Building Consensus on Privacy Budgets for Record Linkage: Template Language for IRB Applications

INFORMATION SHEET FOR PARTICIPANTS (ELSI EXPERTS)

Thank you for your interest in this project. This sheet provides more information about the study to help you decide whether you desire to participate. Before you participate in this study, we will review this information with you and ask you to sign an informed consent form. We will send the informed consent form to you ahead of our meeting for your review. If you decide not to participate, there will be no disadvantage to you and we thank you for considering our request.

What are the research aims?

This research study will design an institutional review board (IRB) application template for studies using our prototype software called MINDFIRL, which stands for Minimum Necessary Disclosure for Interactive Record Linkage, for patient-centered comparative effectiveness research that requires record linkage. The researchers will solicit input and consensus from and among ELSI experts on a prototype template IRB application, which will serve as the basis for future study applications using our software for record linkage. This study will inform us in developing the proper IRB template language, and will include suggestions from ELSI experts to improve and finalize the IRB application template.

Who is being invited to participate?

This research study will involve one group of participants:

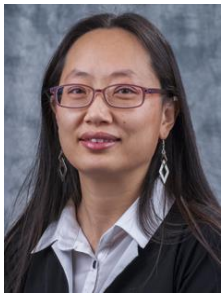
1) IRB, legal, and bioethics experts, who we will collectively refer to as Ethical, Legal and Social Implications (ELSI) experts.

Participants must be 18 years of age or older, speak English and have a professional ELSI role.

Who is conducting the research?

The study is being conducted by three academic researchers at Texas A&M University. The study is funded by the Patient-Centered Outcomes Research Institute (PCORI), a non-profit organization that funds research in order to help patients and those who care for them make better-informed decisions about their healthcare choices. Dr. Hye-Chung Kum is an associate professor at Texas A&M University and is cross-trained in computer science and social work. Dr. Kum holds expertise in data science and data mining in support of accurate evidence-based decisions for policy, management, legislation, evaluation and research. Dr. Alva O. Ferdinand is an assistant professor at Texas A&M University and is cross-trained in public health (DrPH) and law (JD) with expertise in using large secondary data sources for population-level research. Drs. Kum and Ferdinand will be joined by Professor Cason Schmit, who is also an assistant professor at Texas A&M University and the HIPAA compliance officer

at the university's School of Public Health. The research team consists of avid researchers and experts in the role of law and data in health systems. You can read more about their work at the web addresses listed below:



Hye-Chung Kum, PhD
https://sph.tamhsc.edu/hpm/faculty/kum.html

Alva O. Ferdinand, DrPH, JD
https://sph.tamhsc.edu/hpm/faculty/ferdinand.html

Cason Schmit, JD
https://sph.tamhsc.edu/hpm/faculty/schmit.html

What will participants be asked to do?

Should you agree to take part in this project, you will be participating in a three-round Delphi session with Professors Kum, Ferdinand, and Schmit, which will be held on an online platform. You will be given 7 days to complete each round at our own pace. There are no right or wrong answers to any questions. We are interested in your views and experiences. You will be asked to individually comment, raise concerns and provide suggestions for improvement of the IRB application template. We will gather your feedback, prepare copies of all the information captured through the first round and proceed to alterations based on that to the IRB application. In the next two rounds, this procedure will be repeated as needed until consensus is reached. We will finalize the document and share one last time to guarantee that all issues have been resolved to finalize the IRB application template, which will serve as the basis for future IRB study applications using the MINDFIRL software.

Who will see my interview responses?

No identifying information, such as your name, will be shared with other participants or anyone else. We also will not share information about who participated in the study. We will not use your name in any study publications or presentations.

Will I be compensated for participating?

Yes. Participants will receive graduated payments for each round which will add up to $100 in total.

What if I have further questions or want to participate?

We would be delighted to tell you more about the study. The contact information for the research team is listed below. A member of the research team will follow up with you in a few days' time with a reply.

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This study has been approved by the Texas A&M University Institutional Review Board, which is charged with protecting the welfare of participants in human research. Should you wish to speak with them, you can call 979-458-4067 or toll free at 1-855-795-8636.

Thank you for your consideration! We look forward to meeting you!