CAP Policies and Procedures for Data Distribution to Users.

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 the research community 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 maintain ownership of their data and control the uses to which their data are put. Qualified investigators can apply for access to the data for specific research purposes. This document sets out the policies and procedures governing the distribution of CAP data, and the responsibilities of those who request data from CAP. The primary purposes of this document are to assure protection of participant privacy, responsible handling of data, acknowledgement of the Contributing Studies, and appropriate allocation of rights to inventions, information or intellectual property arising from use of the data.

Definitions:

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.

CAP Data Distribution Approval Process:

All Users who wish to request data from CAP will be required to submit a Research Project to the CAP Steering Committee. The committee will review the proposal and assess its eligibility with respect to the goals of the CAP project. If approved, CAP will liaise with each of the Contributing Studies whose data is required for the Research Project. Each Contributing Study (or nominee) will then review the proposal and assess its eligibility with respect to the goals of the Contributing Study. If the proposal is approved by all Contributing Studies, the User will be required to sign and abide by a Data Distribution (DDA) agreement for each of the Contributing Studies involved. A separate DDA is required for each Contributing Study because the terms and conditions which govern the use of the data are specific to the goals and rationale of each Contributing Study. All DDAs should adhere to the policies and procedures governing CAP data distribution, given below.

CAP Data Distribution Policies and Procedures:

These policies and procedures will be adhered to by all Contributing Study DDA agreements. Specific DDAs may vary according to the goals, rationale, funding criteria, ethical approvals, etc, of the Contributing Study.

1. Prohibited Use: The Data will be used by the User solely for the purpose defined in the Research Project, and will not be used for any other purpose. The User must adhere to the terms and conditions specified in the DDA agreements for each Contributing Study.
2. Non-transferability: The DDA is not transferable to another investigator. Substantive changes made to the Research Project, and/or appointment by the User of another Investigator to complete the Research Project, should require execution of a new DDA in which the new Investigator and/or new Research Project are designated.
3. Publication: The User must comply with the publication policy stated in the DDA for each Contributing Study. Copies of final manuscripts or abstracts published in journals or conference proceedings should be provided to the CAP for reporting and dissemination purposes.
4. Acknowledgements: The User must acknowledge the Contributing Studies and their funding sources, as well as the CAP and its funding source (NHLBI), in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data reviewed under the DDAs.
5. Non-identification: The User must agree that the Data will not be used, either alone or in conjunction with any other information, in any effort to determine the individual identities of any of the participants from whom Data were obtained.
6. Security and Restricted Transfer: The User will retain control over Data provided to User, and unmodified or modified derivatives thereof, in a secure environment, and not transfer Data, and unmodified or modified derivatives thereof, with or without charge, to any other entity or any individual in a manner not previously approved by the CAP.

When the Research Project is completed, the Data should be deleted from the User's computers, unless other arrangements are agreed upon or an extension is obtained.

7. Non-data: The obligations of the DDAs should not extend to any information disclosed by the User:
    a. that can be demonstrated to have been publicly known at the time of disclosure; or
    b. that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to User from another source prior to disclosure; or
    c. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by User; or
    d. that can be demonstrated as independently developed or acquired by User without reference to or reliance upon Data provided under the DDA; or
    e. that is required to be disclosed by law, provided the User takes responsible and lawful actions to avoid and/or minimize such disclosure.
8. Compliance with Participant's Informed Consent: User must agree that the Data, their progeny, and unmodified or modified derivatives thereof, will not be used for any purpose contrary to a participants' applicable signed informed consent document(s). It is the responsibility of the User to consult with the CAP to ascertain, specifically and in detail, the terms and conditions of applicable Contributing Studies' informed consent documents.
9. Indemnification: The User should hold the CAP Steering Committee, the CAP investigators, and the Steering Committees and investigators of all Contributing Studies, and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of the User's use of Data for any purpose.
10. Costs/No warranties: Cost for distribution of Data should be covered by the User. No warranties express or implied, are offered as to the merchantability or fitness for any purpose of the Data provided to the User under the DDA, or that the Data may be exploited without infringing the intellectual property or proprietary rights of any third parties. CAP or Contributing Studies are not responsible for the accuracy of Data provided.
11. Amendments: Amendments to the DDAs should be made in writing and signed by authorized representatives of all parties.
12. Termination: The Contributing Studies may terminate the DDAs if the User is in default of any of its conditions and such default has not been remedied within 30 days after the date of written notice to the User by the CAP Steering Committee of such default.
13. Intellectual Property: The User must comply with any licensing arrangements or protection of existing intellectual property specified by the DDAs. Users are entitled to use CAP resources, including visualization and modeling tools, provided they comply with the licensing agreements contained in these resources. Intellectual Property pertaining to the endpoints or specific aims of a Contributing Study, for example pertaining to the investigation of a therapeutic drug or device which formed the rationale

of the Contributing Study, should be the property of Contributing Study. Rights to any inventions or new information arising from the particular characteristics or design of a Contributing Study should be freely available to Contributing Study investigators. Intellectual property developed by Users, not relating to the design of any Contributing Study (for example pertaining to the characterization of cardiac images, cardiac wall motion, or the development of computational atlases), will remain the property of the User or the User's host institution.

14. Commercial Use: The User cannot use Data for commercial use without the permission of the Contributing Studies.
15. Disqualification, Enforcement: To protect the confidentiality and privacy of participants, Users of CAP Data must adhere to the requirements of the appropriate DAA. Failure to comply with a DDA could result in denial of further access to CAP Data. Violation of the confidentiality requirements of this agreement may leave Users liable to legal action on the part of Contributing Study Investigators, their participants, their families, or the U.S. government.