HBP
Research Integrity SOP

Table of Contents

1. Background

The Human Brain Project wishes to clarify its position with regards to research integrity. Increasing attention to research integrity is driven by governmental organisations such as the European Commision and the Organisation for Economic Co-operation and Development (OECD), as well as non-governmental organisations such as Science Europe and All European Academies (ALLEA).

The H2020 AGA – Annotated Model Grant Agreement states that in Article 34 (Appendix 1) that 'all beneficiaries of must carry out the action in compliance with: (a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity'.

The HBP is committed to research excellence. This SOP sets out the principles and the responsibilities to which researchers and the HBP should adhere. In order to maintain the highest standards of research quality the HBP upholds the principles of the ALLEA and ESF European Code of Conduct for Research Integrity.

All researchers acting under the auspices of the Human Brain Project, including Partnering Projects, are expected to adhere to the highest standards of professional conduct and behaviour and are expected to perform their role with honesty, integrity and respect for their colleagues and research partners. The Human Brain Project is dedicated to promoting and supporting these standards and this level of performance.

These guidelines should be read in combination with and understood to apply in addition to other Human Brain Project/H2020 policies and documents, including, but not limited to: H2020 research ethics self-assessment, the Consortium Agreement, the HBP Compliance Management Standard Operating Procedure (SOP), and all other SOPs on ethical issues (listed in Appendix 2). All those who are involved in research in the Human Brain Project are expected to read this SOP.

2. Principles

2.1. Introduction

The research environment at Human Brain Project is based on the key qualities of honesty, openness, care, and accountability. The HBP is committed to developing and nurturing a culture of research integrity. This is achieved through actively supporting researchers and defining clearly how they can comply with ethical guidelines and good research practice. The aim is to create a framework for understanding how to design, manage, conduct, and disseminate research in a conscientious and responsible manner.

2.2. Definitions

'Research' may be defined as: an original investigation undertaken in order to generate new knowledge, understanding, and insight. It refers to all aspects of the research process. Research may also be defined by the Frascati classification.

'Researchers' are defined as: anyone who is involved in contributing to research. This includes academic, research, and relevant research support staff employed by the Human Brain Project, and other individuals carrying out research under the auspices of the Human Brain Project.

There can be some confusion about the difference between research integrity and research ethics, and how the two interrelate. One of the best explanations comes from the FWO (a Research Foundation):

> 'Research integrity is closely linked but not quite identical to research ethics. Integrity specifically involves those aspects that are linked to the quality of research practice and its results. Ethics is primarily about standards and values to be taken into account by the researcher to protect the well-being of humans and animals involved in research and the results thereof. A researcher may falsify data without immediately putting humans or animals at risk. Such a researcher does not act with integrity, for the results of his research are unreliable, but he does not engage in direct unethical conduct with respect to humans, animals and their environment. However, the fact that the use of such manipulated results may eventually cause harm to humans, animals and their environment, shows that integrity and ethics can never be completely separated. From a broad ethical point of view, falsification of research data or otherwise tampering with research data is, of course, unacceptable.

It should be further noted that:

- Poor practice in research does not include differences in the design, execution, interpretation or judgement in evaluating research methods or results, or what might be deemed academically poor research.

2.3. Values and Aims

2.3.1. Honesty and Openness

Researchers should be honest in respect of their own actions and intentions when undertaking research and in their responses and intentions towards the research of others. This applies to all aspects of the research process.

The Human Brain Project recognises the need for researchers to protect their own research interests in the process of planning their research and obtaining their results. Nevertheless, the HBP encourages researchers to be as open as possible in disseminating their work. For further guidance on the uploading, storage, and use of data please see the Data Policy Manual. Researchers should declare any potential or actual conflicts of interest in relation to their research when reporting their findings at meetings or in publications. For information on financial CoIs see the SOP on Conflicts of Interest.

2.3.2. Care

Researchers should show care and respect for all participants in and subjects of research, including humans, animals, the environment, and cultural objects. Those engaged in research must also show care and respect for the stewardship of research and scholarship for future generations.

2.3.3. Conflict of Interest

Researchers must be honest about conflict of interest issues, whether real, potential or perceived, at the earliest opportunity and at all stages of research, e.g. when applying for funding, when identifying collaborators and when reporting results. Please see the Human Brain Project's SOP on Conflict of Interest.

2.3.4. Accountability

Researchers must ensure that the research that they are undertaking is consistent with the terms and conditions covered by the Human Brain Project grant agreements and consortium agreements. This includes, but is not restricted to, ensuring that the research programme carried out is as defined in the original proposal, unless amendments have been agreed in writing; that all finance is used solely for the research purpose for which it was intended; that reports and deliverables are both accurate and produced on time; and that conditions relating to publication and ownership and use of data are adhered to.

2.3.5. Obligations

Researchers must comply with all applicable national and European laws and statutes relevant to the conduct of research.

3. Responsibilities

3.1. Research Environment

The Human Brain Project is responsible for supporting good research practice and ethics. This includes supporting researchers to understand and act according to expected standards, making Standard Operating Procedures and other policies easily available, and having procedures in place to ensure that research is conducted ethically and with integrity. The Ethics Management and wider SP12 Ethics and Society are working on providing ethics and integrity training on ethical issues and good research practices.

3.2. Leadership

The central governance bodies of the HBP, the Stakeholder Board, Science and Infrastructure Board and Directorate are responsible for the overall leadership and integrity of the project.

Work Package and Task Leaders are primarily responsible for maintaining good research practice in their research areas of the HBP.

4. Designing Research

4.1. Ethical Guidelines

All research must be designed and carried out with the necessary ethical approval and review. The overriding principle must be that no harm should be caused by the research investigation or the dissemination of its results. More details on the HBP's processes regarding ethics can be found in the Compliance Management SOP and related SOPs (appendix 2).

Before research begins Task Leaders should make all those involved in the research aware of the relevant legal and ethical requirements, appropriate methods of record keeping, data governance, and the importance of recognising and reporting unforeseen results or incidents (e.g. incidental findings).

5. Conducting Research

5.1. Research Involving Humans and Animals

In addition to designing research in accordance with ethical guidelines and health and safety policies, special care must be taken to ensure that research projects that include human participants or animals comply with the highest standards of research conduct:

- Research involving human participants, human material or personal data must comply with all legal and ethical requirements and any other applicable guidelines. Appropriate care should be taken when research projects involve: vulnerable groups, such as the very old, children or those with mental illness; and covert studies or other forms of research which do not involve full disclosure to participants. The dignity, rights, safety and well-being of participants must be the primary consideration in any research study. Research should be initiated and continued only if the anticipated benefits justify the risks involved.
- Research involving animals must adhere to all legal and ethical requirements and other applicable guidelines. The opportunities for reduction, replacement and refinement of research involving animals in research projects must always be considered.

For specific subject guidelines on research involving humans and animals see the H2020 Research Ethics Self-Assessment.

6. Documenting and Disseminating Results

6.1. Critical Approach

Researchers should always be prepared to question the outcomes of their research. The Human Brain Project expects all research results to be checked before being made public. It is important that research ideas can be challenged and tested once published.

6.2. Reproducibility

Reproducibility is the ability to duplicate the results of an experiment or research when it is repeated by other researchers. One of the consequences of poor research conduct is lack of reproducibility in a number of research subjects from Economics to Cancer studies.

As one of the aims of the HBP is to build a neuroscience infrastructure through which future research can flourish, it is especially important to avoid this issue. Often the causes of findings being unreproducible are lack of sufficient detail in the description of the methodology or limited sharing of the underlying datasets. These are often perfectly legitimate reasons for the research not being duplicated.

However, a lack of reproducibility can also indicate exaggeration or reduction of data significance, flawed statistical analysis, or even outright fraud. The 'pressure to publish' ethos does nothing to incentivise researchers to avoid the above problems. However, it is important to not 'cut corners' or alter findings. For more information on this topic see these articles: Research Integrity and Reproducibility and the Nature special Challenges in irreproducible research.

6.3. Research Data

See the Data Policy Manual for more information.

7. Publishing Conduct

The issue of authorship is important in the context of good research practice, and the Human Brain Project expects the matter to be taken seriously. It is advisable to address publication and authorship issues at an early stage of the project, and to document agreed decisions. Work Package Leaders, Task Leaders, and PIs must ensure that where appropriate all researchers have the opportunity to contribute to the publication process.

Researchers should clearly acknowledge all sources used in their research and seek

permission from any individuals if a significant amount of their work has been used in the publication.

In order to ensure a high standard of publication, researchers should, where appropriate, submit their work for peer review prior to publication.

Additionally, the ALLEA Code of Conduct states:

> 'Results should be published in an open, transparent and accurate manner, at the earliest possible time, unless intellectual property considerations justify delay. All authors, unless otherwise specified, should be fully responsible for the content of publication. Guest authorship and ghost authorship are not acceptable. The criteria for establishing the sequence of authors should be agreed by all, ideally at the start of the project.
>
> Contributions by collaborators and assistants should be acknowledged, with their permission. All authors should declare any conflict of interest. Intellectual contributions of others should be acknowledged and correctly cited. Honesty and accuracy should be maintained in communication with the public and the popular media. Financial and other support for research should be acknowledged.'

8. Research Misconduct

8.1. Definition

The definition includes, *but is not limited to*, the following:

8.1.1. Fabrication

This comprises the creation of false data or other aspects of research, including documentation and participant consent.

8.1.2. Falsification

This comprises the inappropriate manipulation and/or selection of data, imagery and/or consents.

8.1.3. Plagiarism

This comprises the misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.

8.1.4. Misrepresentation, including:

- Misrepresentation of data, for example suppression of relevant findings and/or data, or knowingly, recklessly or by gross negligence, presenting a flawed interpretation of data
- Undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication
- Misrepresentation of interests, including failure to declare material interests either of the researcher or of the funders of the research
- Misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience which are not held
- Misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution

8.2. Breach of duty of care

Whether deliberately, recklessly or by gross negligence:

- Disclosing improperly the identity of individuals or groups involved in research without their consent, or other breach of confidentiality;
- Placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent; this includes reputational danger where that can be anticipated
- Not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, to ensure appropriate informed consent is obtained properly, explicitly and transparently
- Not observing legal and reasonable ethical requirements or obligations of care for animal subjects, human organs or tissue used in research, or for the protection of the environment
- Improper conduct in peer review of research proposals or results (including manuscript submitted for publication); this includes failure to disclose conflicts of interest (for information on financial CoIs see the SOP on Conflicts of Interest); inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for peer review purposes

8.2.1. Improper dealing with allegations of misconduct:

- Failing to address possible infringements including attempts to cover up misconduct or reprisals against whistle-blowers
- Failing to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct.

8.2.2. Differing Research Norms

In the HBP where partners and task leaders may be relying on their particular scientific, cultural, and disciplinary norms, and these may differ between institutions and countries. This can be problematic when agreeing on good research conduct and/or when individuals raise concerns regarding research conduct - what is acceptable in one place is bad practice elsewhere. Adherence to the principles outlined in this document and the ethical requirements of H2020 projects will avoid most conflicts.

8.3. Reporting Concerns Regarding Research Misconduct

If anyone (whether part of the HBP or not) wishes to get clarification on an issue regarding research conduct or report suspected research misconduct within the HBP they can do so (anonymously if required) via PORE. In addition, advice can be sort from the relevant SP Ethics Rapporteurs, the Ethics Management team.

8.4 Investigation of Research Misconduct

8.4.1 Assessment of Allegation(s)

If an allegation(s) of research misconduct is made via any of the aforementioned channels (PORE, Ethics Management, Ethics Rapporteurs) a preliminary assessment will be made regarding the nature of the complaint, the evidence available, and the action required. Unless the allegation(s) is obviously frivolous, malicious, or mistaken this assessment will be made in collaboration with the Ethics Advisory Board and the Ombudsperson.

The assessment will determine whether any immediate action is necessary to ensure safeguarding of animal or human subjects and/or whether any legal action is required. If neither of these actions are required then the issue will be brought to the attention of the relevant institutions as well as the SIB and DIR. The HBP expects all institutions conducting research on behalf of the project to investigate any such allegations in a thorough and fair manner with full written documentation of the steps taken and the evidence acquired.

8.4.2 Allegation(s) Not Upheld

If the respondent (the person about whom the allegation(s) was made) is found not to have committed research misconduct they must not receive any unfair or prejudicial treatment because of the investigation. A full and public (if they so wish) statement must be made establishing that they are cleared of any wrongdoing.

8.4.3 Allegation(s) Upheld

If the respondent is found guilty of research misconduct then the partner institution must treat the matter as a disciplinary offence. Should it be found that the matter has not been satisfactorily dealt with there may be penalties, as outlined in Article 34 of the Annotated Model Grant Agreement. This may include the grant being reduced or the participation of the researcher(s) being terminated.

In formulating this SOP, HBP Ethics Management has been informed by:

- ALLEA and ESF The European Code of Conduct for Research Integrity
- De Montfort University Guidelines For Good Research Practice
- The Universities UK Concordat to Support Research Integrity
- Code of Practice for Research, UK Research Integrity Office
- RCUK Policy and Guidelines on Governance of Good Research

Appendix:

1. H2020 AGA Annotated Model Grant Agreement: Article 34 - Ethics

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for
instance, in the European Code of Conduct for Research Integrity47 — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the 'ethics requirements' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the [Commission][Agency] copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or

- the coordinator has obtained explicit approval (in writing) from the [Commission][Agency] (see Article 52).

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

List of Ethics SOPs

- HBP SOP Conflict of Interest,
- HBP SOP Informed Consent,
- HBP Data Policy Manual (draft),
- HBP SOP Non-EU Animal Data,
- PORE SOP,
- EAB SOP,
- HBP Ombudsman SOP,
- SOP Rapporteur Programme