The Cardiac Atlas Project

Collaborative Cardiac Imaging Resource
Coded Data Deposition Agreement
Between
Northwestern University
and
The Regents of the University of California
on behalf of its Los Angeles Campus
and
The University of Auckland

WHEREAS, The University of Auckland (University of Auckland Bioengineering Institute), in New Zealand, and the Regents of the University of California on behalf of its Los Angeles Campus (UCLA CardioVascular Imaging Laboratory), in the USA are working together to establish The Cardiac Atlas Project (CAP), which is intended to be a central repository for cardiac images, data and analysis from multiple past, present and future cardiac imaging studies around the world; and

WHEREAS, the host institution of CAP will be the University of Auckland, with a sub-award via the University of Auckland to UCLA ; and

WHEREAS, it is the intent of the parties that the University of Auckland Bioengineering Institute will responsible for the development of: (i) open source cardiac image analysis and visualization tools; (ii) open source modeling tools; (iii) ontologies and metadata formats; (iv) analytic tools; and (v) strategies and designs, relating to CAP; and

WHEREAS, it is the intent of the parties that the UCLA Diagnostic CardioVascular Imaging Laboratory will be responsible for: (i) operational management of the CAP project partnership and contributing studies; (ii) development and management of the CAP Production Database; (iii) development of Center for Computational Biology infrastructure; (iv) definition of domain dependent classifiers; and (v) management of the distribution of data to approved users; and

WHEREAS, in order to fulfill these responsibilities and the overall goals for the CAP project, two databases have been developed: (i) the Production Database, to be hosted by the UCLA Center for Computational Biology, the purpose of which is to provide a mechanism by which approved third party users can access the de-identified data and derived information; and (ii) the Research Database, to be hosted by the University of Auckland Bioengineering Institute, with a mirror at the UCLA Diagnostic CardioVascular Imaging Laboratory, the purpose of which is to enable CAP researchers to develop the required analytic tools for visualization, modeling and classification of cardiac MRI data and derived information; and

WHEREAS, it is the intent of the parties that data from the DETERMINE project described below be transferred into CAP pursuant to the terms and conditions of this Coded Data Deposition Agreement.

NOW THEREFORE, THIS CODED DATA DEPOSITION AGREEMENT is made and entered into as of the date of full execution ("Effective Date"), by and between Northwestern University, with a place of business at 633 Clark Street, Evanston, Illinois 60208, hereafter "Holder" and the following recipients: (1) The Regents of the University of California on behalf of its Los Angeles Campus (UCLA) located at 11000 Kinross Avenue, Suite 200, Los Angeles, California 90095, hereafter "UCLA Recipient"; and (2) The University of Auckland, with a mailing address of School of Medical Sciences, Private Bag 92019, Auckland Mail Centre, Auckland 1142, New Zealand ("Auckland Recipient"). UCLA Recipient and Auckland Recipient may be referred to hereinafter jointly as "Recipients."

TERMS AND CONDITIONS.

1. This agreement sets forth the terms and conditions pursuant to which Holder will provide Coded data to the Recipients. Dr. Alan Kadish, M.D., Holder's employee and not a party to this Agreement ("Holder Principal Investigator"), will oversee Holder's activities under this Agreement. Dr. J. Paul Finn, M.D., UCLA Recipient's employee and not a party to this Agreement ("UCLA Recipient Principal Investigator"), will oversee UCLA Recipient's activities under this Agreement. Dr. Alistair Young, Auckland Recipient's employee and not a party to this Agreement ("Auckland Recipient Principal Investigator") will oversee Auckland Recipient's activities under this Agreement. The UCLA Recipient Principal Investigator and the Auckland Recipient Principal Investigator may be referred to hereinafter jointly as the "Principal Investigators."

2. Terms used, but not otherwise defined, in this Agreement shall have the meaning given the terms in the Office for Human Research Protections regulations (45 C.F.R. §§ 46.101 *et seq.*).

3. Data Holder Responsibilities.

   3.1. The Data Holder will provide only coded data obtained in accordance with applicable laws and regulations and each subject's IRB-approved informed consent. Recipients must receive a copy of the current IRB approval letter prior to data deposition.

   3.2. The Data Holder agrees that the key to the coded data will never be released to Recipients.

4. Data Use.

   4.1. Except as otherwise specified herein, Recipients may make all uses and disclosures of the Coded Data Set necessary to conduct the research described as follows:

   The Cardiac Atlas Project ("Research Project") seeks to establish a structural and functional atlas of the heart. Initially comprising cardiac magnetic resonance imaging (MRI) examinations, together with derived functional analyses and associated clinical variables, the database will be extendible to allow inclusion of data from a variety of imaging and other sources. The initial goals of this project are to facilitate statistical analysis of regional heart shape and wall motion characteristics, across population groups, via the application of parametric mathematical modeling tools. This project will combine cardiac modeling and biophysical analysis methods developed by the University of Auckland, New Zealand, with structural database and probabilistic mapping infrastructure developed by the UCLA Center for Computational Biology (CCB). The specific aims of this project are to:

   A. Establish a database of de-identified cardiac MRI studies of asymptomatic and symptomatic patients for current and future research purposes. Data from two large studies will be used to initiate the database: MESA (Multi-Ethnic Study of Atherosclerosis), consisting of 5,004 subjects, and DETERMINE (Defibrillators to Reduce Risk by Magnetic Resonance Imaging Evaluation), consisting of the records of those subjects who have consented to the use of their data for the Research Project (approximately 10,000 patients with myocardial infarction). For clarification, the parties acknowledge that individual DETERMINE sites and individual subjects participating in the DETERMINE Study may elect to not share their data with the CAP Research Project.

   B. Develop tools and procedures to enable cardiac MRI studies to be classified, labeled, and searched using standardized protocols. Procedures and ontologies for the characterization and classification of anatomical and physiological data will be extended to cardiac MRI examinations.

C. Develop downloadable software tools for the mapping of cardiac structure and function, transformation of results between studies, and the probabilistic evaluation of temporal abnormalities in regional heart wall motion, in relation to population subgroups.

5. Publication and Data Use.

5.1. DETERMINE data will not be made available for commercial use without the permission of Holder, the Holder Principal Investigator Alan Kadish, MD and the study sponsor, St. Jude Medical.

5.2. In addition to the Recipients, the individuals, or classes of individuals, who are permitted to use or receive the Coded Data Set for purposes of the Research Project include: external researchers who have been approved for specific research projects by both the Holder and the Recipients as described in separate recipient data use agreements, which separate data use agreements will apply all the Terms and Conditions contained in this Data Use Agreement to each external researcher.

5.3. Any scientific projects which utilize DETERMINE trial data even as part of a coded data set will require approval of the DETERMINE executive steering committee and the Principal Investigator, Alan Kadish, MD.

5.4. Any publication, presentation, or abstract that incorporates or relies on any DETERMINE trial data ("Publication") shall be submitted to the DETERMINE Executive Steering Committee and the Principal Investigator, Alan Kadish, M.D. for review and comment. Further, any Publication shall be subject to the DETERMINE Publication Policy, attached hereto as Exhibit A and incorporated herein by reference.

5.5. Subject to any applicable U.S. government rights, terms will be negotiated between the parties hereto for any sale of DETERMINE trial data.

5.6. Parties to the Data Use Agreement will agree to use and/or disseminate data in compliance with applicable consenting documents, the Privacy Rule enacted pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and all other applicable privacy laws and regulations, safeguarding subjects' privacy and confidentiality.

5.7. The parties hereto expressly acknowledge and accept the terms of the Cardiac Atlas Project Intellectual Property Statement, attached hereto as Exhibit B and incorporated herein by reference.

6. Recipient Responsibilities.

6.1. Recipients will not use or disclose the Coded Data Set for any purpose other than permitted by this Agreement pertaining to the Research Project or as required by law;

6.2. Recipients will use appropriate administrative, physical and technical safeguards to prevent use or disclosure of the Coded Data Set other than as provided for by this Agreement;

6.3. Recipients will not attempt to re-identify the information contained in the Coded Data Set.

7. Term and Termination. The terms of this Agreement shall be effective as of the Effective Date, and shall remain in effect until all data provided to the Recipients is destroyed or returned to the Holder.

8. General Provisions.

8.1. This Agreement shall not be assigned by any Recipient without the prior written consent of the Holder.

8.2. Each party agrees that it will be responsible for its own acts and the results thereof to the extent authorized by law and shall not be responsible for the acts of the other party or the results thereof.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

HOLDER:

Date: 2/1/10

NORTHWESTERN UNIVERSITY

By: Bruce W Elliott

Bruce W. Elliott, Jr., Ph.D.
Director, Office for Sponsored Research

UCLA RECIPIENT:

Date: 1/26/2010

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
ON BEHALF OF ITS LOS ANGELES CAMPUS

By: Lillian Smith

Lillian L. Smith, J.D.
Director, Material Transfer & Industry Sponsored Research
UCLA Office of Intellectual Property & Industry Sponsored Research

AUCKLAND RECIPIENT:

Date: 14TH DECEMBER 2009.

THE UNIVERISTY OF AUCKLAND

By:

Name: DR JOHN SMART

Title: DIRECTOR OF RESEARCH OFFICE

Read and Understood:

Date: 2/1/10

HOLDER PRINCIPAL INVESTIGATOR

By:

Dr. Alan Kadish, M.D.
Principal Investigator

Read and Understood:

Date: 6th Jan 2010

UCLA RECIPIENT PRINCIPAL INVESTIGATOR

By:

Dr. J. Paul Finn, M.D.
Director, Diagnostic CardioVascular Imaging Laboratory

Read and Understood:

Date: 14 Dec 2009

AUCKLAND RECIPIENT PRINCIPAL INVESTIGATOR

By:

Dr. Alistair Young
Director, The Cardiac Atlas Project

EXHIBIT A

DETERMINE - Publications Policy

Since the Study is being conducted in multiple study centers, it is intended that the results of the Study will be published and/or presented in an integrated manner reflecting the results observed across all participating centers (Institutions). Accordingly, decisions on the timing and content of publications and presentation of the collective results from the Study Steering Committee, Principal Investigators, and the Sponsor will be made in communication with participating centers contributing subjects to the Study protocol. In the event that no multi-center study publication is approved and submitted within 12 months of the completion of the Study protocol, Northwestern University's ("the Institution's") designated principal and co-investigators may publish the results of the study data from those subjects enrolled in a study at the Institution provided that the Sponsor, the Executive Steering Committee, and the Publications Committee is provided a copy of such paper or presentation to review at least 30 days prior to its submittal. Such review is for comment and does include editorial privileges.

All papers or abstract topics exclusive of the Collective Results must be submitted to the Executive Steering Committee for review and comment of their appropriateness and scientific merit. The Executive Steering Committee will accommodate data and analysis requests for approved topics as resources allow. The Publications Committee and Executive Steering Committee will review papers prior to publication. The Publications Committee and Executive Steering Committee may recommend changes prior to providing approval. The Institution and the designated Investigator/Co-investigators agree that their data may be pooled for the purpose of publications, and that having agreed to pool data shall then have access to this data for publication purposes after the Study is completed.

Institution shall be free to use the data it contributed to the Study for its own teaching, research, education, clinical and publication purposes without the payment of royalties or other fees. In such case, Institution shall submit to Publications Committee and Sponsor for their review and comment, a copy of any proposed manuscript resulting from the research at least thirty (30) days prior to the estimated date of submission for publication. If no response is received within thirty (30) days of the date submitted to Publications Committee, it will be conclusively presumed that the publication may proceed without delay. If Sponsor determines that the proposed publication contains patentable subject matters which require protection, Sponsor may require the delay of publication for a period of time not to exceed thirty (30) days for the purpose of filing patent applications.

EXHIBIT B

Cardiac Atlas Project- Intellectual Property Statement

IP Arising from CAP Software

All software produced by the Cardiac Atlas Project (CAP) will be made freely available, via the CAP website, to biomedical researchers and educators in the non-profit sector, such as institutions of education, research institutes, and government laboratories.

Tools developed by the CAP, including database tools, and heart modeling tools using CMGUI (the open source finite element modeling package developed by the University of Auckland Bioengineering Institute), will be available using the Mozilla Public License (MPL). This software will comprise tools for the database management and access, uploading and downloading, web browser interface, conversion of data formats, data visualization, and parametric modeling of shape and motion.

Commercialization of enhanced or customized versions of the software, or incorporation of the software or pieces of it into other software packages will be permitted, subject to the terms of the MPL. Researchers outside the Project are permitted to modify the source code and are strongly encouraged to share modifications with other colleagues as well as with the Project.

The CAP will take responsibility for creating the original and subsequent "official" versions of the software, and will provide a mechanism to manage the dissemination or adoption of improvements or customizations of that software by others. Other users' contributions such as extensions, compatible modules, or plug-ins will be made available through the site. CAP software will be in a completely documented form such that if the development team does not maintain the software subsequent to the lifetime of the CAP, another individual or team can make use of our previous work to continue development and maintenance of our computational tools. Source code for this project will be made available through the CAP website. Support for installation on users' computers will be provided by the CAP.

IP Arising from CAP Development

Existing intellectual property of the collaborating groups will remain the property of the owner. Licenses to use this existing intellectual property will be sought on a case by case basis. Intellectual property developed during the course of this project by CAP researchers will be owned by the researchers' institution(s). For example, intellectual property developed during the course of this project at the University of Auckland will be owned by Auckland UniServices Limited. Auckland UniServices is a wholly owned company of the University of Auckland in which, by its agreement, the University vests all of its intellectual property. UniServices recognizes the wish of the NIH to allow free and open access to software developed during the course of this project. UniServices therefore supports and will abide by the provisions for software dissemination plans put forth in the CAP. Similarly, intellectual property developed during the course of this project at the University of California Los Angeles will be owned by the University of California Los Angeles, which supports and will abide by the provisions for software dissemination plans put forth in the CAP. Inventions or information arising from multiple institutions will be treated on a case by case basis.

IP Arising from CAP Users

Researchers outside the Project can apply to use the CAP data by submitting a Data Use Proposal to the CAP Steering Committee. If the Proposal meets the scientific goals of the CAP, the CAP SC will forward the application to each of the relevant Contributing Study Committees for approval. Each Data Use Proposal must identify the sources (i.e. Contributing Studies) of all the data required for the proposal, and will provide details of the rationale, aims and outcomes expected from the use of the data. Each Contributing Study Committee will require the applicants to sign a Data Use Agreement, which may be different for each Contributing Study. The Data Use Agreements may detail Intellectual Property terms and conditions pertaining to the specific use of the Contributing Study data. 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, should in general be the property of the 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 the Contributing Study investigators. Researchers using CAP data to develop new methods for the analysis and characterization of heart wall motion, new mathematical models, or new tools for computational atlases, are encouraged to share these developments with other colleagues as well as with the Project. Intellectual property developed by third party researchers using CAP data, not relating to the specific character of the Contributing Studies, should remain the property of the developers.

IP Arising from CAP Contributors

The CAP recognizes the substantial effort and expense as well as careful attention to protocol and design required to acquire data. In many cases, substantial intellectual property exists in the Contributing Study design or protocol. This existing intellectual property will remain the property of the owner. Any data dissemination will require approval from the Contributing Study Steering Committee. As part of this process, CAP Users will be required to sign a Data Use Agreement, written and approved by the Contributing Study, which details Intellectual Property terms and conditions pertaining to the specific use of the data. The Data Use Agreement will typically state that 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, will be the property of the Contributing Study. Rights to any inventions or new information arising from the particular characteristics or design of a Contributing Study will typically be freely available to the Contributing Study investigators. Intellectual property developed by third party researchers using CAP data, not relating to the specific character of the Contributing Studies, will typically remain the property of the developers.