Thank you for your interest in our project entitled, “Development of CGM Data Analysis Tools.” This project is being organized by the Diabetes Technology Society (DTS) to explore the development of novel tools to support the analytic and data sharing needs of researchers that use CGMs. If successful, these tools will be made freely available to the research community.

In this early discovery phase, we are hoping to identify researchers who have existing CGM datasets that they would be willing and able to share with us to inform development. If you are interested, please read on for additional details about participating.

**What is being asked of me?**

If you agree to participate, we will ask three things of you:

1. Provide us with copies of raw CGM data collected as part of a research project. We can accept as many tracings, of any duration, from as many participants as you have. If you have them, we would also be interested in the accompanying AGP for each tracing.
2. Participate in a brief, 20-minute virtual conference call to provide us a brief overview of the study, review the format of the files, and any thoughts you would like to share about your existing process to analyze and manipulate CGM data files.
3. Provide limited demographic information (age, sex, race/ethnicity, diagnosis) about the participants that originated each CGM tracing.

Items #2 and #3 are optional.

**What format should the CGM data be in?**

Ideally, we would like to get copies of the original, unedited CGM data files as exported from the CGM data platform (e.g., Clarity, Libreview, Carelink) in a .csv format; one file per participant. The AGPs should be PDFs or images. However, we are happy to work with any files in any format that you currently have. If you decide to participate, we will share additional details about data formatting.

**How do I know if I can share the data?**

Prior to releasing data to us, you should verify that:

1. There is no embargo or restriction on data sharing placed on you by the study sponsor or your institution
2. Sharing the data, even fully de-identified data, is consistent with the consent signed by the participants of your study and acceptable by the IRB of record.

The best way to verify both of these points is with your IRB administrator.

**How should I share the data?**

We are asking for an anonymous, anonymized, or fully de-identified dataset (no PHI or PII). This gives us several ways to exchange data, including encrypted email, secure file sharing services, and SFTP. We can be flexible and use a method of your choosing.

**Do we need a DUA?**

Strictly speaking, DUAs are only required for Limited Data Sets (LDS) or fully identified data, but we recognize that institutions may choose to request DUAs for all types of datasets. We can work with your institution and use your existing DUA template to start.

**Who owns the data?**

Sharing the data with us does not constitute transfer of ownership; you (or your organization) retain ownership. We will not share the data with anyone outside of our project collaborators without your explicit consent. We will not commercialize the data you share with us.

**Who will see my data?**

The raw CGM data you share will only be seen by the active participants in this project organized by DTS. The project is being led by Dr. David Klonoff (DTS), Dr. Juan Espinoza (Lurie Children’s Hospital), and Mr. Shahid Shah (Netspective, a government subcontracting firm supporting DTS and other federal agencies such as NIH). Aggregate and derived data may be included in presentations and publications about this project, but never linked to you or your participants.

**What benefits are there for me?**

We are grateful for your meaningful participation in this project, and can offer the following:

* Any data tools developed during this project will be made available for free to you and your team
* Any analyses that we perform on your data set as part of development will be shared with you
* If there are specific analyses that you would like to have performed on these datasets, we are happy to consider them as part of our testing phase
* You will be included in the acknowledgements of any presentations and publications related to this effort
* You will be given the opportunity to earn authorship per [ICMJE recommendations](https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html) on any manuscripts resulting from this work

Thank you again for considering contributing data to this project. If you have any questions, please feel free to reach out.

Sincerely,

David C. Klonoff, M.D., FACP, FRCP (Edin), Fellow AIMBE

President, Diabetes Technology Society

Clinical Professor of Medicine, U.C. San Francisco

Editor-in-Chief, Journal of Diabetes Science and Technology

Medical Director, Diabetes Research Institute

Mills-Peninsula Medical Center

Juan Espinoza

Chief Research Informatics Officer

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Director, Consortium for Technology & Innovation in Pediatrics (CTIP)

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