**Application for a statement from the HAW Hamburg Ethics Commission on a proposed research project**

**Notes:**

Timing of the application:

As a rule, the Ethics Commission only reviews applications that are submitted BEFORE the research work begins. Applications submitted retroactively cannot be reviewed.

Submission process:

Wherever possible, please submit the application and all supporting documents as a PDF document.
In the event of revisions or additions, please highlight the elements that have been revised in colour.

Complete documents:

A positive ethics statement on a proposed research project requires the submission of all questionnaires, declarations of consent, guidelines, etc. If it is not possible to include these documents when the application is submitted, the applicant needs to explain why this is the case and submit the necessary documents as soon as possible following submission of the application. A conditional positive statement can be issued until all of the documents have been submitted.

Second statements:

In the event that a positive initial statement has been made by another ethics commission and there is a justified wish for a second statement from the HAW Hamburg Ethics Commission, such a second statement can be prepared.

Follow-up research / new research questions:

Applicants are required to apply for the ethical review of new research questions that may arise during the research process and lead to corresponding follow-up research. The result of the review can subsequently be integrated into the existing positive statement via an addition to the initial application.

**Legal regulations:**

Applications that are subject to [Section 40](https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p1004) Paragraph 1 of the [Medicinal Products Act (Arzneimittelgesetz, AMG)](http://de.wikipedia.org/wiki/Arzneimittelgesetz_%28Deutschland%29) (AMG), [Section 20](http://bundesrecht.juris.de/mpg/__20.html) Paragraph 1 of the [Medical Products Act](http://de.wikipedia.org/wiki/Medizinproduktegesetz) (MPG) or [Section 8](http://bundesrecht.juris.de/stzg/__8.html) / [Section 9](http://bundesrecht.juris.de/stzg/__9.html) of the Stem Cell Act (StZG) should be submitted to the legally responsible ethics commissions. Furthermore, professional codes of ethics for various professions, such as physicians, may specify additional regulations and jurisdictions.

Application for a statement from the HAW Hamburg Ethics Commission on a proposed research project

# Applicant[[1]](#footnote-1)

Name:

Faculty and department:

Competence Center or Research and Transfer Centre (FTZ) (where applicable):

Position:

Address

Email:

Telephone:

**In the case of final theses for a particular degree[[2]](#footnote-2):**

Name of the supervising professor:

Faculty and department:

Competence Center or Research and Transfer Centre (FTZ) (where applicable):

Position:

Address

Email:

Telephone:

Short title (acronym) of proposed research project (max. 50 characters):

Title of proposed research project:

Date of application:

# 1. General information

Does the proposed research project[[3]](#footnote-3) involve...?

Primary research [ ]

Secondary research [ ]

A final thesis [ ]

Other [ ]  Please explain:

Click or type here to enter text.

Has the proposed research project already been submitted to another ethics commission?

*No* [ ]  *Yes* [ ]

If yes, when and where?[[4]](#footnote-4)

Click or type here to enter text.

*Has the proposed project been approved by the above-mentioned commission? (Please include a copy of the statement.)*

*No* [ ]  *Yes* [ ]

Comment:

Click or type here to enter text.

Is the proposed research project submitted here a sub-study that is part of a larger research project?

*No* [ ]  The proposed research project is an independent study.

Yes [ ]  The proposed research project is a sub-study as part of the following project.

*Title of the overarching project:*

*If yes, please provide details about the overarching project and the role of the sub-study:*

Click or type here to enter text.

**Additional information:**

A positive ethics statement on a proposed research project requires the submission of all questionnaires, declarations of consent, guidelines, etc. If it is not possible to include these documents when the application is submitted, the applicant needs to explain why this is the case and submit the necessary documents as soon as possible following submission of the application. A conditional positive statement can be issued until all of documents have been submitted.

**Research question/goal, framework and methodology of the proposed research project**

*Please describe the question or goal of the proposed research project, the academic justification (theoretical framework, relevance)*[[5]](#footnote-5)*, the design, and the intended methodology (ideally in no more than 1,000 words; please do not refer to other, more detailed documents; please include the bibliography under the corresponding point at the end of the application).[[6]](#footnote-6)*

Click or type here to enter text.

Has the academic quality of the proposed research project been reviewed by a third party?

|  |  |
| --- | --- |
| *Independent or external reviewer* | [ ]  |
| *Company-internal review* | [ ]  |
| *Review within a multi-centre or interdisciplinary research group* | [ ]  |
| *Review by the individual responsible for the project**Institution or guest institution* | [ ]  |
| *Review within the research team* | [ ]  |
| *Review by the supervisor* | [ ]  |
| *No review by a third party* | [ ]  |
| *Other (Please explain)* | [ ]  |

Click or type here to enter text.

# 2. Research on and with human subjects

Are people involved as participants in the project?[[7]](#footnote-7)

No [ ]  Please go to Point 3.

Yes [ ]

How will potential participants be selected? Please list the criteria for selection and non-selection.

Click or type here to enter text.

How will potential participants be contacted (recruitment)?

Click or type here to enter text.

How will potential participants be enrolled in the study (see also ‘Obtaining consent’ under Point 2.1)?

Click or type here to enter text.

Is cooperation with other institutions/partners necessary for recruitment and enrolment?

No [ ]

Yes [ ]  If yes, please provide more detail.

Click or type here to enter text.

## 2.1 Consent

Will data or information about people be collected without them knowing that this is the case?

*No* [ ]

*Yes* [ ]  If yes, why is this justified?

Click or type here to enter text.

Has a voluntary and informed declaration of consent to participate in the study been completed?[[8]](#footnote-8)

*Yes* [ ]  Please include the information about the study and the declaration of consent in the appendix.

*No* [ ] If no, please list the specific reasons for this.

Click or type here to enter text.

How are participants being informed about the research project? Will other methods of providing information besides information sheets be used (e.g. videos, interactive media)? *A copy of the information sheet and other relevant examples should be included with this application.*

Click or type here to enter text.

Will a written declaration of consent be obtained from the study participants following the provision of information about the study?

*Yes* [ ]  If yes, please describe the following aspects: Who will obtain the declaration of consent? When and how will they do so?

Click or type here to enter text.

*No* [ ]  If a declaration of consent will not be obtained from the study participants, please explain the specific reason why this is the case.

Click or type here to enter text.

Where and how will the declarations of consent be stored? How will confidentiality be ensured? Who is responsible for ensuring that the declarations will be destroyed/deleted after a maximum of 10 years in compliance with data protection regulations?[[9]](#footnote-9)

Click or type here to enter text.

How much time do potential participants have to decide whether or not they want to participate in the study?

Click or type here to enter text.

Will the participants be informed that they can choose not to participate (without facing consequences) or can withdraw from the study at any time (before the data is anonymised)?

*No* [ ]

*Yes* [ ]

Will financial or other incentives be provided to study participants?

*No* [ ]

*Yes* [ ]  If yes, please specify the type and amount of incentive/payment.

Click or type here to enter text.

## 2.2 Vulnerable groups

Does the proposed research project include participants who are not able to provide informed consent?[[10]](#footnote-10)

*No* [ ]

Yes [ ]  If yes, please check the boxes that apply:

Does it involve children/minors? [ ]

Does it involve patients who are currently receiving medical treatment? [ ]

Adults who are unconscious or severely ill [ ]

Adults with terminal illnesses [ ]

Adults in crisis situations [ ]

Adults with mental illnesses [ ]

Adults with dementia [ ]

What preventative measures will you take to ensure the highest possible level of protection for these people? (Please outline in detail.)

Click or type here to enter text.

Are the circumstances of the proposed research project such that the choice not to participate is made more difficult (e.g. relationships of dependency, such as when potential study participants are also students of the researcher/s)?

*No* [ ]

Yes [ ]  If yes, please outline the reasons that choosing not to participate could be more difficult and how you plan to deal with this.

Click or type here to enter text.

## 2.3 Research process

Will topics that are sensitive, embarrassing, invasive or could be perceived as stigmatising be discussed within the proposed research project as part of conversations, interviews or questionnaires? (Please include the questionnaire/interview outline or similar documents as an appendix.[[11]](#footnote-11))

No [ ]

Yes [ ]  If yes, please provide more detail and explain why this is justified and how it will be dealt with.

Click or type here to enter text.

Could criminal or other activities that require appropriate measures possibly come to light as part of the proposed research project (e.g. a study on drug consumption)?

No [ ]

Yes [ ]  If yes, please provide more detail and explain why this is justified and how it will be dealt with.

Click or type here to enter text.

Does the proposed research project involve physical procedures (invasive procedures) being carried out on the participants?

No [ ]

Yes [ ]  If yes, which measures will be taken to ensure the safety of participants? Is the individual carrying out these procedures adequately qualified to do so?

Click or type here to enter text.

Is it possible that physical, mental or social harm (e.g. trauma) could occur as a result of the questioning/examination?

No [ ]

Yes [ ]  If yes, what can be expected and how will you deal with it? (E.g. is there follow-up care?)

Click or type here to enter text.

Does the research involve deception regarding the goals or intentions?

No [ ]

Yes [ ]  If yes, will the participants be informed of this? When? How? By whom?

Click or type here to enter text.

## 2.4 Research data from human subjects

Is it permissible to use the data collected under current data protection law? Please outline the legal basis.

Click or type here to enter text.

Will non-anonymised personal information from your own or external sources be collected, stored or processed as part of your proposed research project?[[12]](#footnote-12)

No [ ]  Please go to Point 3.

Yes [ ]

Will the participants be informed about their data protection rights? (Please include documentation of this.)

Click or type here to enter text.

Where, how and by whom will the personal data be stored and processed? Who has access to this data? Which personal data may possibly be passed on to whom?

Click or type here to enter text.

In the case of collaborations: What contractual agreements will ensure the upholding of data protection regulations?

Click or type here to enter text.

Which measures will be used to ensure the confidentiality of personal data? Please describe whether you will carry out pseudonymisation (coding list) or another form of anonymisation and, if yes, which form and in which phase of the project?

Click or type here to enter text.

Who is responsible for ensuring confidentiality?

Click or type here to enter text.

When will personal data be deleted or anonymised (where applicable: how will anonymisation be carried out)? Who is responsible and how will the deletion or anonymisation be guaranteed?

Click or type here to enter text.

*Is subsequent use of the data for other purposes planned (e.g. open data)? If yes, for which set of users? Will access be regulated? Which measures are being taken to prevent de-anonymisation? How is this information being conveyed in the declaration of consent?*

Click or type here to enter text.

# 3. Research on and with human cells/tissue[[13]](#footnote-13)

Are you planning to carry out research on human cells or tissue?

No [ ]

Yes [ ]  If yes, what is the ethical basis for this research? Where applicable, please outline the legal aspects (e.g. Directive 2004/23/EC).

Click or type here to enter text.

# 4. Research on and with human embryos/foetuses[[14]](#footnote-14)

Are you planning to carry out research on human embryonic stem cells?

No [ ]

Yes [ ]  If yes, please outline the legal basis that makes this research permissible. What is the ethical basis for this research?

Click or type here to enter text.

# 5. Sustainability

Can conflicts with human rights or sustainability (particularly with respect to the United Nations sustainable development goals or the Paris agreement) be expected as a result of the proposed research project and the accompanying goals?

No [ ]

Yes [ ]  If yes, please provide more detail. Please also describe how you plan to address these conflicts.

Click or type here to enter text.

# 6. Human rights

Can conflicts with human rights be expected as a result of the proposed research project and the accompanying goals?

No [ ]

Yes [ ]  If yes, please provide more detail. Please also describe how you plan to address these conflicts.

Click or type here to enter text.

# 7. Environmental protection and ecology

Are the proposed research project and the accompanying goals in conflict with environmental and climate protection (particularly with respect to the United Nations sustainable development goals or the Paris agreement)?

No [ ]

Yes [ ]  If yes, please provide more detail. Please also describe how you plan to address these conflicts.

Click or type here to enter text.

Does the proposed research project contain elements that impact the environment, animals or plants?

No [ ]

Yes [ ]  If yes, please provide more detail. Please outline why this is justified and what protective measures you plan to implement.

Click or type here to enter text.

Do you plan to work with protected species?

No [ ]

Yes [ ]  If yes, please provide more detail. Please outline why this is justified, the legal basis that makes it permissible and what protective measures you plan to implement. Are additional authorisations required?

Click or type here to enter text.

## 8. Evaluation of technological consequences

Are you planning to develop new technologies or further develop existing technologies?

No [ ]

Yes [ ]  If yes, please describe those areas where you believe that the proposed research project could have an impact. To do this you can, for example, use the following perspectives as orientation: (overall total of **max.** 750 words)

- Legal aspects (e.g. legal aspects related to animal welfare)

- Economic aspects (e.g. business models)

- Societal aspects (e.g. influence on social structures/political consequences)

- Ecological aspects (e.g. influence on environmental factors)

- Ethics of technology dimension (e.g. data, media and machine ethics)

- Interactions between the dimensions discussed

Click or type here to enter text.

If you believe that there are potential areas where societal conflict could arise regarding the acceptance of the proposed research project’s findings, please describe these briefly.

Click or type here to enter text.

## 9. Autonomous technologies and artificial intelligence

Will the proposed research project involve or develop technologies which can be expected to violate the ethical principles of upholding human autonomy, damage prevention, fairness and explainability?[[15]](#footnote-15)

No [ ]

Yes [ ]  If yes, please provide more detail. Please outline why this is justified and what protective measures you plan to implement. How is responsibility for the consequences of the application addressed?

Click or type here to enter text.

Will the proposed research project involve or develop technologies (hardware or software) which can be expected to have the task of ethically relevant decision-making support/preparation, or that could or should make ethically relevant decisions in future?

No [ ]  Please go to Point 10.

Yes [ ]  If yes, please provide more detail.

Click or type here to enter text.

How is responsibility for the consequences of the application addressed?

Click or type here to enter text.

What data will serve as the basis for the preparation and taking of the decisions outlined above? How will you ensure that these decisions are made in a fair and non-discriminatory manner?

Click or type here to enter text.

# 10. Research in low- and middle-income countries

Will resources from low- and middle-income countries be used for the proposed research project?

No [ ]

Yes [ ]  If yes, what type of benefit compensation is planned?

Click or type here to enter text.

Will the proposed research project entail data collection in low- and middle-income countries?

No [ ]

Yes [ ]  If yes, how will the respective countries be provided access to the data and research findings?

Click or type here to enter text.

# 11. Dual use[[16]](#footnote-16)

Are there concerns or a more than minimal probability that the research findings could be used for military purposes?

No [ ]  Please go to Point 12.

Yes [ ]  If yes, please provide more detail.

Click or type here to enter text.

Which measures are being taken to prevent military use?

Click or type here to enter text.

Does the research project involve dual-use items (items with a double purpose pursuant to the EU Council Regulation 428/2009 – i.e. items that include data-processing programmes and technologies and that could be used for civil as well as military purposes)?

No [ ]  Please go to Point 12.

Yes [ ]  If yes, please provide more detail.

Click or type here to enter text.

*How is responsibility for the consequences of the application addressed? Please describe this briefly.*

Click or type here to enter text.

# 12. Misuse of research results

Is there potential for your research findings to be misused[[17]](#footnote-17)?

No [ ]  Please go to Point 13.

Yes [ ]  If yes, please provide more detail.

Click or type here to enter text.

Which measures are being taken to prevent misuse of the research results?

Click or type here to enter text.

# 13. Carrying out the project

Where will the project take place? (Setting, location)

Click or type here to enter text.

Who is covering the costs of the research project?

Click or type here to enter text.

Please outline all potential conflicts of interest that could arise for the project, the project leads and the project participants.

Click or type here to enter text.

Please outline all other aspects possibly requiring ethical consideration which the commission should be aware of.

Click or type here to enter text.

How is publication of the research findings planned? Will research data from the project be made available for further use? Where applicable, which licence is being considered for this?

Click or type here to enter text.

# 12. List of attachments

Which attachments/documents are included with the application?

|  |  |
| --- | --- |
| Informational material / Brochures, etc. for potential study participants | [ ]  |
| Declaration of consent for participants | [ ]  |
| Data protection policy | [ ]  |
| Letter to participants | [ ]  |
| Letter to parents/guardians, etc.  | [ ]  |
| Letter of approval from ethics commission or another letter of approval  | [ ]  Please list:Click or type here to enter text. |
| Copy of the study protocol | [ ]  |
| Other relevant documents | [ ]  Please list:Click or type here to enter text. |

# 13. Signatures:

* I hereby confirm that I have answered the questions in this application truthfully and to the best of my knowledge.
* I guarantee that the research work that is the focus of this application has not yet been started.
* I will inform the Ethics Commission of changes or additions to this application in a timely manner, providing documents for review where necessary.
* In the event that the research findings are published, I will provide a copy of the publication to the Ethics Commission, indicating the file number (this does not apply to final degree theses/dissertations).[[18]](#footnote-18)

Signature of the lead researcher:

……………………………………………………….

Date: …………………………………………..

Signature of supervising professor at HAW Hamburg or the head of the study (if applicable):

I have reviewed the application and support it as presented in this version.

……………………………………………………….

Date: .………………………………………….

# Sources

1. The person submitting the application should also be the principal researcher (project head). [↑](#footnote-ref-1)
2. For example, doctoral dissertation, Master’s thesis, Bachelor’s thesis [↑](#footnote-ref-2)
3. The terms ‘proposed research project’, ‘research project’ and ‘study’ are used here interchangeably. [↑](#footnote-ref-3)
4. Studies that are currently being evaluated by another German ethics commission will not be reviewed by the HAW Hamburg Ethics Commission until the other process is completed. [↑](#footnote-ref-4)
5. Guideline 9 of the German Research Foundation’s ‘Guidelines for Safeguarding Good Research Practice: Code of Conduct’ states the following: Researchers take into account and acknowledge the current state of research when planning a project. To identify relevant and suitable research questions, they familiarise themselves with existing research in the public domain. HEIs [higher education institutions] and non-HEI research institutions ensure that the necessary basic framework for this is in place. [↑](#footnote-ref-5)
6. The description should make it possible for members of the Ethics Commission to obtain an understanding of the proposed research project that is clear enough for them to evaluate it. The description should be written in such a way that it can also be comprehended by academically educated people who do not work in the specific area of the proposed research project. [↑](#footnote-ref-6)
7. Appendix 2 (HAW Hamburg Ethics Commission) of the Statute on Ensuring Good Academic Practice at HAW Hamburg expressly emphasises that ‘ethical standards with respect to a humane approach and the dignity, self-determination and autonomy of the individual’ must be respected. For a more detailed description, reference is made to the Declaration of Helsinki, which covers medical research but should also applied wherever possible to research on and with human subjects. In particular, the principles related to privacy and confidentiality (Point 24) and informed consent (points 25–32) should be observed. [↑](#footnote-ref-7)
8. In accordance with principles 25–32 of the Helsinki Declaration from the World Medical Association: <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> [↑](#footnote-ref-8)
9. According to the explanations provided under Guideline 17 of the German Research Foundation’s ‘Guidelines for Safeguarding Good Research Practice: Code of Conduct’, research data are ‘generally archived in an accessible and identifiable manner for a period of ten years at the institution where the data were produced or in cross-location repositories.’ [↑](#footnote-ref-9)
10. See footnote 8 or further additions from <https://www.forschungsdaten-bildung.de/einwilligung> for comparison. [↑](#footnote-ref-10)
11. If the final questionnaire/interview outline will not be developed until later in the proposed research project, this should be submitted to the Ethics Commission well in advance of the start of data collection for supplementary evaluation. [↑](#footnote-ref-11)
12. The General Data Protection Regulation (GDPR) should be taken into account in order to assess whether data protection is relevant to the proposed project. It does not contain a definition of **anonymisation**; it provides guidelines only: ‘The principles of data protection should ... not apply to anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.’ (Recital 24 GDPR)

‘**Pseudonymisation** means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person.’ (Article 4 GDPR) [↑](#footnote-ref-12)
13. The Ethics Commission reserves the right to refer applications to the jurisdiction of another ethics commission. [↑](#footnote-ref-13)
14. The Ethics Commission reserves the right to refer applications to the jurisdiction of another ethics commission. [↑](#footnote-ref-14)
15. Particularly in terms of the following: • The priority of human action and human supervision • Technical robustness and security • Data protection and data quality management • Transparency • Diversity, non-discrimination and fairness • Societal and ecological welfare • Accountability.

 <https://www.demographie-netzwerk.de/site/assets/files/5064/ethicsguidelinesfortrustworthyai-depdf.pdf> [↑](#footnote-ref-15)
16. The preamble of the HAW Hamburg university statute states: ‘HAW Hamburg views itself as obligated to take on societal responsibility in its academic, teaching and administrative activities and to work in a lasting way towards the peaceful social, just and democratic political, technological, ecological and economic development of society in its teaching, research and professional continuing education.

The research, teaching and degree studies at HAW Hamburg are committed to peaceful goals and are intended to fulfil civil aims; the research, in particular the development and optimisation of technical systems, as well as the degree studies and teaching are centred around civilian use.’ [↑](#footnote-ref-16)
17. E.g. Could the materials, methods, technologies and knowledge generated cause damage to humans, animals, plants or the environment it they were changed or developed further? [↑](#footnote-ref-17)
18. If the publication is part of a book and an electronic version is not available, the provision of the publication details to the Ethics Commission will suffice. It is requested that a copy of the book be made available to the HAW Hamburg library. [↑](#footnote-ref-18)