1.0 Policy Statement

Protection of human subjects and researchers during the COVID-19 outbreak is a critical priority. Public health guidelines and individual health needs may require deviation from KPNW IRB- or Compliance-approved research plans. Regulatory flexibility will be utilized to the extent possible to facilitate research continuity while ensuring participant and researcher safety.

2.0 Purpose

This policy describes permitted deviations from typical KPNW Research Compliance policies and procedures during the COVID-19 outbreak.

3.0 Scope/Coverage

3.1 This policy applies to all researchers who are employed by the following entities:

3.1.1 Kaiser Foundation Health Plan of the Northwest (KFHPNW);
3.1.2 Northwest Permanente, P.C., Physicians and Surgeons (NWP)
3.1.3 Permanente Dental Associates, P.C. (PDA)
3.1.4 Contingent workers, vendors, volunteers, students and/or individuals affiliated with KP who are legally required to follow KP policy

4.0 Definitions

N/A

5.0 Provisions

5.1 Federal regulations permit researchers to deviate from the IRB-approved research plan if necessary to eliminate an apparent immediate hazard to subjects. This includes any actions needed to protect subjects from risks associated with COVID-19 for which there is not time to obtain prospective IRB approval.

5.2 For research overseen by the KPNW IRB:

5.2.1 Research protocols involving in-person visits or interventions may conduct those visits or interventions by phone, video, or similar technology without first obtaining KPNW IRB approval for the change if:

5.2.1.1 Physical examination of the participant is not necessary to ensure the participant’s safety, and
5.2.1.2 Conducting the visit or intervention virtually does not adversely impact the ability to accomplish the stated research purpose and gather all data as described by the protocol.

Such changes to the research plan made in response to evolving government and public health guidelines are not considered changes in the research that require prospective IRB review and approval.
5.2.2 Research protocols that require signed informed consent may instead obtain verbal or electronic informed consent¹ without first obtaining IRB approval for the change if:

5.2.2.1 The KPNW IRB has previously determined that the study is Minimal Risk, and

5.2.2.2 The study does not involve procedures for which written informed consent is normally required outside the research context. This includes surveys, questionnaires, interviews, focus groups, behavioral health assessments/interventions, and physical assessments.

The KPNW IRB, through this policy, grants a waiver of documentation of informed consent for all minimal risk research meeting the above criteria in which in-person interactions must be minimized or eliminated due to COVID-19.

Greater than minimal risk research continues to require prospective IRB approval for any changes to the informed consent process.

5.2.3 Communications with individual participants regarding logistical changes related to COVID-19 are not considered changes to the research that require prospective IRB approval; for example, a phone call to notify the participant that a visit will take place virtually instead of in person. Note, this is not a change from current IRB requirements.

5.2.4 Incorporating clinically recommended screening for COVID-19 into a research visit or interaction is not considered a research activity and does not require KPNW IRB approval.

5.2.5 Other changes to the study that are not made to eliminate an apparent immediate hazard to a subject must obtain prospective KPNW IRB approval. This includes temporary changes due to the COVID-19 outbreak.

5.3 Research overseen by an IRB other than the KPNW IRB must comply with that IRB’s policies and procedures.

5.4 All KP privacy and security policies still apply, including NWRC.PRIV.04 – Data Privacy and Security for Research. Existing provisions particularly relevant to the COVID-19 situation include:

5.4.1 Researchers working remotely do not need to complete a Data Transfer Request (DTR) if PHI will only be accessed through the CHR or KPNW secure network.

¹ Electronic informed consent in this case means using electronic communication to confirm the participant’s decision to participate – for example, a participant reads a consent statement online and clicks a button to continue to a questionnaire. It does not refer to the use of an electronic signature, which carries certain additional authentication requirements.
5.4.2 A DTR is required if PHI will be stored anywhere outside of the secure CHR/KPNW network, including on paper or on a removable electronic device (e.g. laptop hard drive, thumb drive, audio recorder) at a researcher’s home or other site.

5.4.3 Researchers are responsible for taking other steps as needed to ensure participant privacy while working remotely. This includes finding a private location for participant phone/video interactions, viewing PHI in an area where it is not visible to others, and similar precautions.

6.0 Procedures

6.1 Research teams that have invoked provision 5.1 must report the deviation to the KPNW IRB within 5 business days per policy NWRC.HRP.071, Prompt Reporting Requirements. Studies overseen by another IRB must report per that IRB’s policy, as described in NWRC.HRP.071.

6.2 Research teams needing to invoke provisions 5.2.1 and/or 5.2.2 during the COVID-19 outbreak do not need to submit a modification to the IRB. Instead:

6.2.1 Document in a Note to File a description of how the study applied these provisions.

6.2.2 Submit the Note to File with the next Continuing Review or Annual Update.

6.3 For other temporary changes to the research protocol due to COVID-19, the KPNW IRB has created a template memo that you may use to describe the change you are proposing and any impact on risks to participants or others. You are not required to use this template, but your IRB modification submission should address all points outlined in the template. Examples of such changes include:

6.3.1 Studies involving in-person physical safety assessments may be conducted virtually if doing so is commensurate with applicable KPNW clinical guidelines around the use of telehealth, including any guidelines that have been adjusted due to the COVID-19 outbreak.

6.3.2 Currently enrolling studies that have been determined by the IRB to involve greater than minimal risk may need to obtain approval for an altered informed consent process or documentation procedure. Section 5.2.2 above does not apply to studies that are greater than minimal risk.

6.3.3 Studies for which COVID-19 results in the need for additional communication to participants may need to obtain IRB approval for those participant communications or notifications unless they fall within sections 5.1 or 5.2.3. For example, a written communication to be mailed to all participants would require prospective IRB approval.

6.3.4 Studies may need to alter eligibility criteria to ensure participant safety.
6.3.5 Studies for which in-person interactions cannot be eliminated may need to implement certain procedural changes to ensure safety of participants and staff.

6.3.6 Studies may need to modify procedures to accommodate staff working remotely or a reduction in available staff due to illness.

7.0 References/Appendices

7.1 Regulations:

7.1.1 21 CFR 56.108(a)(4)

7.1.2 45 CFR 46.108(a)(3)(iii)

7.2 Guidance: Effects of Disasters on Human Research Protections Programs, OHRP, Issued May 14, 2018

7.3 Policies:

7.3.1 NWRC.HRP.070 – Investigator Obligations

7.3.2 NWRC.HRP.071 – Prompt Reporting Requirements

7.3.3 NWRC.PRIV.04 – Data Privacy and Security for Research

7.4 KPNW COVID-19 Information

8.0 Approval

This policy was approved by the Research Compliance Committee.

Review History:

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