Last updated on 7/13/2020

COVID-19 HRPO and IRB FAQs

The Washington University IRB and the Human Research Protection Office are committed to protecting the safety and welfare of our research participants and the research community as a result of the coronavirus.

This guidance provides important information that reflects our current recommendations for managing human subjects research during periods of disruption and will be updated periodically as the situation evolves. This guidance should be reviewed in conjunction with the following guidance documents that provide important information on the conduct of clinical research:

- Guidelines for Clinical Research Transitioning from Orange to Yellow
- Considerations in Restarting a Clinical Research Study
- Guidance for Clinical and Human Subjects Research during COVID-19 (PDF)

HRPO has set up a dedicated phone line and email account for questions about IRB requirements related COVID-19.

Email: HRPO@wustl.edu
Phone: 314-371-6189

1. Is HRPO and the IRB operating as usual?

   All HRPO staff are working remotely and are monitoring both email and voice mail regularly. IRB meetings are being held remotely. While in-person office hours have been placed on hold until further notice, you may contact the SWAT line to set up a phone call or Zoom meeting to discuss your study questions or obtain assistance with IRB submissions. For COVID-19 related questions, please contact our dedicated phone line or email account.

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   Phone: 314-371-6189

2. Is the IRB or institution considering suspending any research studies?

   No, however, we strongly urge you to consult the University's guidance that describes essential and non-essential research COVID-19 Guidance for clinical and human subjects researchers.

3. What needs to be reported to the IRB if I voluntarily suspend my study?

   - **Suspending recruitment activities only**
     - Reporting to the IRB is not required.
     - If your study requires continuing review, report the suspension at that time.
     - You should document the suspension in your research records.

- **Suspending the study-DOES NOT negatively impact the safety of participants or integrity of study data**
    - Send an email to hrpo@wustl.edu (not a modification)
    - Include in the email:
        - IRB number
        - Study title
        - PI name
        - Date of suspension
        - What activities are being suspended.
        - Verification that this suspension does not impact currently enrolled participants or the integrity of study data
    - The email should come from the PI or the PI should be copied on the email.
    - If you plan to send written communications to the participants, this should be submitted as a modification.

- **Suspending the study- DOES negatively impact the safety of participants or integrity of study data**
    - Submit a modification
    - In the modification provide your rationale for the suspension and what measures you will take to minimize risks to participants and/or negative impact on study data. For example:
        - procedures, if any, that will be conducted prior to suspending the study in order to ensure safety of the participant;
        - decisions about transitioning treatments to standard care; or
        - sending written communication to currently enrolled participants.

Voluntary suspension of research may require notice to funding agencies and industry sponsors. For federally funded research, contact your program officer. For assistance with industry sponsors or other funding agencies, please contact researchcontracts@wusm.wustl.edu.

4. Should I voluntarily suspend recruitment for my study?

   Institutional guidance on suspending recruitment activities is available. See COVID-19 Guidance for clinical and human subjects researchers.

5. What changes can I make to my study without IRB approval?

   - **COVID-19 screening of research participants prior to planned study visits.** You do not need to submit a modification to the IRB in order to screen your participants for COVID-19. See COVID-19 Guidance for clinical and human subjects researchers.

     For COVID related research, a more robust plan for screening and minimizing risk of exposure of participants and study team members may be required, particularly if including higher risk populations.

- **Changes to protocols to prevent an immediate hazard to research participants.** The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and wellbeing of the participant. If there is a need, the PI may make the change without first obtaining IRB approval. This option is only available for changes that impact participants already enrolled in the study. It is not appropriate to make such a change in order to enroll a new participant.

  Follow the steps below if a change is made to prevent immediate hazard without IRB approval:
  - Submit a "Reportable Event Form" to the IRB via myIRB within 10 working days of the change. If the change is in response to the death of a research participant, report the event within one working day.
  - Document the change and rationale for making the change in your research records (e.g. in a note to file.)
  - This change may apply to one subject or a group/all subjects in the research study.

- **Minor protocol deviations which do not have the potential to negatively impact participant safety or integrity of study data or affect participant's willingness to participate in the study.** Minor protocols deviations could include:

  - Conducting the same study procedure remotely instead of in-person.
  - Conducting research visits outside of window in a timeframe that does not present a safety or study data integrity issue.
  - Omitting a research procedure that is not for safety purposes and will not negatively impact the integrity of the study data.

  If your study requires a continuing review, minor protocol deviations should be reported to the WU IRB at that time. Regardless of the continuing review requirement, you should document these deviations in your research records.

6. What changes can I make to my consent process without obtaining IRB approval?
   - If your study is approved for a verbal consent, you may continue without additional IRB approval even if transitioning from an in person visit to a phone visit.
   - If you are obtaining written consent you may do the following process without additional IRB approval:
     - Mail or email the consent form to the participant.
     - Discuss the study over the phone or other remote means.
     - Have the participant sign the consent form and return it to the study team. This can be by mail or email.
     - If by email, a scanned copy or photos taken of each page will be accepted.
     - HIPAA requirements should be followed when communicating via email.
   - Any other changes to the IRB approved consent process should be submitted to the IRB (see question #7).

7. What changes require IRB approval?

Changes to the protocol that may impact participant safety or the integrity of the study data. This may include:

- Administering study drug without performing a key safety lab or procedure.
- Revising or omitting study procedures that are required for safety purposes.
- Revising or omitting study procedures that impact the integrity of the study data.
- Performing study procedures at other locations (ex. Private physician office). Note: the use of a commercial lab for blood draws does not require a modification.
- Shipping the investigational product to the participant's home (see question 11).

Significant changes to the informed consent process.

- The most common example will be changing from a written paper consent process to an e-consent process. For example, Redcap can be used to obtain consent.
- Keep in mind 21 CFR Part 11 requirements for electronic signatures may apply to studies involving investigational drugs or devices.
- The mHealth research core through the ICTS can provide assistance with developing an e-consent process. https://mhealth.wustl.edu/navigation-tools/redcap-e-consent/

When requesting a change for one participant submit a protocol exception form. Otherwise, submit a modification.

Reference COVID-19 in the final comment text box just before you submit your form for appropriate prioritization. Do not include changes outside of your modification to address the COVID-19 situation and do not submit the modification with a continuing review. This will impact our ability to prioritize the reviews.

8. Can I conduct my research as a home visit?

Some studies are currently approved to conduct home visits. The PI must ensure that the activity can continue to be conducted safely within the home and that the study team implement the mandatory screening measures prior to the planned study visit. See COVID-19 Guidance for clinical and human subjects researchers.

Any additional requests to conduct a study visit or portion of a study visit as a home visit **must** be submitted to the IRB as modification for review and approval. Sending staff to participants' homes is not something to be undertaken lightly. There are numerous practical, clinical and employment issues to be considered, and is not generally recommended, especially if staff are not clinically credentialed and trained to do this. See COVID-19 Guidance for clinical and human subjects researchers. You should carefully consider this decision in line with this guidance on essential and non-essential study visits.

9. Should I modify my research procedures, to replace in-person study visits with "remote" options for questionnaires, surveys, check-ins, screening, and consenting?

   To reduce the risk of COVID-19 transmission and promote social distancing, effective immediately or as soon as possible, all clinical research visits that can be postponed or performed remotely (e.g. by phone, Zoom, local lab or other means) should be conducted this way whenever possible. See COVID-19 Guidance for clinical and human subjects researchers.

   Review question #5, 6 and 7 to determine if the changes you plan to make require the submission of a modification form or can be considered a minor deviation. If the submission of a modification form is required you may want to word the changes or update the protocol in a way that avoids having to submit another modification once you are ready to revert back to your current practice. For example, you can state that the changes will be implemented during the time the institutional policy is effect limiting external visitors to Washington University's Danforth and Medical campuses. If you are adjusting safety monitoring visits, provide a justification as to why the new methods will continue to ensure the safety of the participant.

10. What electronic means can I use to communicate with research participants remotely?

    The preferred means of remote communication with research participants is Zoom.

    The institution offers two versions of Zoom, one of which is HIPAA compliant. This distinction is important because there are additional security measures available with the HIPAA compliant version that ensures the appropriate privacy protections are in place. Most researchers on the Medical School campus have the HIPAA compliant version.

    Researchers on the Danforth campus may or may not have the HIPAA compliant version. When research involves the collection of identifiable health information or other identifiable sensitive information such as, illegal drug use, illicit sexual activity or other personal information that could be stigmatizing, the HIPAA compliant version is the preferred method of communication.

    If you are unsure if you have the HIPAA compliant version you can check by logging into https://wustl.zoom.us/ using your WUSTLKey and clicking on the "account profile". The account name will show either Wustl or WustlHIPAA. If you have questions or want to join the WustlHIPAA group, contact the WU IRB help desk at 314-933-3333.

    While not preferred, alternatives to Zoom are the WU version of Skype and Microsoft Teams.

    FaceTime is an option but is the least preferred. Be aware that use of FaceTime requires access to an Apple device for both the researcher and participant(s).

    In all cases, researchers should notify participants that use of these means of communication introduce privacy risks. This should be communicated prior to starting the remote visit.

11. What should I do if I want to ship investigational product to the participant's home?

    Unless you need to take immediate action to protect the safety and wellbeing of the participant, you should submit a modification and include the following information:

    - Number of participants on treatment
    - How long each participant has been on treatment
    - Confirmation that processes have been put in place to ensure proper shipment for drug accountability and pharmacy guidelines. It is not necessary to describe these processes.
    - Sponsor approval, if a sponsored study
    - Submit written communication to participants, if any
    - If you are not able to conduct in-person safety related procedures remotely, (ex. safety labs, adverse event assessments) describe these procedures and what alternatives will be used to minimize risks to participants.
    - Describe what measures will occur remotely to ensure the participant is compliant with their medication dosing and schedule.

    When submitting the modifications enter COVID-19 in the PI comments text box so we can prioritize as quickly as possible.

    If drug is shipped to a participant without IRB approval due to urgent safety concerns, submit a reportable event form with 10 working days.

12. How should I handle participant safety monitoring?

    Researchers should plan for alternatives to in-person monitoring visits, if possible. For clinical studies that do not require in-person study visits to conduct safety monitoring, visits should be held via telephone or video call.

    Some clinical studies require in-person study visits in order to conduct safety monitoring of the participants. For example, participants in a drug/instrument/device treatment study may need to have regular examinations, interviews, or laboratory tests for specific possible side effects. In such situations, visits may need to be performed. Consideration should be given to the timing of the visit, or to the need for in-person visits. See COVID-19 Guidance for clinical and human subjects researchers.

13. Has anything changed with the Single Patient Emergency Use requests to use an experimental drug or device?

    The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the COVID-19 situation.

14. What if I am conducting research outside of the Washington University campus, outside of the St. Louis area or internationally?

You should follow international, state, local, institutional and business restrictions that are in place at that location. You should also follow Washington University policies regarding COVID-19, as applicable to the conduct of your research.

15. What should I do if I conduct my research at a nursing home?

    Given that this population is particularly vulnerable to COVID-19, you should carefully consider the safety of these participants and the appropriateness of going on site to conduct research. Many nursing homes have placed restrictions on visitors. You should check with the nursing home.

16. I rely on an external IRB, what should I do?

    In addition to complying with WU institutional policies around the COVID-19 outbreak, you should check with your external IRB to determine what additional actions are required. Direct your IRB related questions to your external IRB. It is important to note that each IRB may implement specific guidance for studies they oversee which may be different from WU IRB guidance.

17. The NCI CIRB oversees my study. Where can I find more information about their requirements?

    NCI CIRB recently posted information in response to the COVID-19 outbreak. This information can be found here: https://ncicirb.org/content/nci-cirb-information-about-covid-19

18. Will I be charged a fee for submitting a modification to adjust my study due to the COVID-19 situation?

    Yes, if your study is supported by industry funding. At the onset of the COVID crisis, HRPO fees for the review of modifications were waived given the expectation that many studies would require immediate modification to address the restrictions around in-person visits. As of June 1, 2020, fees will no longer be waived.

19. What if I have questions about ICH compliance or best practices for documenting our response and actions related to COVID-19 in the research record?

    Andrea Morris , the Manager of the Human Research Quality Assurance Program, can assist with questions about best practices for documentation in the research record.

    morrisam@wustl.edu
    314-747-5525

20. Who should I contact for clinical research operational issues?

    Yi Zhang, Assistant Dean for Clinical Research, will be available to assist with your operational questions.

yizhang@wustl.edu
314-362-6864

21. Can I receive priority review for a modification submitted to the IRB in response to COVID-19?

    Yes. Reference COVID-19 in the final comment text box just before you submit your form for appropriate prioritization. Do not include changes outside of your modification to address the COVID-19 situation and do not submit the modification with a continuing review. This will impact our ability to prioritize the reviews.

22. Can I receive a priority review from the IRB if I am submitting a new study related to COVID-19

    Yes. If you are submitting a new study related to COVID-19 your review will be prioritized. Call or email us as soon as possible.

    Email: hrpo@wustl.edu
    Phone: 314-371-6189

23. If I am unable to obtain a wet signature for the HRPO assurance document when submitting a new study or adding a new PI what are my options?

    - Certified electronic signature (Adobe Acrobat Pro has this functionality)
    - Email verification from the PI/Dean/Department Head/Faculty sponsor, as required, attesting that they have read the assurance and agree to comply with the terms as outlined in the document. The emails AND the assurance document should be uploaded into myIRB as one document.

24. How can I consent hospitalized patients that are on isolation for confirmed/suspected COVID-19?

    In light of COVID-19 infection control measures, the FDA has issued guidance on how to obtain written consent in a manner that will reduces the risk of exposure for research staff.

    A description of this process can be found in Q10 of the FDA guidance document: https://www.fda.gov/media/136238/download.

    A description of this process should be included in your IRB application. A process flow document and toolkit have been created to outline the steps for this consent process.

25. What other options are available for written consent when obtaining a signed consent form from a participant is not possible?

    The FDA has provided additional guidance in the following scenarios:

    - A patient is unable to travel to a clinical trial site and electronic informed consent is not an option; and
    - A prospective trial participant (or legally authorized representative) cannot print and sign a paper copy of the consent form provided electronically by the investigator/designee, they cannot electronically sign the informed consent form, and providing a paper copy of the consent form via mail/courier is not feasible within the time frame for enrollment into the clinical trial.

    Refer to the FDA guidance FAQ 11 and 12 for details. A description of this process should be included in your IRB application.

26. Does the IRB need to review the departmental plan I created to restart my research?

    No, this plan does not require IRB approval. It is the responsibility of the PI to develop this plan, in concert with institutional and departmental requirements, and obtain departmental approval prior to restarting the research.

    Prior to restarting research, it is recommended that the PI review the IRB application against the departmental plan to ensure the IRB application is consistent. If not consistent, a modification should be submitted, unless the change is one outlined in this document as not requiring IRB approval. For example, your plan for screening participants for COVID-19 does not require IRB approval.