CAP Policies and Procedures for Private Health Information and Identified Data.

Introduction:

The Cardiac Atlas Project (CAP) is a world-wide collaborative project to establish a standardized database of cardiac imaging examinations, together with derived analyses, for the purposes of statistical characterization of global and regional heart function abnormalities. By merging data from many different sources in a standardized manner, the CAP aims to provide researchers with a valuable resource for the study of heart disease. Cardiac imaging data and derived results have been contributed to CAP by several Contributing Studies, which have obtained local IRB approval to contribute de-identified data from participants. CAP data is de-identified before upload and contains no private health information (PHI) under the HIPAA rule. CAP does not retain the original study codes or the mapping between original study codes and CAP codes. Therefore the UCLA Institutional Review Board (IRB) has ruled that CAP does not constitute human subjects research. However, from time to time CAP personnel must review identified data, original study codes and PHI. This may occur in the correction of errors in the de-identification process, technical assistance to Contributing Studies and ongoing checks of the database for PHI. The primary purpose of this document is to define the CAP policies and procedures relating to PHI and original study identifiers.

Definitions:

Participant: Person who has provided informed consent to contribute their de-identified images and data to a pool of studies for the purposes of facilitating research into cardiac disease.

Contributing Studies: Studies or projects which have collected cardiac imaging data and derived results from participants, and contributed de-identified data to the CAP. Each Contributing Study maintains ownership over its data in the CAP, and controls the use of the data through Data Distribution Agreements (DDAs). These are different for each Contributing Study, depending on the terms and conditions required by each Contributing Study under which their data is distributed.

Research Project: A document outlining the reasons for the use of CAP data, and the uses to which the data will be put. Each project must identify the sources (i.e. Contributing Studies) of all the data required for the project, and will provide details of the rationale, aims and outcomes expected from the use of the data. A time-line for the project and dates of usage must be given, after which the data must be deleted. A plan for the archival of results must be given, which should include contribution of results to the CAP project for other Users.

CAP User (also User): Representative of the institution where the Research Project will be performed and where requested Data are to be sent. The representative may be the Department Chair or other appropriate official from the department of the Principal Investigator of the Research Project, as required by the DDA.

Data: Information that has been contributed to CAP, including de-identified cardiac images and derived information, such as contours or models derived from the images. Some clinical information may also be available for particular Contributing Studies, which may include age, gender, height, weight, primary diagnosis, systolic and diastolic blood pressure, hypertension classification, heart rate, race/ethnicity, diabetes classification, smoking classification, alcohol classification, and ECG classification.

HIPAA: The Health Insurance Portability and Accountability Act. The HIPAA Privacy Rule from the U.S. Department of Health and Human Services provides guidelines for protected health information (PHI). It describes what type of information is regarded as PHI, principles for the use and disclosure of the data, and ways to de-identify information.

IRB: Institutional Review Board

PHI: Private health information as defined under the HIAA Privacy Rule.

Policy on PHI and Identified Data:

Every effort should be made to exclude PHI and identified data from being uploaded into the CAP databases. As part of the upload procedure, checks are made to ensure that PHI is not included and the data has been correctly de-identified. See the CAP Image De-Identification and Upload Validation Procedure.

If at any stage in the CAP project, information contained in the CAP database is classified as containing PHI, the CAP will act in accordance with HIPAA § 164.526, 45 CFR Parts 160 and 164:

1. The CAP will act no later than 60 days after notification of the finding.
2. The CAP will make the amendment to the protected health information or record that is the subject of the finding by:
    a. Identifying the records in the CAP database that are affected by the amendment;
    b. Appending the required amendment to the records; and
    c. Modifying the Debabeler De-Identification mapping to reflect the actions of the amendment.
3. The CAP will inform others and provide the amendment within reasonable time to:
    a. Persons identified by the CAP as having received protected health information and needing the amendment; and
    b. Persons, including business associates, that the CAP knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.
4. The CAP will keep a record of the type of PHI and objects of the CAP database involved with the amendment.

As part of the de-identification process, some Contributing Studies may require technical assistance with the de-identification software or data upload issues. Since CAP does not wish to be an undue burden on Contributing Study resources, every effort will be made to facilitate this

process. This may require CAP personnel to visit the host institution of the Contributing Study to assist in the de-identification and upload process. In such cases the following procedure must be followed:

1. All identified data, including original study codes and PHI must be removed from all devices and media transferred out of the Contributing Study host institution.
2. If possible, no identified data should be copied to any device or media which is not the property of the Contributing Study.