
Open Brain Consent Documentation

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Contents

1	Statement of the problem	1
2	Overall approach	3
2.1	Consent form	3
2.2	Anonymization	4
3	Useful links	5
4	Content	7
4.1	Sample consent forms	7
4.2	Recommendations	7
4.3	Discussions	8
4.4	Ultimate consent form	9
4.5	Anonymization tools	11
4.6	Contribute	12
4.7	Contact information	12

Statement of the problem

The ideology of open and reproducible science makes its way into various fields of science. Neuroimaging is a driving force today behind many fields of brain sciences. Despite possibly terabytes of neuroimaging data collected for research daily, just a small fraction becomes publicly available. Partially it is because management of neuroimaging data requires to conform to established legal norms, i.e. addressing the aspect of subjects privacy. Those norms are usually established by institutional review boards (IRB, or otherwise called ethics committees), which are in turn “governed” by the federal regulations, such as [45 Code of Federal Regulations Part 46](#) in US.

Flexibility in interpretation of original regulations established in the past century, decentralization of those committees, and lack of a “community” influence over them created the problem: **for neuroimaging studies there is no commonly accepted version of a Consent form template which would allow for collected imaging data to be shared as openly as possible while providing adequate guarantees for subjects’ privacy.** In majority of the cases, used Consent forms simply do not include **any** provision for public sharing of the data to get a “speedy” IRB approval for a study. Situation is particularly tricky because major granting agencies (e.g. NIH, NSF) nowadays require public data sharing, but do not provide explicit instructions on *how*.

Overall approach

We would like to facilitate neuroimaging data sharing by providing an “out of the box” solution addressing aforementioned human subjects concerns and consisting of

- widely acceptable consent form allowing deposition of anonymized data to public data archives
- collection of tools/pipelines to help anonymization of neuroimaging data making it ready for sharing

Consent form

Goal minimum

To address this problem we decided to collect *Sample consent forms* which have been previously approved by ethic committees in different institutions. Such samples could serve a basis for introducing similar *ad-hoc* consent forms at other institutions so they fulfill the desires of any particular committee, while allowing public sharing of collected data.

Ultimate goal

Analysis of those might allow us to distill an *Ultimate consent form* (or a set of those for different use-cases and jurisdictions, and/or guidelines) which would be compliant with all regulatory statues, while allowing for open sharing and access to the neuroimaging data.

If regulated by the same federal/state laws, there is really no objective reason why there could be no consensus among IRB committees within the same jurisdiction. Although somewhat a utopian statement, we hope that with examples/precedent cases and possibly **your** enthusiastic involvement we could achieve our goal.

Anonymization

Data must be de-identified before distribution. We will collect information on *existing* and possibly establishing an *ultimate* easy to use pipeline to standardize anonymization of neuroimaging data to simplify data sharing.

CHAPTER 3

Useful links

- http://en.wikipedia.org/wiki/Institutional_review_board
- <http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>

Sample consent forms

samples/ directory of our [git repository](#) contains samples of the consent forms found online. Because there is no explicit permission allowing their re-distribution we are not including them in this repository/site, but rather link to them as they are available on the web. Our [git repository](#) is also a [git annex](#) repository so you should be to *git annex* any file of interest, if it is still available online.

And here you can find a list of those files contained under *samples/*:

- [Arizona_consent.pdf](#)
- [CMU_fmri-consent-v-april-201011.doc](#)
- [Dartmouth-fMRI-Consent-Template.doc](#)
- [NMR_MGH_samplefMRIconsent.html](#)
- [UCB_SpatialRep_MRI.pdf](#)
- [UCLA_sample_consent.html](#)
- [UK_cf_CUBRIC_InfoConsentDebrief_fmRIonly.doc.html](#)
- [UK_gla_fmri_study_consent_form_0820110.doc](#)
- [USC_Informed-Consent-Template-3-29-13-FMRI.doc](#)

Recommendations

Here we would like to list existing recommendations from various foundations and organizations

International Coordination Facility (INCF) Neuroimaging taskforce

[Data Sharing Language Recommendations](#) (J.Turner, D.Kennedy, JB Poline, J. Roberts) provides a thorough summary over current state of used consent forms among neuroimaging studies and some data sharing initiatives. It further develops a set of recommendations on consent form language for perspective studies and analysis of public sharing of legacy data.

Discussions

Chris Gorgolewski (Max Planck Institute for Human Cognitive and Brain Sciences)

Source:

Furthermore, I agree that my anonymised data may be made available to a central MRI data centre. A data centre is an Internet server for anonymised MRI data and makes published image data accessible to researchers around the world. This allows further supplementary processing and repeated analyses. It also serves the purpose of making the results more transparent and accelerating the progress of research in the brain sciences. Some scientific journals already make the on-line availability of data a prerequisite for publication.

Feedback to the post

Pierre Bellec Apr 8, 2014

Thanks for sharing the template ! I tried to get such a paragraph in a consent form three years ago, and after one year of discussion with the IRB I had finally to remove it. I found that at least at my institution it is very important to describe the data repository, data use agreement and anonymization strategy (as well as other variables shared in addition to imaging) in order to get approval.

Michael Hanke Apr 8, 2014

Thanks! That adds some facets that I haven't used in mine before. Another aspect that I found necessary is to inform participants that data is actually accessible by anyone, not just scientists – this avoids concerns regarding access permissions and authentication. Moreover, at least in Germany participants can change their mind on the data sharing permission and can ask for their data to be removed from a database – even if it may not have an actual effect on privacy once data were out in the open. Lastly, I can confirm that information on what kind of data are shared is important, and at least a rough idea what kind of anonymization strategy is used. Ah and, not giving permission to share data must not lead to “disadvantages” for a person – this is mandated by law in Germany. Not sure what this means in the context of a scientific study, but I would not exclude a participant solely based on his or her unwillingness to share data.

Cyril Pernet Apr 9, 2014

In UK it's getting crazy. For our data bank we are planning de-identification ie face and ear removal and or scrubbing, you know is case your insurance compagny decides to make 3d models of data, recognize you, and found something weird in your brain that our radiologists and neurologist haven't seen before ...

Ultimate consent form

The following consent form has been put together, by merging best parts of existing consent forms and consulting with experts in research ethics.

Single access type version (all data shared publicly; recommended)

English

The data and samples from this study might be used for other, future research projects in addition to the study you are currently participating in. Those future projects can focus on any topic that might be unrelated to the goals of this study. We will give access to the data we are collecting, including the imaging data, to the general public via the Internet and a fully open database.

The data we share with the general public will not have your name on it, only a code number, so people will not know your name or which data are yours. In addition, we will not share any other information that we think might help people who know you guess which data are yours.

If you change your mind and withdraw your consent to participate in this study (you can call <PI name> at <phone number> to do this), we will not collect any additional data about you. We will delete your data if you withdraw before it was deposited in the database. **However, any data and research results already shared with other investigators or the general public cannot be destroyed, withdrawn or recalled.**

By agreeing to participate, you will be making a free and generous gift for research that might help others. It is possible that some of the research conducted using your information eventually could lead to the development of new methods for studying brain, new diagnostic tests, new drugs or other commercial products. Should this occur, there is no plan to provide you with any part of the profits generated from such products and you will not have any ownership rights in the products.

To the best of our knowledge, the data we release to the general public will not contain information that can directly identify you. The data will not have your name on it, only a code number, so people will not know your name or which data are yours. In addition, the data will not include data that we think might help people who know you guess which data are yours, such as your facial features or the date that you participated. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. However, by using additional data linked to your name (for example brain scans obtained from your medical records) one could potentially associate your imaging or other information in our database back to you. In addition a security breach (break in or cyber attack) might lead to someone being able to link you to your data. This risk is very low because your data are stored in a secure database, and the information about your identity is stored separately from the data themselves, linked only through a code.

We will keep the private portion (name, contact information etc.) of your data in a secure location for at least <x> years. This way if one of the researchers that obtained the data from us will find something in your brain scans that would have a diagnostic value we will be able to contact you. After this period of time we will destroy this information to protect your privacy.

Letting us use and share your data is voluntary. However, you must be willing to share your data in this way in order to participate in this study. If you are not willing, you cannot participate in this study.

By signing below, you agree to provide your data for future research. You agree that these may be shared with other investigators at other institutions from around the world. The details, results, and implications of these studies are unknown.

German

(translation courtesy of Sara Fernández)

Wir möchten die in dieser Studie erhobenen Daten, inklusive der fMRT-Bilddaten, der Allgemeinheit zur Verfügung stellen (über eine öffentliche Internetdatenbank). Es ist daher möglich, dass die Daten der Untersuchung, an der Sie aktuell teilnehmen, zukünftig auch für andere Forschungsprojekte genutzt werden. Diese Projekte könnten andere Zielsetzungen verfolgen, als die aktuelle Studie.

Alle Daten, die wir teilen, werden anonymisiert. Ihr Name wird nicht gespeichert, sondern nur eine Codenummer, so dass niemand weiß, welche Daten zu Ihnen gehören. Zusätzlich dazu werden wir Daten entfernen, die unter Umständen dazu führen könnten, dass Rückschlüsse auf ihre Person gezogen werden könnten (wie zum Beispiel Gesichtsmerkmale oder das Datum der Teilnahme). Wenn Sie Ihre Meinung ändern und die Zustimmung zur Teilnahme zurückziehen möchten, können Sie dies tun (dazu können Sie <experimenter name> unter <experimenter phone number> anrufen). In diesem Fall werden wir keine zusätzlichen Daten erheben und die bereits erhobenen Daten werden gelöscht, bevor diese in die Datenbank hochgeladen werden. **Allerdings können Daten und Forschungsergebnisse, die bereits auf die öffentliche Datenbank geladen und mit anderen Forschern geteilt wurden, nicht wieder gelöscht oder zurückgezogen werden.**

Es ist möglich, dass Studien, die Ihre Informationen nutzen, zu neuen Entwicklungen zur Erforschung und zum Verständnis des Gehirns, zu neuen Methoden, neuen Diagnosemethoden oder neuen (pharmazeutischen) Produkten führen. Durch die Zustimmung zur freiwilligen Weitergabe der Daten gibt es keine Möglichkeit, an den Profiten durch diese Produkte teilzuhaben. Auch die Rechte an diesen Methoden oder Produkten werden nicht weitergegeben.

Die Weitergabe Ihrer Daten ist freiwillig. Sie können trotzdem an der Studie teilnehmen, auch wenn Sie nicht wollen, dass die Daten weitergegeben werden.

Mit Ihrer Unterschrift bestätigen Sie, dass Sie die Daten für zukünftige Forschungen bereitstellen. Sie stimmen zu, dass diese global mit anderen Forschern und Instituten geteilt werden. Die Einzelheiten, Resultate und Implikationen dieser Studien sind unbekannt.

Two access types version (some data shared publicly, more data shared to approved researchers)

English

The data and samples from this study might be used for other, future research projects in addition to the study you are currently participating in. Those future projects can focus on any topic and might be unrelated to the goals of this study. We will give access to some of the data, including the imaging data, to the general public via the Internet and a fully open database. The data we will share publicly are limited to <explain what will you share publicly>. Additionally we will make all of our data available to other investigators through a controlled access database. To minimize risks to your privacy, a committee of experts will carefully review every data request from other scientists before allowing them to use this controlled access database, in order to make sure they can also protect your personal information. These other investigators may be at <your institution> or at other research centers (academic or commercial) around the world.

If you change your mind and withdraw your consent to participate in this study (you can call <PI name> at <phone number> to do this), we will not collect any additional data about you. We will delete your data if you withdraw before it was deposited in the database. **However, any data and research results already shared with other investigators or the general public cannot be destroyed, withdrawn or recalled.**

By agreeing to participate, you will be making a free and generous gift for research that might help others. It is possible that some of the research conducted using your information eventually could lead to the development of new methods for studying brain, new diagnostic tests, new drugs or other commercial products. Should this occur, there is no plan to provide you with any part of the profits generated from such products and you will not have any ownership rights in the products.

To the best of our knowledge, the data we release to other investigators or the general public will not contain information that can directly identify you. The data we share with other scientists or the general public will not have your name on it, only a code number, so people will not know your name or which data are yours. In addition, the data made

available to members of the general public will not include data that we think might help people who know you guess which data are yours, such as your facial features or the date that you participated. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. However, by using additional data linked to your name (for example brain scans obtained from your medical records) one could potentially link your imaging or other information in our database back to you. In addition a security breach (break in or cyber attack) might lead to someone being able to link you to your data. This risk is very low because your data are stored in a secure database, and the information about your identity is stored separately from the data themselves, linked only through a code.

We will keep the private portion (name, contact information etc.) of your data in a secure location for at least <x> years. This way if one of the researchers that obtained the data from us will find something in your brain scans that would have a diagnostic value we will be able to contact you. After this period of time we will destroy this information to protect your privacy.

Letting us use and share your data is voluntary. However, you must be willing to share your data in this way in order to participate in this study. If you are not willing, you cannot participate in this study.

By signing below, you agree to provide your data for future research. You agree that these may be shared with other authorized investigators at other institutions from around the world. The details, results, and implications of these studies are unknown.

Anonymization tools

Sanitization of headers/filenames

- see http://www.researchgate.net/post/Best_free_tool_for_DICOM_data_anonymization discussion on sanitization of DICOM headers
- DeID (see paper), which provides an interactive tool for inspection and sanitization of Analyze and NIfTI images

Elimination of facial (and dental) features

Skull stripping

One of the approaches is perform complete skull stripping, e.g. using

- BET of FSL
- 3dSkullStrip of AFNI
- FreeSurfer

Some dedicated anonymization tools work on this principle, e.g. DeID

Faces/dental stripping

More “gentle” approach is to strip out only the areas of face/mouth leaving skull, which might be important for some types of analysis. Usually achieved through alignment of pre-crafted mask to the subject anatomy and removing of the masked out regions.

- mri_deface from FreeSurfer (paper from 2007 with overview)
- <https://github.com/poldrack/openfmri/blob/master/pipeline/facemask/deface.py>
- https://github.com/hanke/gumpdata/blob/master/scripts/conversion/convert_dicoms_anatomy#L26

- <https://github.com/hanke/mridefacer>

Rendering faces unrecognizable

Even more data/information preserving approach is to just obscure facial features in the anatomical images:

- [Obscuring Surface Anatomy in Volumetric Imaging Data Used for HCP data](#)
- [QuickShear](#)

Contribute

Researchers

Survey

Please first fill out the VERY brief survey about the consent forms for your studies: <http://goo.gl/forms/2lsmYcOsAs> . It has only few questions and should take only a few minutes to fill out. Even if your Consent form doesn't include yet any provision for data sharing – your contribution would be very valuable, although would consist of simply saying “No”.

Additional materials

Please report to [GitHub issues](#) or even send a new pull request via [GitHub pull requests](#) with

- samples of consent forms allowing re-distribution/deposit to public archives
- relevant publications and discussions
- changes/recommendations for the **ultimate** consent form formulation

IRB committee members

We would welcome your feedback very much, in particular

- what concerns on public sharing of neuroimaging data you might have if any identifiable information removed (e.g. skull stripped) and subjects agreed to those terms?
- what particular consent form composition and wording aspects would you recommend? (e.g. “make it an explicit additional form requiring a separate signature”) and why?

Contact information

- directly via email open-brain-consent@datalad.org
- [GitHub issues](#) page

[Issues](#) | [Pull requests](#) | [Build status](#) | [Website](#)