CAP Policies and Procedures for Ethics and Informed Consent.

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. The primary purpose of this document is to define the CAP policies and procedures relating to limitations on data access due to the informed consent of the participants and the conditions imposed by the IRB approvals for the Contributing Studies.

Definitions:

Participant: Person who has contributed de-identified images and text data to a pool of studies for the purposes of facilitating research into cardiac disease.

Contributor: Studies, institutions, projects or physicians which have collected cardiac imaging data and derived results from participants, and contributed de-identified data to the CAP. Each Contributor 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 Contributor, depending on the terms and conditions required for access to the data. These terms and conditions are often imposed by the nature of the informed consent and IRB approval under which the data were acquired.

Research Proposal: 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. Contributor) 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, 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 HIPAA Privacy Rule.

Policy on Ethics and Informed Consent:

All data contributed to CAP must be obtained with the appropriate written informed consent and/ or local IRB approval. CAP recognises that some institutions do not require written informed consent to contribute de-identified data; however, we recommend that written informed consent is obtained if possible using the language provided below. All access to data via CAP must not violate the informed consent, or the IRB approval terms and conditions under which the data were obtained by the Contributor. The informed consent and IRB approval must be compatible with multi-center data sharing of de-identified images and text data for research purposes.

There are two types of access to data in CAP: restricted access and unrestricted access. Restricted access requires the Contributor to agree to each Research Proposal on a case by case basis. A separate DDA is required to be signed by the Contributor and the User for all Research Proposals. In some cases, the informed consent and/or IRB approval is compatible with unrestricted access, in which case the data can be accessed publically through web or internet access without requiring any further approvals.

Informed Consent Language for Restricted Access:

The informed consent compatible with restricted access should include language in the participant information sheet similar to the following:

You will also be asked to contribute your images and some clinical information to a large database which will be available to international research scientists studying heart disease. The clinical information includes age, gender, height, weight, blood pressure, smoking, alcohol, ethnicity and medical conditions. All personal details such as your name or anything that might identify you will be removed from your scan and clinical information. If you agree, the data may be shared with other researchers subject to approval of CONTRIBUTOR, from this time and in the future.

The written informed consent sheet should include language similar to the following:

I agree to my scan and data (with all personal details removed) being used in a large scale database for research on heart disease, now and in the future. Yes □ No □

Informed Consent Language for Unrestricted Access:

The informed consent compatible with unrestricted access should include language in the participant information sheet similar to the following:

You will also be asked to contribute your images and some clinical information to a large database which will be available to the public for research, education and teaching purposes. The clinical information includes age, gender, height, weight, blood pressure, smoking, alcohol, ethnicity and medical conditions. All personal details such as your name or anything that might identify you will be removed from your images and clinical information. If you agree, the data will be placed on publicly accessible websites, from this time and in the future.

The written informed consent sheet should include language similar to the following:

I agree to my scan and data (with all personal details removed) being included on publicly accessible websites to facilitate research, teaching and education of cardiac disease. Yes □ No □

IRB Approval Process:

CAP can assist Contributors in applying for local IRB approval to contribute data to CAP. For sample letters for IRBs see:
-- Restricted Access letter
-- Unrestricted Access letter