HIPAA Waiver of Authorization Approval Notice

$$GenerationDate$$

$$PIFormattedName$$
$$PIDepartment$$
$$PIAddress$$

Project Title: **$$StudyDescription$$**
Project Number: **$$ProtocolCode$$**

Dear $$PIPrefix$$ $$PILastName$$:

This letter serves to inform you that the Committee for the Protection of Human Subjects (CPHS) has reviewed and approved your request for a Waiver of Authorization through [expedited review/full board review] under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule for the above-referenced research project.

Approval Details:

Criteria Met: The IRB has determined that the proposed research project meets the following criteria necessary for a HIPAA Waiver of Authorization:

- The use or disclosure of Protected Health Information (PHI) involves no more than minimal risk to the privacy of individuals.
- The research could not practicably be conducted without the waiver.
- The research could not practicably be conducted without access to and use of the PHI.
- There is an adequate plan to protect the identifiers from improper use and disclosure.
- There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or retention is otherwise required by law.
- There are adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this waiver.

Protected Health Information Needed:

A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board.

Duration of Waiver:
This waiver is effective as of the approval date of the research project and will remain in effect until the conclusion of the research project as specified in the application, unless sooner terminated or amended by the IRB.

Reporting Requirements:
Please remember to report any modifications to the research protocol or changes in the use of PHI to the IRB prior to implementation to ensure continued compliance with HIPAA regulations and IRB policies.
If a project has been completed or is no longer active, CPHS must be notified of its completion or that it is being withdrawn. Any unanticipated problems, adverse events, protocol deviations, and breaches in data security must be reported to CPHS via a Report Form within 48 hours of the event (even if also reported to another IRB). Instructions for these processes can be found in the *CPHS IRBManager Manual for Researchers* located on the CPHS website.

If you have any questions, please contact our office at (916) 651-5599 or CPHS@chhs.ca.gov.

Thank you for your attention to the protection of participant privacy and adherence to HIPAA regulations in conducting this valuable research.

Sincerely,

Darci Delgado, PsyD.
Committee for the Protection of Human Subjects (CPHS) Chair.