COVID-19: Considerations for Research Studies

The KPNW Research Compliance Team is receiving many questions about the appropriate process for making changes to studies in response to the COVID-19 situation. Federal regulations and guidance provide flexibility to accommodate emergency situations on a case-by-case basis.

The regulations specifically permit protocol deviations when necessary to eliminate apparent immediate hazards to participants and there is no time for IRB approval. Don’t let concerns about IRB approval prevent you from taking necessary action to protect participants.

KPNW Research Compliance has adopted a policy to address the COVID-19 situation as it applies to research. Please read it thoroughly: NWRC.RIM.099 – Research Continuity and Protection of Human Subjects During COVID-19.

We encourage investigators and study teams to think about aspects of your projects that may need to be modified if/when COVID-19 has spread more broadly.

Below are examples of issues to consider when determining if your study should alter procedures due to COVID-19:

- Would it be appropriate to consider using virtual/telehealth procedures instead of in-person visits? In what context?
- Do you work with a population where exposure to COVID-19 could become a safety issue?
  - Along these same lines, are any study staff at higher risk if exposed to COVID-19?
  - Does this mean that you potentially need to exclude participants from participation and if so, how does this affect your methods, data, procedures, etc.?
- Would it be necessary or appropriate for researchers to conduct a visit/procedure in a participant’s home if the participant is ill or quarantined and the visit/procedure is necessary to ensure safety or continuity of treatment?
- If staff need to work remotely, are appropriate resources and data management procedures in place? If multiple staff are ill, are appropriate cross-training and back-up plans in place?
- Consider suspending procedures involving care providers to maximize their availability to provide needed care for patients.

FAQs:

1. **If emergency actions are necessary, do I have to inform the IRB first?**
   No. However, you must report the action to the IRB within five business days. Please consider whether changes should be submitted to the IRB now to avoid the need for emergency action later. Note that, per the new policy, certain minor changes due to COVID-19 do not require IRB review.

2. **May I use Teams to conduct and record study interviews?**
   Yes. Teams has been HIPAA certified to store PHI, PII and PCI. Recordings/files can also be extracted and deleted. Please note that in order to ensure the virtual Teams activity is compliant with KP privacy and security requirements, it must be generated from an existing KP Teams account. If you are working with non-KP collaborators, additional data protection procedures may be required.

3. **May I contact participants via text or email?**
   Only if you are approved to do so by the IRB and you are following all applicable privacy and security procedures. CHR researchers should refer to the guidance document, Best Practices for Sending Emails to Research Participants or Recruits.
4. **How do I document that informed consent was obtained if I am obtaining it verbally or electronically under the new policy (NWRC.RIM.099)?**
   On the signature line of the existing IRB-approved consent form, write a note explaining how consent was obtained, when, and by whom. State that informed consent was documented per policy NWRC.RIM.099. Complete follow-up documentation as directed in section 6.2.

5. **For a greater than minimal risk study that requires signed consent, can the consent discussion take place virtually and the signature be obtained by mail?**
   Yes. A consent discussion for any study would fall under section 5.2.1 of policy NWRC.RIM.099. Signature obtained by mail is considered signed/documented consent. You do not need to submit a modification to the IRB to utilize this procedure. Instead, complete follow-up documentation as directed in section 6.2.

6. **Do I need to do a Data Transfer Request (DTR) to access PHI from home?**
   Only if the PHI is stored or brought outside the secure CHR/KPNW network. We do not expect that this will be necessary in most cases. All KP Office 365 applications are within the secure network, even if accessed from home. If you already have a DTR approved to access data through an online application hosted by another site, you may continue to access that application from home. If you do submit a DTR to request approval for staff to maintain PHI at home, please note the following (these are not changes from previous requirements):
   - For each project that involves staff maintaining PHI at home, submit one DTR that describes what PHI is being kept at staff members’ homes and how it is used. You do not need a separate DTR for each individual.
   - The DTR should list study role(s), rather than individual names, to describe the staff who will keep PHI at home. This will minimize the need for future changes.

7. **How do we handle changes happening at collaborating sites due to COVID-19?**
   If KPNW is the IRB of record, consult the new policy (NWRC.RIM.099) and share it with relying sites as needed. If another site is the IRB of record, you must follow their applicable policies and procedures as well as the applicable Reliance Agreement. If another site is changing the way they are handling KPNW PHI or other confidential information, update your DTR accordingly in the Data Commitments system and email CHR_ComplianceApprovals@kpchr.org if you think a data or specimen sharing agreement needs to be updated.

8. **The policy says I don’t need to submit an IRB modification for the change I need to make, but the study’s sponsor/funder/lead site requires documentation of IRB approval. What should I do?**
   Provide the sponsor/funder/lead site with the temporary policy. If they still require prospective IRB approval, submit a modification and alert us to the reason for your request. Note that some changes to your study may require prospective approval by the sponsor/funder/lead site even if they do not require prospective approval by the IRB.

9. **What will happen if the Research Compliance Team is short-staffed due to illness or if the queue of IRB reviews and questions gets long?**
   We will prioritize safety-related reviews first. If you have a safety concern, please call that to our attention when you contact us. We are also in regular communication with our colleagues in other KP regions and will collaborate on a plan to ensure continuity of IRB review and oversight across the organization as needed.

10. **What is the best way to reach the Research Compliance / IRB Team if I have read the policy and this document and I still have a question?**
    Given that our schedules and availability may become less predictable due to remote work and/or illness, please email CHR_ResCompTeam@kpchr.org. This email box goes to our entire team and we will be able to triage and respond appropriately. Teams is a great way to contact us individually.

We appreciate your flexibility during this time as we all work together to address this rapidly evolving situation!