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Compliance and Privacy Office

COVID-19: Supplemental guidance for remote clinical research at UCI Health (updated September 15, 2020)

This guidance document is effective immediately and subject to change as federal, state, and institutional regulations are updated.

The UCI Health Research Compliance Program ensures that conduct of research activities follow federal, state and institutional regulations. This interim guidance provides COVID-19 related considerations during the declared national and statewide emergency.

For questions, please contact [Jinah Chang](#), Research Compliance Principal Analyst.

This guidance complements the information found on:

- UCI Office of Research (OR) [Research Continuity website](#)
- UCI Health [Telehealth Resource Center](#)
- FDA [Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)

This guidance includes the following sections:

- Remote Research Visits
- Important Considerations for Remote Research Visits
- Remote Research Consents
- Use of DocuSign for Electronic Signatures
- Additional Considerations for FDA-regulated Research
- Documentation Requirements for Informed Consent
- Does the FDA 1572 need to be updated for COVID-related changes?
- Health Information Management (HIM) Considerations
- Research Billing Considerations
- Investigational Drug Services (IDS) Considerations

Remote Research Visits

Prior to implementing remote visits, the study team should discuss with the sponsor and reviewing IRB, as applicable. The Principal Investigator, or designee, determines if a remote visit is acceptable or if an in-person visit is necessary.

The Office for Civil Rights (OCR) has allowed¹ covered health care providers to use popular applications for audio or video communications. OCR will not impose penalties for noncompliance² during the COVID-19 nationwide public health emergency. Providers should notify participants that these applications may introduce privacy risks. Providers should use all available encryption and privacy modes.

ALLOWED Applications:

- Zoom for Healthcare – highly preferred

¹ [HHS Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency](#)

² HIPAA Rules related to the good faith provision of remote communications

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- Skype for Business / Microsoft Team – next preferred
- 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 be *specific* and include the reasons for contingency measures. “Due to COVID-19” is not sufficient documentation. Rather, the specific details should be documented:
 - Why COVID-19 led to changes in study conduct
 - Duration of changes
 - Other participant-specific limitations
- Training for investigators, or designee, on conducting remote visits.
- Procedures in place to maintain participant’s privacy.
- The study team should discuss an identity verification plan with the sponsor.
- Specific documentation for remote research visits is recommended:
 - Identity verification of investigator and participant
 - Date and time
 - Location of the participant
 - Location of the investigator, or designee, conducting the remote visit
 - Additional participants involved, such as witness, family member, etc.
 - Other alternative processes
- The FDA does not consider these interactions as electronic records and are not subject to 21 CFR Part 11.

Remote Research Consents

Prior to implementing remote consents, the study team should discuss with the sponsor and reviewing IRB, as applicable.

- The investigator must obtain a complete informed consent process and Research HIPAA Authorization, unless previously waived by the IRB.
- Use of a witness during the informed consent process should follow UCI IRB [Policy for the Role of a Witness and/or Participant Advocate](#).
- The investigator should document the specific process for obtaining remote consent.
- Acceptable methods for remote consent and HIPAA authorization:
 - Phone call
 - Zoom for Healthcare
 - EPIC remote visits
 - Mail through USPS, UPS, FedEx, etc.
 - Fax
 - Email through UCI Health Sciences account: [ucsecure] method
 - DocuSign
- The research participant or their legally authorized representative (LAR) must sign and date the informed consent form (ICF) before beginning study-related procedures. If the participant-signed ICF cannot be collected, the participant/LAR should confirm verbally during the consent

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interview that the participant/LAR has signed and dated the ICF. The investigator must document that informed consent was obtained prior to participation in the study.

- Use HIPAA compliant practices when emailing or faxing documents with PHI paired with a signature (e.g. diagnoses).
- For FDA-regulated studies, any remote consent process not personally witnessed by the study team must include a method of identity verification. Aside of Part 11 compliant electronic systems, the FDA³ allows two acceptable options (attestation or photograph).

Use of DocuSign for Electronic Signatures:

- **Security** – For security reasons, research participant/LAR should not use public devices for e-signing research informed consents and HIPAA Authorization forms. The participant/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. Use of the current UCI licensed version for FDA-regulated studies is only approved for limited use⁴ 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. Electronic systems used to generate electronic signatures on clinical trial records, including informed consent documents, during the COVID-19 public health emergency must comply with 21 CFR Part 11 regulations when 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.
- When an electronic system that is Part 11 compliant is not available, FDA-regulated studies must have an alternate means of obtaining required signatures (e.g., handwritten wet ink signatures executed on documents, handwritten stylus or finger-drawn signatures executed on electronic documents that are then printed or appropriately witnessed).
- ***The UCI licensed versions of RedCap and DocuSign have not been evaluated for 21 CFR Part 11 compliance.***

Documentation Requirements for Informed Consent

Compliance with Good Clinical Practices for informed consent process still apply⁵. Particularly, the participant signing the ICF must receive a copy.

- **Need** – Document the *specific* need to obtain remote consent during the COVID-19 public health emergency.

³ [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)

⁴ UCI Office of Research (OR) [Research Continuity website](#)

⁵ 45 CFR 46.117 and 21 CFR 50.27

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- **Verification of Identity** – Document *both* the identity confirmation and the process.
- **Informed Consent Conversation** – Document that the conversation occurred, the method by which it occurred (e.g. telephone call, remote visit), the participant’s understanding of the information presented with verbal confirmation that questions have been answered and they agree to participate.
- **Verification of Signature** – A participant/LAR may e-sign the ICF and HIPAA authorization *during* the informed consent conversation. This process should be documented in the research record. If the participant/LAR signs *after* the informed consent conversation ended, the investigator must follow up to provide an opportunity to ask questions. Re-verification of identity and confirmation that the ICF and HIPAA remain in effect should be documented.
- **If the participant-signed ICF cannot be collected, the investigator should document specifically how the consent was obtained. The ICF signed by the investigator and impartial witness should be in the source documents. For the participant/LAR signature, the FDA considers the following acceptable options⁶:**
 - If it is not feasible to mail the ICF or if the participant is unable sign a paper ICF nor electronically sign the ICF, the participant/LAR may sign and date an attestation. The attestation should:
 - Be written on a blank piece of paper.
 - Include a written statement that they voluntarily agree to participate in the research study.
 - Include both the Protocol Number and brief Protocol Title.
 - Be photographed and sent to the study team. The original attestation can be provided to the study team at a later date.
 - Be recorded or have a witness present, with appropriate documentation.
 - A photograph of the participant-signed ICF with attestation by the study personnel entering the photograph into the research record. The signed and dated attestation should state that it is a photograph of the participant-signed ICF and how the photograph was obtained.
 - A signed and dated attestation by the investigator stating why the informed consent document signed by the patient was not retained. A signed and dated attestation by the witness who participated in the call that the participant confirmed agreement to participate in the study and signed the ICF or alternative attestation. In lieu of a witness, a recording of the conversation may be used, along with the investigator’s signed and dated attestation.
- **When using a recording in lieu of a witness**, the investigator should ensure that the recording is consistent with applicable state and local laws and that all parties agree to be recorded.
 - California law⁷ requires consent of *all parties* to record the conversation. All parties must first be informed that the conversation is being recorded. If, after being so advised, a party does not wish to participate in the conversation, s/he may simply decline to continue the communication. The recording and documentation of the consent process should be included in the research record.
 - Non-UCI Health smart phone devices nor Epic telehealth visits should **NOT** be used for recordings.

⁶ [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)

⁷ [Cal. Penal Code § 632](#)

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- To ensure HIPAA compliance, study teams should use a UCI Health device (i.e. laptop or desktop) and an HS Zoom account. Use of a Zoom recording will prompt the HS user to save a copy of the encrypted file to the user's local drive. The file should be moved to the user's shared drive on the HS server. Recordings should NOT be saved to the Zoom Cloud, as it does not meet HIPAA Privacy and Security standards.
- The study team should collect and archive (original paper or certified electronic) resulting documentation from remote consent processes. Retain in the research record according to applicable FDA record retention requirements.
- FDA regulations require alternative processes to be reviewed and approved by the IRB and sponsor. Changes necessary to eliminate apparent immediate hazards to research participants (e.g., to limit exposure to COVID-19) may be implemented prior to IRB approval⁸. The study team should document protocol changes and submit to the IRB with a subsequent modification. The study team should document protocol deviations using standard processes and submitted to the IRB accordingly.

Does the FDA 1572⁹ need to be updated for COVID-related changes?

- A new 1572 must be signed and completed when:
 - Adding an investigator to the Investigational New Drug Application (IND) for a new protocol.
 - Adding a new investigator to a protocol.

Health Information Management (HIM) Considerations:

- Investigators may use this language to document the verbal consent process on the consent form: "Read consent to [Participant Name] on [xx/xx/xxxx] and in the presence of [Witness Name] the participant agreed."
- Continue to email fully executed ICF and HIPAA Authorizations to HIMEDCOScan@hs.uci.edu, per the standard operating process.
- For remote consents obtained by alternative processes¹⁰, the fully executed ICF may include additional documentation, such as:
 - ICF signed and dated by the investigator.
 - ICF signed and dated by the impartial witness.
 - ICF signed and dated by the participant/LAR.
 - Attestation signed and dated by the investigator.
 - Attestation signed and dated by the witness.
 - Attestation signed and dated by the participant.
 - Photograph of the participant/LAR-signed ICF.
 - Research HIPAA Authorization
- Do NOT submit audio or video recordings to HIM, as they are not considered part of the legal medical record¹¹.
- IMPORTANT REMINDER: Include 2 patient identifiers on the first page of each document.

⁸ In accordance with §46.108 (a)(3)(iii) and 21 CFR 56.108(a)(4).

⁹ 21 CFR 312.53(c) and [FDA Information Sheet Guidance For Sponsors, Clinical Investigators, and IRBs Frequently Asked Questions Statement of Investigator \(Form FDA 1572\)](#)

¹⁰ [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#) and [UCI Health Informed Consent Policy](#)

¹¹ [UCI Health Legal Medical Record Policy](#)

Research Billing Considerations:

- Research Revenue Integrity (RRI) will continue to review remote research visits and charges in the research billing records, based on 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.
- **IMPORTANT REMINDER:** Continue OnCore subject registration within 24 hours of consent. Study teams can no longer fax signed paper consents to RRI and must complete their own OnCore subject registration.

Investigational Drug Services (IDS) Considerations:

- Study teams should continue to communicate with IDS in a timely manner to facilitate proper IP management.
- Ambient investigational products (IP) in its final dosage form may be shipped directly to research participants within California¹².
 - IP storage conditions and drug accountability must be addressed and documented¹³.
 - A protocol amendment is required if home delivery of IP is a specific change to the study protocol and affects the entire study population¹⁴.
 - A protocol deviation may be acceptable if the home delivery is limited to certain participants.
- The Chao Family Comprehensive Cancer Center (CFCCC) Pharmacy may dispense oral IP, when feasible and with prior IDS approval.
- Plans for alternative IP 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.
- **IMPORTANT REMINDER:** Continue OnCore subject registration within 24 hours of consent, as IDS may need to verify participant information.

¹² UCI IDS Pharmacy Emergent Shipment of IP Policy

¹³ 21 CFR 312.60, 312.62, and 812.140

¹⁴ [FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency](#)

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References:

- FDA: [FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic](#) (July 2, 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)
- [California “Two-Party Consent” Law](#)
- [California Code, Penal Code - PEN § 632](#)