COVID-19 and Clinical Research

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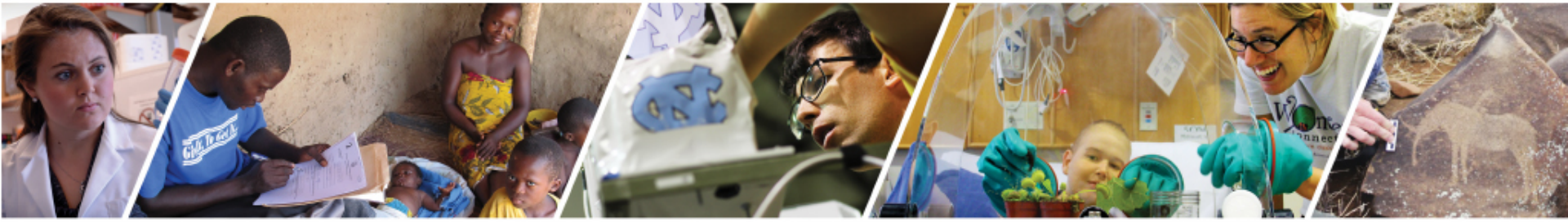


UNC RESEARCH

Objectives

- Review the Temporary UNC Policy on Human Subjects-Related Research Visits at UNC Chapel Hill During the Covid-19 pandemic
- Review some ways researchers are coping with the challenges
- Review the frequently asked questions about conducting human subjects research during the COVID-19 pandemic

Temporary UNC Policy on Human Subjects-Related Research Visits at UNC-Chapel Hill during COVID-19 Outbreak

Effective March 13, 2020 with updates on March 18, 2020

UNC RESEARCH

Key Takeaways

- Reduced operations, main support offices still open working remotely
- Perform visits remotely if possible
- Postpone study visits not providing immediate benefit
- Immediate benefit determined by PI, participant, participant's care provider and current public health guidance.
- **Updated on March 18th , subject to guidance and direction from UNC Health**

Key Takeaways - continued

Only those individuals designated as mandatory by UNC HR will be allowed on campus

Enrollment of new participants

- Participation in the trial is essential to the subject's health or well-being
- The enrollment and subject management can be done remotely

Research Studies may be halted if PPE or other required equipment is unavailable

Research Personnel

- Those designated as essential personnel with study subject direct contact must comply with the following:
  - Receive proper training on phone screening of study subjects prior to face to face visits.
  - Checklist for screening in Epic.
  - Follow UNC Health guidelines regarding screening and PPE
- UNC Health is temporarily allowing remote access to study monitors
  - Must follow policy posted in Research Central
  - Must include a valid reason in the request to UNC Health HIM
  - Currently scheduling remote monitoring visit out to June 2020

Remote Study Visits

School of Medicine

- WebEx can be used

All others

- Need to request and set up a HIPAA compliant Zoom account
- Safe computing website has information for setup
- Zoom accounts have been hacked, please use the waiting room option to ensure only hose invited are able to log into the session

Email to study subjects

- Emails to study subjects should be encrypted

Encrypted emails

Study Subjects may have difficulty opening encrypted emails, please give them the following information:

- If you have a unc.edu email address the email will arrive with (secure) in the subject line and you will be able to open it directly.
- If you have an email address outside of the unc.edu email network, the email message will arrive encrypted with the subject line: “You’ve received an encrypted message from xxxx@unc.edu…”
- When you open the encrypted attachment, you will have the option to access the message by signing in with a Microsoft account or by creating a one-time passcode.
- If you use the one-time password option, a numerical passcode will be sent to your email.
- If you indicate that your computer is secure you will have the option to directly open encrypted messages for up to 12 hours.

All HIPAA Privacy Regulations still apply

HIPAA regulations have not been relaxed

Use only UNC email to contact study subjects, do not use your personal email

While we continue to discourage the use of your personal cell phone to contact study subjects, we understand during this time of remote work it may be your only option.

Please only use UNC IRB approved texting, do NOT text from your personal cell phone

New Clinical Trials

- COVID-19 studies will be prioritized by OHRE, OCT and the Industry Contracting Office
- Investigator Initiated trials related to COVID-19 can be submitted directly to the IRB without review by the Scientific Review Committee
- Non-COVID-19 studies – continue to work on study start up activities that can be done remotely

Consenting Study Subjects in Isolation

FDA Guidance on Conduct of Clinical Trials of medical Products during the COVID-19 Pandemic – March 2020 – Updated April 2, 2020 - FAQ# 10.

- Use electronic methods if available
- If electronic methods are not available
  - Ensure an unsigned consent form is provided to the potential subject by a healthcare worker
  - If direct communication is not feasible or safe, obtain the subject's phone number and arrange a 3-way call or video conference to include an impartial witness
  - Be consistent – identify those on the call, review the ICF, respond to questions and have witness confirm the subject's questions were answered
  - Confirm subject is willing to participate
  - Verbal confirmation by the subject that they want to participate in the trial
  - Have the subject sign and date the ICF in their possession
  - If the ICF cannot be collected for safety reasons, obtain an attestation form the witness who participated in the call that the subject agreed to participate OR Photograph the ICF with an attestation from the person obtaining the photograph

Documentation

Document the informed consent process

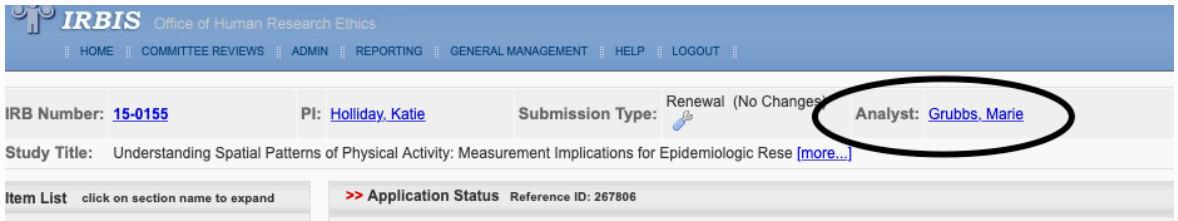
- include the attestation of the witness
- Include the attestation of the photographer of the ICF stating how the photograph was obtained and it is indeed a photograph the subject's signature
- A copy of the ICF with the PI and witness signatures should be placed in the trial records source documents
- Include a statement of why the ICF signed by the subject was not retained, e.g. due to contamination of the document bey infectious material

Documentation

- Be sure to document how restrictions related to COVID-19 led to changes in the conduct of the study
- The duration of those changes
- Which trial participants were impacted
- How those trial participants were impacted
- Important to capture specific information on the CRF explaining why certain data may be missing including the relationship to COVID-19
- Maintain investigation product accountability

Key Takeaway-What does this mean for my IRB submission

- Reduced operations, main support offices still open working remotely:
  - The IRB is still conducting its meetings as scheduled and has added 9 board meetings in response to COVID for April and May.
    - COVID board meetings are for studies that are studying COVID only,
  - Staff are available via email and voice messages left will be returned within 1 working day, as the staff have virtual voicemail.
  - Assigned staff can be identified in IRBIS by accessing the study specific submission:



Key Takeaway-What does this mean for my IRB submission

- Perform visits remotely if possible
  - Submit a modification if you will be conducting research differently than how it has previously been approved
  - Consider if this changes the consent process vs a need to inform subjects.
  - Identify to the IRB in your modification the following:
    - What does this mean for currently enrolled subjects
    - Does this increase risk to subjects
    - Does this affect the consent process?
    - Are these changes only for the COVID time period?

Consent Processes-IRB

Please refer to "Consenting Study Subjects in Isolation and Documentation " slides;

Please remember some of this is dependent upon the risk level of the study (minimal risk/greater than minimal risk) and if its FDA regulated.

Risk Level/Regulations	Full Waiver of HIPAA and Consent	Alt. Or Waiver of Signature (Verbal)	Signature is Required
Minimal Risk-No Intervention/Interaction with subjects *Expedited Categories	Yes	Likely NA	Likely NA
Minimal Risk- Intervention/interaction with subjects *Expedited Categories	Likely NA	Yes	If possible, (For electronic consider Qualtrics or other IT approved mechanism)
Greater than minimal risk- Full board	NA	NA	Yes (For electronic consider Qualtrics or other IT approved mechanism)
Greater than minimal risk-Full Board FDA Regulated	NA	NA	Yes (For electronic must be Part 11 Compliance, check with IT Liaison)

COVID Submission Table-IRB

Type of Change	Risk Analysis State.	COVID State. in Cover Page	Included in Mod Desc.	Updated Consent Section in App	Updated Through-out App	Attach.	Consent Form
Activities Modified due to and during COVID only (No Consent Changes)	Yes	Yes	Yes	No	No	As appl. e.g., Letters from Sponsor	No
Activities Modified due to and during COVID only (Consent Form Changes)	Yes	Yes	Yes	Yes- Outline remote proc. As needed	No	As appl. e.g., Letters from Sponsor	Yes
Activities Modified for COVID and other study changes	Yes	Yes	Yes, outline all changes	As appl. Outline Remote Proc. As needed	As appl.	As appl.	As Appl.
New COVID Related Study	NA	Yes	NA	Outline Remote Consent Proc. As needed	NA	All, including any FDA documents, or IND/IDE worksheets	Consider: -FDA App. -Assay -Return Results
Adding COVID Aims to existing study	Yes	Yes	Clearly outline how this is within current research question	As appl. Outline Remote Proc. As ne eded	Yes	As appl.	Consider: -FDA App. -Assay -Return Results

Key Takeaway-What does this mean for my IRB submission

- Postpone study visits not providing immediate benefit
- Immediate benefit determined by PI, participant, participant's care provider and current public health guidance.
  - The OHRE/IRB is not suspending studies as this has a different regulatory requirement than the institution setting policy such as the OVCR's office or the UNC Health System
  - If the OHRE/IRB were to suspend a study it needs to be reported to the FDA/OHRP, clinical trials.gov and other funders as the study no longer meets the criteria for approval.
  - The OHRE has placed a statement in letters saying that even if approved by the IRB, that researchers must still follow institutional policies about conducting research, which may include stopping research activities due to lack of direct benefit.

What if the IRB has not approved my submission for COVID changes.

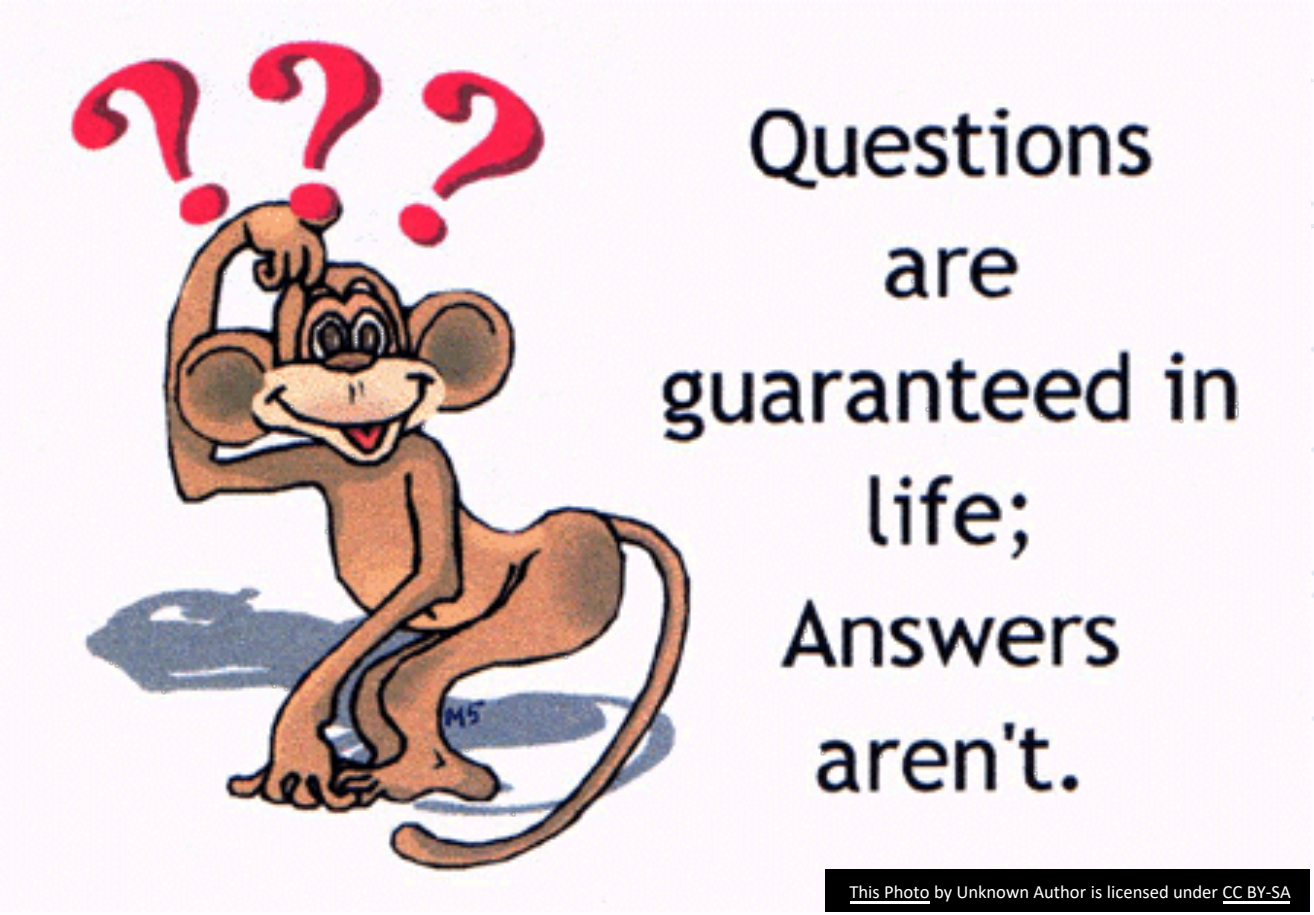
Please refer to the OHRE website and the COVID FAQ's:

As a reminder, initiating research or modifications to research without IRB approval is permitted to eliminate apparent immediate hazards to the human subjects per DHHS OHRP and FDA regulations.

- Please submit the modification as soon as available.
- If you need to "alter your procedures" to remove immediate risk of harm, these should be noted in your deviation log and submitted to the IRB as an NSI if they meet the criteria outline in SOP 1401. Please note your sponsors and monitors are going to want to see analysis of risk in the deviation log.

ClinicalTrials.gov

- Any changes to Overall Recruitment Status or Human Subjects Protection Review Board Status must be made within 30 days after a status change.
- Any protocol amendments necessitating Informed Consent changes must be updated within the CT.gov record by no later than 30 calendar days after IRB approval.
- Given that this information is not centrally tracked, each study team (i.e., Responsible Party) is accountable for ensuring timely CT.gov record updates accordingly.



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Questions