HRPP-OCR COVID-19 Resources

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HRPP Guidance: Remote Consent and Documentation

April 21, 2020

This guidance provides recommendations for remote consent processes including documentation of consent beyond the traditional physical signature on paper. Federal regulations and institutional policy permit remote consent procedures when participants are not physically present. Whether the consent process takes place in person or remotely, researchers must ensure that information is provided to participants in a manner which includes an opportunity for participants to ask questions and have those questions answered and ultimately result in an informed decision. Numerous options are available for remote consent process and documentation and are outlined below.

Important Terms

Documentation of consent – Required by federal regulations and usually refers to the signature of the participant and person obtaining consent. These signatures are required to fulfill appropriate documentation requirements of informed consent.

Electronic Consent (eConsent) – The use of electronic media to provide information about the research, evaluate comprehension, and document consent. This may include informed consent technology (i.e., DocuSign) or the use of technology to deliver information (use of videos, hyperlinks, etc.).

Remote Consent – Obtaining informed consent when the participant and the person obtaining consent are not meeting in person (face-to-face).

References

Guidance, Regulations, and Policy

US Department of Health and Human Services (HHS), Office of Human Research Protections (OHRP)

- 45 CFR 46.116 General Requirements for informed consent
- 45 CFR 46.117 Documentation of informed consent
- Informed Consent FAQs
- Use of Electronic Informed Consent: Questions and Answers (Joint OHRP/FDA Guidance) December 2016

Food and Drug Administration

- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency March 2020, (Updated on April 16, 2020)
- Use of Electronic Informed Consent: Questions and Answers (Joint OHRP/FDA Guidance) December 2016
- 21 CFR 50 Subpart B Informed Consent of Human Subjects
- 21 CFR Part 11 Electronic Records, Electronic Signatures – Scope and Application
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers June 2017

UT Southwestern Policies

- Human Research Protection Program (HRPP) 3.1 Informed Consent Requirements
- Health System Operations HSO-253 Clinical Research Documentation in the Electronic Health Record
- University Hospital UHLD 01 Medical Research – Hospital Policy

Remote Consent Process
This section describes the steps to obtain and document informed consent remotely

1. **Provide informed consent document** (prior to the consent discussion) to prospective participant/LAR by any of the following:
    a. Postal mail
    b. Encrypted email (type *securemail* in the subject line of the email before sending)
    c. Facsimile – consent may be faxed
    d. Hyperlink to online/virtual consent document

2. **Conduct the consent discussion**
    Informed consent is a process, and all required elements of consent must be provided to prospective participants/LARs. The consent discussion can be conducted via:
    a. Telephone calls
    b. Video call – used to provide a virtual consent discussion
    c. Online (including the use of videos/hyperlinks for more information, etc.)
        i. MUST include contact information to the study team to have questions answered *prior* to providing informed consent

3. **Obtain Signatures (document informed consent)**
    The following are the most common options for documenting informed consent. If you have questions about options not listed, contact HRPP for assistance.
    a. REDCap: Redcap is HIPAA compliant and may be used to document informed consent.
        i. Recipients must have access to an internet-enabled device to view and sign the consent via REDCap.
        ii. FDA regulated research: REDCap may be configured to comply with 21 CFR Part 11 requirements. Contact the REDCap Technical Support team for more information.
    b. DocuSign: UTSW has licenses available for DocuSign (send requests for a user seat license to ServiceDesk).
        i. Recipients must have an email address and internet-enabled device to receive and sign the consent via DocuSign.
        ii. For FDA-regulated research: contact HRPP to request information about 21 CFR Part 11 Compliant Module for DocuSign
    c. Photograph of a signature on paper consent which may be mailed, emailed, or otherwise sent/saved electronically.
    d. Postal Mail: Consents may be signed by the participants, and then mailed back to the study team for signature.
        i. A consent note should be drafted to explain the difference in signature dates between the research participant and the study team.

e. E-Mail: Signed consents may be photographed/scanned and emailed back to the study team for signature.
    i. A consent note should be drafted to explain the difference in signature dates between the research participant and the study team.

4. Provide copy of consent to participant/LAR

a. Postal Mail: Fully executed (signed consents) may be mailed to participants
b. Encrypted Email: signed consents may be emailed to participants using encryption (type *securemail* in the subject line of the email before sending)

5. Save consent documentation

a. All signed copies of the consent must be uploaded to EPIC (at UTSW and based upon institutional policy at affiliate institutions) unless the IRB waived this requirement
b. A consent note explaining how the informed consent process was completed should be entered into EPIC (if required) and research records
c. Save the signed consent(s) in the regulatory files for future audits and monitoring visits
    i. Consent may be saved electronically (there is no requirement to print the signed electronic consents or maintain a hard copy of the original signed version)

Information Sheets for FDA Guidance

FDA provided guidance for clinical investigations during the COVID-19 pandemic. You may read the full FDA guidance by clicking on the title below.

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic
Guidance for Industry, Investigators, and Institutional Review Boards

The Simmons Cancer Center drafted the information sheets (on the following pages) for use by investigators and IND holders at UT Southwestern Medical Center.

COVID-19 Protocol Documentation Guidance
March 18, 2020

- Recent FDA Guidance entitled "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" offers non-binding guidance to sponsors, IRBs and investigators regarding the management of subjects and trials during this time. Please see here: https://www.fda.gov/media/136238/download

- The FDA recognizes that there may be disruptions to the conduct of clinical trials at this time.

- Our HRPP office is updating information and frequently asked questions. Reference our HRPP FAQ's here: https://www.utsouthwestern.edu/research/hrpp/assets/covid-19-faqs.pdf
  Please see HRPP website here: https://www.utsouthwestern.edu/research/hrpp/

- *Important documentation recommendations from the FDA Guidance:*

  Sponsors and clinical investigators *should document* how restrictions related to COVID-19 led to the changes in study conduct and duration of those changes and indicate which trial participants were impacted and how those trial participants were impacted.

  COVID-19 screening procedures that may be mandated by the health care system in which a clinical trial is being conducted do not need to be reported as an amendment to the protocol even if done during clinical study visits unless the sponsor is incorporating the data collected as part of a new research objective.

  The implementation of alternative processes should be consistent with the protocol to the extent possible, and sponsors and clinical investigators *should document the reason for any contingency measures implemented.*

  Changes in study visit schedules, missed visits, or patient discontinuations may lead to missing information (e.g., for protocol-specified procedures). It will be important to capture ***specific information in the case report form that explains the basis of the missing data*, including the relationship to COVID-19 for missing protocol-specified information.

  Existing regulatory requirements for maintaining investigational product accountability remain and should be addressed *and documented.*

  Robust efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts *should be documented.*

  **May precipitate changes to the EDC in the future

- It is critical to thoroughly document any protocol non- compliance or variances that are a direct result of disruptions caused by COVID-19 outbreak. This includes but is not limited to disruption or delays in treatment, study assessments, drug availability, subject availability, diagnostic test acquisition, testing and shipment.

COVID-19 Protocol Documentation Guidance
March 18, 2020

- Please document all efforts put forth in resolving issues as well. For example, efforts to contact or re-schedule subjects, communications with sponsors and CRO's and so forth.

- Very clearly document any COVID-19 screening efforts and the response from the subject.

- Helpful to track (by study) subjects who whose participation has been affected.

- Examples:
  "Patient unable to pick up study medications due to self-quarantine related to COVID-19 outbreak. Study drug shipped directly to patient's home address. Patient confirms he is self quarantining as a precautionary measure only. Currently asymptomatic for fever/cough/respiratory illness." "Patient verified receipt of study drug. Dosing delayed **days until shipment arrived"

  "Subject X experienced treatment delay due to delayed receipt of drug shipment from the sponsor. Sponsor reported the shipping delay was due to COVID-19 restrictions in place at the manufacturing site. Dosing delayed by XX days. Sponsor, PI and pharmacy determine dosing may proceed.

COVID-19 Related Documentation Guidance Information for IND Holders
March 18, 2020

- Recent FDA Guidance entitled "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" offers non-binding guidance to sponsors, IRBs and investigators regarding the management of subjects and trials during this time. Please carefully review the document here: https://www.fda.gov/media/136238/download as you may be considered both the sponsor and the clinical investigator of your trial.

- The FDA recognizes that there may be disruptions to the conduct of clinical trials at this time.

- Our HRPP office is updating information and frequently asked questions. Reference our HRPP FAQ's here: https://www.utsouthwestern.edu/research/hrpp/assets/covid-19-faqs.pdf
  Please see HRPP website here: https://www.utsouthwestern.edu/research/hrpp/

- **Sponsors and clinical investigators** are encouraged to engage with IRBs/IEC as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19.

- *If you are an IND holder conducting a clinical trial, specific guidance addressing the sponsor's responsibilities as well as the clinical investigator's responsibilities may apply to you. Highlights related to documentation from the FDA Guidance and other recommendations:*

  - ✓ **Sponsors** and **clinical investigators** *should document* how restrictions related to COVID-19 led to the changes in study conduct and duration of those changes and indicate which trial participants were impacted and how those trial participants were impacted.

  - ✓ The implementation of alternative processes should be consistent with the protocol to the extent possible, and **sponsors and clinical investigators** *should document the reason for any contingency measures implemented.*

  - ✓ Changes in study visit schedules, missed visits, or patient discontinuations may lead to missing information (e.g., for protocol-specified procedures). It will be important to capture ***specific information in the case report form that explains the basis of the missing data,* including the relationship to COVID-19 for missing protocol-specified information.

  - ✓ Robust efforts by **sponsors, investigators**, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts *should be documented.*

    **May necessitate changes to your data capture mechanisms.

- ✓ Careful attention to contemporaneous documentation of events related to COVID-19 will facilitate reporting to the FDA in the future. It is highly recommended to track protocol deviations, variations and adverse events specific to COVID-19 disruptions by protocol and by subject to ease reporting in the future.

- ✓ Recommend development of a study specific tracking tool to help gather data as described above. Please reference the FDA guidance document for reporting expectations.

- ✓ Protocol documentation at a minimum should include all changes made to conduct of the trial related to COVID-19, including when, how and why the change was implemented.

- ✓ Subject documentation should include at a minimum any changes affecting the subject's participation including treatment and procedure deviations as well as all adverse events that may have occurred related to COVID-19.

COVID-19 Screening Tools

The screening tools on the following pages may be used with participants and visitors to assess for COVID-19 symptoms.

As announced by the Office of Clinical Research Personnel on March 13, 2020

RESEARCH PARTICIPANTS:

Within 24 hours prior to a research participant arriving on campus, a member of the study team should conduct a phone survey with the research subject and the individual(s) who will be accompanying the subject. The surveys are found on the following pages in English and Spanish.

If the subject or the accompanying individual has flu or cold-like symptoms, they should be counseled that it is in their best interest not to travel or come to any UT Southwestern hospital or clinic.

As announced by the Emergency Operations Center on March 14, 2020:

HUMAN SUBJECT RESEARCH LIMITED TO TREATMENT-BASED VISITS ONLY

Effective March 16, 2020, UT Southwestern is suspending all in-person, non-essential research participant visits. Treatment-related visits should continue; the Principal Investigator of the IRB-approved protocol on which the research participant is enrolled will determine whether a visit is treatment-related.

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RESEARCH SUBJECT SURVEY

NAME of Patient or person providing information:_____

DOB of research subject:_____

Have you been in contact with anyone suspected or known to have Coronavirus or to anyone who is in quarantine?

YES or NO

Have you traveled outside of the U.S. within the last 21 days?

YES or NO

Have you been to New York, California, or Washington in the past 21 days?

Yes or No

Have you had a fever within the last 21 days?

YES or NO

Are you having any of the following symptoms? (Circle):

- Cough
- Shortness of breath
- Sore throat
- Malaise (feeling poorly)
- Chills
- Pneumonia
- Altered Mental Status
- Vomiting
- Severe headache
- Muscle aches

STU#:_____

DATE of survey completion:_____

Printed name of person conducting survey:_____

Comments/disposition: (patient has no risks, patient has risks and will reschedule visit, etc)

_____

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ENCUESTA PARA SUJETO DE INVESTIGACION

NOMBRE del Paciente o persona proporcionando la información: _____

FECHA DE NACIMIENTO del sujeto de investigación: _____

¿Ha estado en contacto con alguien que se sospecha o se sabe que tiene el Coronavirus o alguien que está en cuarentena?

SI o NO

¿Ha viajado fuera de los Estados Unidos en los últimos 21 días?

SI o NO

¿Ha estado en New York, California o Washington en los últimos 21 días?

SI o NO

¿Ha tenido fiebre en los últimos 21 días?

SI o NO

¿Está teniendo alguno de los siguientes síntomas? (Marque con un círculo)

- Tos
- Dificultad al Respirar
- Dolor de Garganta
- Malestar (sentirse mal)
- Escalofríos
- Neumonía
- Estado Mental Alterado
- Vómitos
- Dolor de Cabeza Severo
- Dolor Muscular

STU#:_____

DATE of survey completion:_____

Printed name of person conducting survey:_____

Comments/disposition: (patient has no risks, patient has risks and will reschedule visit, etc)

_____

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Covid 19 Risk Mitigation Visitor Survey

UT Southwestern Medical Center is committed to protecting our employees and patients from inadvertent exposure to Covid 19 (coronavirus). As a visitor to our campus, you will be denied access to UT Southwestern premises if you pose a risk of having or having recently been exposed to coronavirus. Please complete this survey and document the truthfulness of your responses.

NAME of individual providing information:_____

Company/CRO:_____

Date of survey completion_____

Have you been in contact with anyone suspected or known to have Coronavirus or to anyone who is in quarantine?

YES or NO

Have you traveled outside of the U.S. within the last 21 days?

YES or NO

Have you been to New York, California, or Washington in the past 21 days?

Yes or No

Have you had a fever within the last 21 days?

YES or NO

Are you having any of the following symptoms? (Circle):

Cough. Shortness of breath Sore throat Malaise (feeling poorly)

Chills Pneumonia. Altered Mental Status

Vomiting Severe headache Muscle aches

I certify that all statements given on this survey are true, complete, and without evasion to the best of my knowledge.

Signature _____

Date _____

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Encuesta Para Visitante sobre Mitigación de Riesgo del COVID-19

UT Southwestern está comprometido a proteger a nuestros empleados y pacientes de exposición accidental al COVID-19 (coronavirus). Como un visitante a nuestro campus, se le negara acceso a las instalaciones de UT Southwestern si usted presenta un riesgo de tener o haber estado expuesto recientemente al coronavirus. Por favor complete esta encuesta y documente la honestidad de sus respuestas.

Nombre del individuo proporcionando la información: _____

Compañía/CRO: _____

Fecha en la que completa la encuesta _____

¿Ha estado en contacto con alguien que se sospecha o se sabe que tiene el Coronavirus o alguien que está en cuarentena?

SI o NO

¿Ha viajado fuera de los Estados Unidos en los últimos 21 días?

SI o NO

¿Ha estado en New York, California o Washington en los últimos 21 días?

SI o NO

¿Ha tenido fiebre en los últimos 21 días?

SI o NO

¿Está teniendo alguno de los siguientes síntomas? (Marque con un círculo)

Tos Dificultad al Respirar Dolor de Garganta Malestar (sentirse mal)

Escalofríos Neumonía Estado Mental Alterado

Vómitos Dolor de Cabeza Severo Dolor Muscular

Yo certifico que todas las declaraciones dadas en esta encuesta son verdaderas, completas, y sin evasión hasta donde yo tengo conocimiento

Firma _____

Fecha _____