the legal medical record (LMR), in accordance with the UCI Health Legal Medical Record policy.

Research Billing Considerations:

- Research Revenue Integrity (RRI) will continue to review remote research visits and other charges in the research billing records, in accordance with the study coverage analysis.
- The recharge rate for remote research visits may differ from the original budgeted amount. In these instances, RRI will communicate with the study team.
- It is imperative to continue adherence to OnCore subject registration within 24 hours of consent. Study teams faxing signed paper consents to RRI will now need to complete their own OnCore subject registration.

Investigational Drug Services:

- Ambient investigational products in its final dosage form may be shipped directly to research participants within California, per UCI IDS Pharmacy Emergent Shipment of IP Policy.
    - FDA regulations require addressing and documenting the required investigational product storage conditions and investigational product accountability, in accordance with 21 CFR 312.60, 312.62, and 812.140.

  - If the home delivery of investigational product is a specific change to the study protocol and affects the entire study population, FDA guidance requires a protocol amendment. However, if the home delivery is limited to certain participants, a protocol deviation may be acceptable.
- Investigational products may be made available at the CFCCC Pharmacy, when allowable.
- Study teams should continue to communicate with IDS in a timely manner to facilitate proper management of investigational products.
- It is imperative to continue adherence to OnCore subject registration within 24 hours of consent, in cases where IDS may need to verify patient information.
- Investigational products normally administered in a health care setting with plans for alternative administration (e.g. home nursing, alternative health care sites by non-study personnel) should be discussed with the sponsor and reviewing IRB, as the sponsor may need to consult with the FDA review division.

References:

- FDA: FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic (May 14, 2020)
- FDA: Coronavirus (COVID-19) Update: FDA updates on surveillance inspections during COVID-19 (May 11, 2020)
- CMS: COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers (updated May 11, 2020)
- HHS: HIPAA, Civil Rights, and COVID-19 (Office of Civil Rights, April 10, 2020)
- HHS: OHRP Guidance on COVID-19 (April 8, 2020)
- FDA: Enforcement Policy for Remote Ophthalmic Assessment and Monitoring Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 6, 2020)
- FDA: Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (April 4, 2020)
- OCR: Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency (March 30, 2020)
- HHS: Emergency Situations: Preparedness, Planning, and Response: COVID-19 and HIPAA (March 27, 2020)
- FDA: Notifying FDA of a Permanent Discontinuance or Interruption in Manufacturing Under Section 506C of the FD&C Act (March 27, 2020)
- NCI: Memorandum on Additional Guidance Regarding Alternative Procedures for Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program (CTEP) and NCI Community Oncology Research Program (NCORP) (March 23, 2020)
- FDA: Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency (March 22, 2020)
- FDA: Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease-2019 (COVID-19) Public Health Emergency (March 20, 2020)
- FDA: Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic (March 20, 2020)
- FDA: FDA Advises Patients on Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) (March 19, 2020)
- FDA: Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections (March 18, 2020)

- HHS: Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (March 17, 2020)
- CMS: Medicare Telemedicine Health Care Provider Fact Sheet (March 17, 2020)
- FDA: Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency (March 16, 2020)
- NCI: Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP) (March 13, 2020)
- PRIM&R: Webinar: COVID-19: How HRPPs Are Preparing and Responding—A Discussion Forum (March 23, 2020)
- CMS: Coverage and Payment Related to COVID-19 Medicare (March 05, 2020)