Individual Investigator Agreement

Name of Institution with the Federalwide Assurance (FWA): Kaiser Foundation Research Institute (on behalf of the Kaiser Permanente Medical Care Program)

Applicable FWA #: FWA00002344

Individual Investigator's Name:

Research Covered by This Agreement: Studies conducted as part of the National Dental Practice-Based Research Network Cycle 3 (2019-2026)

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1. The above-named investigator has reviewed: 1) T*he Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Appendix A), 2) the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46 (Appendix B); 3) the KP Federalwide Assurance (FWA) summary of terms (Appendix C); 4) the IRB policies for the protection of human subjects (Appendix D); and 5) the KPNW Ultimate Guide to Research-Related Training (Appendix E).

2. The investigator understands and accepts responsibility for compliance with the regulations and KP policies stipulated in the above documents and to protect the safety, rights, and welfare of research participants involved in research conducted under this Agreement.

3. The investigator will comply with all federal, state and local laws and regulations that may provide additional protection for research participants.

4. The investigator will abide by all determinations of the IRB and will accept the final authority and decisions of the IRB, including but not limited to, directives to terminate research activities.

5. The investigator will complete all KP-required education and training before initiating the research.

6. The investigator will promptly report and obtain IRB approval for any proposed changes in the research.

7. The investigator will not initiate changes in the research without prior IRB approval, except where necessary to eliminate apparent immediate hazards to participants.

8. The investigator will report immediately to the KP Principal Investigator any unanticipated problems involving risks to research participants or others in research.

9. The investigator agrees to follow the protocol or research plan, and report deviations, protocol violations, exemptions, and adverse events to the KP PI or KP IRB, as necessary.

10. The investigator will obtain, document, and maintain records of informed consent, as required by the IRB, from each participant or the participant's legally authorized representative as required under DHHS and FDA regulations and stipulated by the IRB.

11. The investigator acknowledges and agrees to cooperate in the IRB's responsibility for initial and continuing review, record keeping, and reporting.

12. The investigator will provide to the IRB in a timely fashion all information, forms, approvals, etc. as required by the IRB and needed to provide a comprehensive review and monitoring of the study.

13. The investigator will not contact or enroll research participant or accept access to patient identifiable or KP proprietary information prior to approval of the Individual Investigators Agreement by KFRI **and** the study is approved by the KP IRB.

14. In conducting research involving FDA-regulated products, the investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities.

15. Emergency medical care may be delivered without IRB review and approval only to the extent permitted under applicable Federal regulations and State law. However, data and information obtained as a result of emergency medical care may not be used for research purposes.

16. This Agreement does not preclude the investigator from taking part in research not covered by the Agreement.

17. The investigator acknowledges that he/she is responsible for safeguarding the rights and welfare of each research participant, and that the participant's rights and welfare must take precedence over the goals and requirements of the research.

Signature	Date	Investigator's Signature	Date

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Name & Degree:

Title:

Address:

Phone:

E-mail:

Appendix A: The Belmont Report

Appendix B: 45 CFR 46: DHHS Regulations on the Protection of Human Subjects and Institutional Review Boards, including Subparts A, B, C, and D

Appendix C: Terms of the Federalwide Assurance (FWA) of Protection for Human Subjects

Appendix D: KPNW IRB Standard Operating Procedures (SOPs)

Appendix E: KPNW Ultimate Guide to Research-Related Training