Research Ethics Committee
of the University of Bayreuth

UNIVERSITÄT BAYREUTH

Request

for the University of Bayreuth Research Ethics Committee's assessment and expert opinion on a research project

I. Information on the applicant and research funding

1. Applicant(s) (if more than one applicant, please list all names)

2. Title of the project

3. Sponsor of the project/ context

a) The project (also) pursues commercial interests
yes ☐ no ☐
If so, which ones:

(b) the project is aimed at the award of a degree or diploma
yes ☐ no ☐
If so, which one:

4. Project period

5. Is the ethics vote required by a third party?
yes ☐ no ☐
If so, by whom?

6 a) This request is for an ethics vote in accordance with
§ 1 para 1 ☐ *or* *§ 1 para 2* ☐
of the Rules of Procedure of the Research Ethics Committee at the University of Bayreuth.

6 b) An ethics vote is considered necessary in my own estimation because

Which aspects should be given special consideration?

7. The project, taking into account the valid regulation, is subject to a procedure pursuant to
a) REGULATION (EU) No. 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL or § 40, § 40a - 40d and § 41 AMG (Medicinal Products Act)
yes ☐ no ☐

b) REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL or § 23 - 37 MPDG (Medical Device Law Implementation Act)
yes ☐ no ☐

Links to the relevant German and European regulations

German legal texts

https://www.gesetze-im-internet.de/amg_1976/

https://www.gesetze-im-internet.de/mpdg/

EU Regulations

https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32014R0**536**

https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:02017R0**745**-20170505&from=EN

II Information on the project

Risk summary from the researcher's perspective: Please summarize possible risks that could arise directly or indirectly from the research project (e.g., risks to humans, animals, the environment, social relationships, etc.). - Please limit yourself to 5 -10 points if you do in fact see a basis for risk from your research project project.

1. Description of the project
a) the objective of the project:

b) methods used:

2. If the project includes test persons
a) selection and exclusion criteria
(number, age, educational level, gender, application of criteria for differentiating human diversity, for example in this context ethnicity, specific genetic characteristics, etc.)

b) method of recruitment

c) Are the test persons put under physical or psychological strain?
(Physical stress, e.g. through invasive methods such as blood collection or medication, saliva collection, invasive or non-invasive measurements; psychological stress, e.g. via related traumatization risks or negative experiences, duration of activity)
yes ☐ no ☐
If so, please provide a rationale:

III. Informing the test persons and obtaining consent

1. Are test persons fully informed from the outset about the objectives, duration, and course of the project?
yes ☐ no ☐
If not, please provide a rationale:

2. Are test persons informed from the outset that they should not expect to receive any personal benefit as a result of participation, or (if applicable) are they informed of what personal benefit they can expect to receive?
(e.g. expense allowance, learning experience)
yes ☐ no ☐
If not, please provide a rationale:

3. Are study participants informed of the scientific significance of the study?
yes ☐ no ☐
If not, please provide a rationale:

4. Prior to the start of the study, are test persons informed of burdens and risks that result from specific experimental procedures?
yes ☐ no, because no risks are known ☐
If so, what risks exist and how? To what extent is information is provided?

5. Do test persons receive feedback regarding
a) the results of the study?
yes ☐ no ☐
If not, please provide a rationale:

b) individual findings of the examination?
yes ☐ no ☐

please provide a rationale:

6. Are test persons informed about how personal data is handled?
yes ☐ no ☐
If not, please provide a rationale:

7. Is a written declaration of consent required?
yes ☐ no ☐
If not, please provide a rationale:

8. Does the declaration of consent contain the information in written form or clearly refer to it?
yes ☐ no ☐
If not, please provide a rationale:

9. Are test persons informed of the possibility of withdrawing their consent without stating a reason?
yes ☐ no ☐
If not, please provide a rationale:

10. Is a copy of the declaration of consent and information together with the official address and signature of the investigator given to the test persons?
yes ☐ no ☐
If not, please provide a rationale:

Section IV: Animal welfare concerns

1. Are animal experiments in the sense of § 7 TierSchG (Animal Protection Act) carried out?
yes ☐ no ☐
If so, please specify the indispensability in terms of § 7a TierSchG:

2. If question IV.1 was answered in the affirmative: Are the requirements of § 9 TierSchG in conjunction with § 3 TierSchVersV guaranteed?
yes ☐ no ☐
If not, please provide a rationale:

3. Has an animal welfare committee been set up within the meaning of § 6 TierSchVersV?
yes ☐ no, a committee is not required ☐
If not, please justify why it is not necessary:

4. Is a permit according to § 11 TierSchG necessary, and has one already been granted?
yes ☐ no permit is required ☐
If so, please specify:

V. Data protection

Please note: Data protection aspects of the project are not reviewed by the Research Ethics Committee for their legality; data protection issues are only included to the extent that they are relevant for the ethical evaluation of the project. A vote by the Research Ethics Committee therefore does not replace consultation with the relevant data protection officer.

1. Is personal data collected and stored in the sense of Article 4 No. 1 DSGVO?
(Personal data means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier, or to one or more particular characteristics expressing the physical, physiological, genetic, psychological, economic, cultural, or social identity of that natural person.)
yes ☐ no ☐
If so, please specify and provide a rationale:

2. In the case of collecting personal data in the sense of Question V. 1, have the subjects been given the opportunity to consent to the processing of the relevant personal data for one or more specific purposes (cf. Article 6 para 1 sentence 1 item a), Article 7 para 1 and 2 DSGVO), and are study participants informed of the possibility of withdrawing consent at any time without consequences (Article 7(3) DSGVO) without stating reasons?
yes ☐ no ☐
If not, please provide a rationale:

3. Are study participants informed about their right to demand the deletion of their personal data at any time (even after the end of the study)?
yes ☐ no ☐
If not, please provide a rationale:

4. If the personal data collected also includes sensitive data in the sense of Article 9 para 1 DSGVO.
(Sensitive data is any personal data revealing racial or ethnic origin, political opinion, religious or philosophical conviction, trade union membership, genetic data, biometric data revealing the unique identity of a natural person, health data or data relating to the sex life, or sexual orientation of a natural person.)
yes ☐ no ☐
If so, please specify and provide a rationale:

5. Is the data (including interview transcripts, etc.) pseudonymized (Article 4 No. 5 DSGVO)?
(Processing of personal data is pseudonymous if it can no longer be attributed to a specific subject without having additional information, provided that such additional information is kept separately and is subject to technical and organisational measures ensuring that the personal data is not attributed to an identified or identifiable natural person).
yes ☐ no ☐
If not, please provide a rationale:
If so, please explain how anonymization and pseudonymization are carried out:

I hereby confirm the correctness of the information given above!

Bayreuth, [date:] _____
(signature of applicant)