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All of Us Data Access Request (DAR) Assurance Form

(For internal use only)

This assurance form must be signed and submitted to compliance@ki.se with all applications.

After signature the from should be registered and archived with the application and reports.

Data Set description: _____

Application Date (YYYY/MM/DD): _____

Project Number: _____

Project Title: _____

Principal Investigator (PI): _____

Approved users with access to data: _____

Department: _____

Assurance Statement:

By signing below;

As the PI, I certify that the statements herein are true, complete, and accurate to the best of my knowledge:

- **I have read and signed the Data User Code of Conduct and I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.**
- **I will follow the U.S. Department of Health and Human Services regulations for the protection of human subjects in research, https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.**
- **I will follow NIH regulations and guidelines relating to use of data from human subjects, https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/policies-and-regulations.**
- **I will use Participant Data in compliance with the requirements of the NIH Policy for Issuing Certificates of Confidentiality, https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc.**
- **I will not upload any personal data to the Research Workbench. Personal data is any type of information that can be linked directly or indirectly, through for example a code and a keycode, to living individuals. Pseudonymized (coded) data are personal data.**
- **If my data request concerns controlled tier data, I will apply for a Swedish ethical approval that describes which datasets from All of US are going to be analyzed and the analyses that are going to be performed on them.**

The Head of Department certifies that the appropriate programmatic and administrative personnel at the Department are aware of federal, state, and local laws and regulations and any relevant KI institutional policies relating to use of patient data. I understand that the Department on whose behalf I am signing this application is responsible for the conduct of the investigator(s) and approved users requesting access to data through this Data Access Request.

Type Principal Investigator Name	Principal Investigator Signature	Date
Type Head of Department Name	Head of Department Signature	Date
Type Name of Signing Official - Office of Research Support & External Relations	Signing Official - Office of Research Support & External Relations	Date