CAP Policies and Procedures for Participants.

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 informed consent to contribute de-identified data from participants. The primary purpose of this document is to define the CAP policies and procedures relating to participants who have agreed to contribute their images and data for research into cardiac disease. In particular, to assure protection of participant privacy, responsible handling of data, and participant rights and privileges.

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.

Participant Privacy:

Only data from those participants who have provided informed consent compatible with the use of de-identified image and data in databases for the purposes of cardiac research into the future will be included in the CAP database. All data will be de-identified in a manner compatible with the HIPAA privacy rule. The de-identification of data occurs before inclusion in CAP data servers, so CAP never has access to original identifiers for the study. This means there is no way CAP personnel or Users can identify individuals. CAP personnel or Users will not attempt at any time to identify participants.

Participant Rights and Privileges:

Participants can withdraw their data from the database at any time by writing to the CAP project manager Carissa Fonseca (CFonseca@mednet.ucla.edu, or c/o UCLA Department of Radiological Sciences, 10945 Le Conte Ave, Suite 3371, Los Angeles, CA 90095-7206, USA).