CAP Policies and Procedures for Contributing Studies.

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. Each Contributing Study has supported collection of data from participants in a well-controlled manner, which provides a valuable scientific resource. In order to take full advantage of such resources and maximize their research value, these data are contributed to the CAP, where they are made widely available to qualified investigators, according to appropriate terms and conditions. The CAP seeks to promote the development of valuable discoveries and inventions beneficial to the public health based upon use of the CAP repository of valuable data. The CAP recognizes the substantial effort and resources, as well as careful attention to protocol and design, required to acquire data from participants. This document sets out the policies and procedures governing the contribution of data into CAP. It aims to ensure that the ownership of the data remains with the Contributing Study, that the data are only used for purposes approved by the Contributing Study, the protection of participant privacy, responsible handling of data, appropriate 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 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 Ownership of Data:

The Contributing Studies Investigators have made a substantial long-term contribution in collecting the data. This contribution includes the design of recruitment, inclusion and exclusion criteria, ensuring high quality of data, and that the participants are well-characterized, as well as significant resources spent on acquisition of the data. All data contributed to CAP is therefore the property of the Contributing Study. The data can only be used for purposes approved explicitly by the Contributing Study, on a case by case basis. All Research Projects which propose to make use of the data arising from the Contributing Study must be approved by the Contributing Study steering committee or nominee. Only those participants with informed consent compatible with the data use will be made available to CAP Users. No data will be distributed to any other entity or any individual in a manner not previously approved by the Contributing Study.

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.

As the authorized representative of the CAP study, the CAP Steering Committee will oversee and coordinate the Data distribution agreements for Users. This includes verifying that Users sign the appropriate agreements and keeping them on file. The CAP Steering Committee will serve as the initial contact for the distribution of Data and will coordinate distribution in conjunction with the appropriate Contributing Studies. The DDA will be reviewed and signed by the CAP Steering Committee and the Contributing Studies Steering Committee before any distribution of Contributing Studies Data.

CAP Contributing Studies Policies and Procedures:

Each Contributing Study may require that CAP enter into and abide by a Data Contribution Agreement (DCA) which specifies the terms and conditions under which the data are contributed to CAP. The DCA may vary from case to case, according to the requirements of the Contributing Study. The following policies and procedures are intended as a set of guidelines for all DCAs to which CAP and all Contributing Studies should adhere.

1. Prohibited Use: The Data will be used by CAP solely for the purposes outlined in the CAP specific aims, and will not be used for any other purpose. CAP must adhere to the terms and conditions specified in the DCA agreements for each Contributing Study.
2. Non-transferability: The DCA is not transferable to another investigator. Substantive changes made to CAP, and/or appointment by CAP of another Investigator to complete the project, should require execution of a new DCA in which the new Investigator and/or new project are designated.
3. Publication: CAP must comply with the publication policy stated in the DCA for each Contributing Study.
4. Acknowledgements: CAP must acknowledge the Contributing Studies and their funding sources, in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data reviewed under the DCAs.
5. Non-identification: CAP agrees 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: CAP will retain control over the Data, 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 and Contributing Studies. When CAP is completed, the Data will deleted from CAPs computers, unless other arrangements are agreed upon or an extension is obtained.
7. Non-data: The obligations of the DCAs should not extend to any information disclosed by CAP:
    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 CAP 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 CAP; or
    d. that can be demonstrated as independently developed or acquired by CAP without reference to or reliance upon DATA provided under the DCA; or
    e. that is required to be disclosed by law, provided the CAP takes responsible and lawful actions to avoid and/or minimize such disclosure.
8. Compliance with Participant's Informed Consent: CAP agrees 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 CAP to ascertain, specifically and in detail, the terms and conditions of applicable Contributing Studies' informed consent documents.

9. Indemnification: CAP should hold the Contributing Studies Steering Committee, investigators, 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 CAP's use of Data for any purpose.
10. Costs/No warranties: Cost for distribution of Data should be covered by CAP. No warranties express or implied, are offered as to the merchantability or fitness for any purpose of the Data provided to the CAP under the DCA, or that the Data may be exploited without infringing the intellectual property or proprietary rights of any third parties. Contributing Studies are not responsible for the accuracy of Data provided.
11. Amendments: Amendments to the DCAs should be made in writing and signed by authorized representatives of all parties.
12. Termination: The Contributing Studies may terminate the DCAs if the CAP 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 CAP by the Contributing Study Steering Committee of such default.
13. Intellectual Property: CAP must comply with any licensing arrangements or protection of existing intellectual property specified by the DCAs. 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 CAP, 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 CAP or CAP's host institution.
14. Commercial Use: CAP cannot use Data for commercial use without the permission of the Contributing Studies.
15. Disqualification, Enforcement: To protect the confidentiality and privacy of participants, CAP must adhere to the requirements of the appropriate DCA. Failure to comply with a DDA could result in denial of further access to Contributing Study Data. Violation of the confidentiality requirements of this agreement may leave CAP liable to legal action on the part of Contributing Study Investigators, their participants, their families, or the U.S. government.