The Open MEG Archive (OMEGA)
Archives MEG Ouvertes (AMEGO)

MANAGEMENT FRAMEWORK

CONTENTS

I. OWNERSHIP OF OMEGA ........................................................................................................ 2
   ADMINISTRATORS .............................................................................................................. 2
II. OBJECTIVES ....................................................................................................................... 2
III. FINANCING ....................................................................................................................... 2
IV. RECRUITMENT ................................................................................................................... 3
   WHO .................................................................................................................................... 3
   WHAT .................................................................................................................................. 3
V. MANAGEMENT AND CONSERVATION OF DATA ............................................................. 4
   MANAGEMENT .................................................................................................................... 4
   CONSERVATION OF DATA ............................................................................................... 4
   Location ............................................................................................................................... 4
   Security measures .............................................................................................................. 4
   Confidentiality of personal information ............................................................................ 4
   Storage Period .................................................................................................................... 4
   Verification of data ............................................................................................................. 4
   Withdrawal from OMEGA / destruction of data ............................................................... 5
   Re-contact of the participants ............................................................................................. 5
   Return of Results ................................................................................................................. 5
   Incidental Findings .............................................................................................................. 5
   Access for audit purposes ................................................................................................. 5
VI. REQUEST FOR DATA ......................................................................................................... 6
   SCIENTIFIC COMMITTEE OF OMEGA ............................................................................. 6
   ADMINISTRATIVE REQUIREMENTS ............................................................................... 6
VII. COMMERCIALIZATION ..................................................................................................... 7
VIII. CONTINUITY ................................................................................................................... 7
IX. FOLLOW-UP OF THE ETHICAL ASPECTS OF OMEGA ................................................ 7
I. OWNERSHIP OF OMEGA

Montreal Neurological Institute and Hospital (the “Neuro”).

The owner of OMEGA has a fiduciary duty towards the participant’s set of brain imaging data and standardized behavioral test scores, collected at the Neuro and/or at the Department of Psychology of the University of Montreal.

ADMINISTRATORS

This bank/repository is from a joint initiative by the MEG (magnetoencephalography) Programs at the MNI and at the University of Montreal. There is a minimum of one administrator for each participating institution:

For McGill/MNI:

• **Sylvain Baillet**, PhD – Interim Director, McConnell Brain Imaging Center - Associate Professor – Dept of Neurology & Neurosurgery
• **Robert Zatorre**, PhD – Professor – Dept of Neurology & Neurosurgery

For University of Montreal:

• **Pierre Jolicoeur**, PhD – Director, MEG Program – Professor – Department of Psychology

II. OBJECTIVES

The objective of The Open MEG Archive (“OMEGA”) is the conservation of brain imaging data collected with different brain imaging techniques and behavioral tests scores from healthy and patient volunteers (any age range), in order to allow future research in the field of high-powered detection of effects in the brain activity of either:

1. an individual patient or a small group of patients when compared with a large group of age-matched healthy controls;
2. distinct groups of participants categorized by age, gender, education level, behavioral test scores, etc.

Overall, the objective of OMEGA is to establish the standard levels of brain activity in the population of healthy participants, in relation to standard factors (age, gender, standardized behavioral tests scores, etc.) and to reveal new markers of abnormal brain activity in patients from the same population subgroup affected by neurological and mental health conditions.

III. FINANCING

OMEGA is financed as a Strategic Initiative of the Quebec Bioimaging Network (QBIN).
There will be no fee for access for users from academic research and education institutions. Fee for access will be required for individual users and users from private companies.

IV. RECRUITMENT

WHO

Two categories of participants will be recruited for inclusion in OMEGA, these include:

- HEALTHY participants from any age, gender, or ethnic group
- PATIENT volunteers from any age, gender, or ethnic group, suffering from any medical condition

Each of these categories of participants may be recruited solely for inclusion in OMEGA, or their data and images may be included on the basis of previously obtained consent for secondary use of data. For any given study, consent for secondary use of data may be provided through the OMEGA consent form (if the participant returns to the BIC), or via the study’s original consent form.

WHAT

Several types of imaging and non-imaging data may be included in OMEGA, these include:

- Magnetoencephalography (MEG)
- Electroencephalography (EEG), and other non-invasive electrophysiological methods (electrooculography, electrocardiography, electromyography, etc.)
- Intracranial EEG (iEEG), and other invasive electrophysiological methods
- Magnetic resonance imaging (MRI), and MRI-based methods (functional MRI, diffusion MRI, MR spectroscopy, etc.)
- Near-infrared spectroscopy (NIRS), and other optical imaging methods
- Positron emission tomography (PET)
- Computed tomography (CT)
- Single-photon emission computed tomography (SPECT)
- 3D digitization, body location/motion tracking, and eye tracking
- Clinical data
- Neuropsychological tests
- Questionnaires (self-report or otherwise)
V. MANAGEMENT AND CONSERVATION OF DATA

MANAGEMENT

OMEGA shall be supervised and managed by its Administrators.

The Administrators may delegate clerical responsibilities with regards to management of OMEGA provided the person(s) he/she designates agrees to respect the confidentiality of OMEGA’s content.

The Administrators may develop Standard Operating Procedures (“SOPs”) for OMEGA in conjunction with OMEGA’s Scientific Committee and the McGill University Health Center (MUHC) Research Ethics Board (REB).

CONSERVATION OF DATA

Location

OMEGA is located at the Neuro, with synchronized duplicate located at the Department of Psychology of the University of Montreal.

Security measures

- Security measures will be taken to guarantee safe, anonymized storage and classification of the data: the participant's name will be removed from the data files and replaced with an encoded version (see Confidentiality).
- Access to OMEGA will be restricted to the Administrators and their authorized representatives.
- The paper records will be stored in a locked filing cabinet, in a locked room, with a copy in each participating institution (MNI and University of Montreal).

The data will be stored as computer records, password protected, in each participating institution. Each storage space will be redundant and synchronized overnight to guarantee data integrity and storage safety.

Confidentiality of personal information

- Data files will receive a code that will link them links to the participant’s identifying information.
- The coded data files and the keys that link the codes to the participants will be kept in a separate secure space. The name of participants will be retrieved by the Administrators only, from a password-protected spreadsheet document, which will be stored in a disk space unaccessible to OMEGA users.
- Only the coded data will be transferred to third parties for future research.

Storage Period

- The data will be stored for an unlimited period of time.
Verification of data

The participants are allowed to have access to their file, in order to verify the correctness of the data and have it rectified if it is erroneous.

Withdrawal from OMEGA / destruction of data

Each participant may withdraw from OMEGA at any time by written request to one of the Administrators.

- Upon participant’s withdrawal, his/her data will be destroyed.
- A letter confirming the destruction of the data will be provided to the participant by the OMEGA’s Administrators.
- The research results obtained from the data will not be destroyed.

The data will be destroyed by deleting all data files related to the participant, on all of OMEGA. The computer command for destroying these data files will be issued by the OMEGA Administrators or one of their authorized staff members.

Re-contact of the participants

Participants may only be re-contacted if they gave specific consent to this effect.

Return of Results

No individual results will be transmitted to the participants.

The publication of studies made in whole or in part using the resources of OMEGA will be centrally listed on the OMEGA website.

Incidental Findings

The data are not subject to examination for clinical abnormalities by a qualified physician or radiologist as the case may be. It is therefore possible that a clinically significant abnormality would not be detected and communicated to the participant and his/her physician.

However, should a suspicion or concerned arises with any aspect of the data, a physician or radiologist may be consulted for a clinical assessment. Should this clinical assessment conclude that there is any significant incidental finding, this result will be communicated to the participant and upon his/her request, to his/her physician.

Access for audit purposes

The following organizations or their duly authorized representatives may access OMEGA for verification, surveillance and quality control:

- McGill University Health Center Research Ethics Board;
- University of Montreal’s competent REB;
- MUHC Quality Assurance and Education Program;
• Regulatory authorities such as Health Canada, FDA, etc. when applicable;  
Sponsors of research projects that received data.  
No photocopy or reproduction of OMEGA’s records shall be taken during these audits.

VI. REQUEST FOR DATA

**SCIENTIFIC COMMITTEE OF OMEGA**

A scientific committee (the “Scientific Committee”) composed of MNI's and University of Montreal respective MEG Research Committees shall evaluate each research project for which data from OMEGA is requested.

The Scientific Committee may only approve research projects that meet the following conditions:

• The research project must coincide with the objective of OMEGA;
• The research project must have scientific value and be scientifically sound;
• The research project must be presented and performed by qualified scientists;
• The research project must be approved by the duly constituted REB(s) that has/have jurisdiction over it.

**ADMINISTRATIVE REQUIREMENTS**

Data may only be released for research projects when the Administrator is satisfied that the following conditions are met:

• The project for which the data is requested has received final approval from the Scientific Committee;
• The project for which the data is requested has received final approval from a duly constituted REB;
• The agreement detailing the terms and conditions for the release of the data has been signed by the third party requesting the data. This agreement shall at least include provisions regarding the following:
  o The price to be paid by the third party for the data and services, as the case may be;
  o The data that will be transferred shall be coded/double-coded;
  o The data will be accessible to the third party for a determined, limited term not exceeding 6 months, unless justification for a longer fixed term has been provided in the research project for which data is requested and the Scientific Committee of OMEGA has approved this longer fix term;
  o The data shall not be used to create a new bank and/or repository;
  o The way in which the contribution of OMEGA will be recognized in any and all publication or presentation of study work/results that was achieved using OMEGA.
VII. COMMERCIALIZATION

The participants will not receive any financial benefit from their participation and/or from the creation of any commercial product made partly or totally from their data.

Should the use of the data for future research or the creation of any commercial product made partly or totally from the data yield earnings, said earnings will be directed to a research fund supporting OMEGA’s administration and development.

VIII. CONTINUITY

In the event of death or vacancy of the Administrator(s), the remaining Administrator(s) shall assume provisional responsibility during the interim and the scientific committee shall appoint new Administrator(s). In the event of death or vacancy of all the Administrators, the scientific committee shall assume the provisional responsibility during the interim.

In the event the Neuro creates a general institution bank, the OMEGA may be merged with it, provided the object for which data was donated is respected and the level of confidentiality protection is maintained.

In the event OMEGA is not being funded anymore or should the Neuro ceases operations or merges with another institution, OMEGA will either be destroyed or merged with an equivalent general institution bank, provided the object for which data was donated is respected and provided that the regulations and standards regarding privacy where OMEGA will be transferred are equivalent to the Canadian regulations and standards at the date of the said transfer.

IX. FOLLOW-UP OF THE ETHICAL ASPECTS OF OMEGA

MUHC REB approved this Management Framework and guarantees its follow-up. A thorough revision of this Policy will be undertaken every five (5) years. In addition, any revision and/or amendment made to this Policy and Information/Consent documents associated to it will have to be approved by the MUHC REB before they are implemented.