**Standardized Form - Specifications cannot be changed!**

**If an item is not applicable, mark it accordingly (e.g. “not applicable”). Do not leave any item blank.**

**Please send your application and all related documents as a single PDF file to** **nadine.mohaupt@uni-potsdam.de****.**

**1 Principal Investigators**

**1.1 Applicant:**

Institution:

Institute/Department at the UP:

Address:

Phone/Fax/E-mail:

**1.2 Principal investigator:**

Same as Applicant ( )

Institution:

Institute/Department at the UP:

Address:

Phone/Fax/E-mail:

**1.3 Participating researchers**

1.3.1

Name:

Institution:

Institute/Department at the UP:

Address:

Phone/Fax/E-mail:

1.3.2 **Participation of more than one institution**

If more than one institution is involved in the project, indicate which institution is authorized to make decisions with regard to the research purposes (reason and goal) *and* the applied research resources (technical facilities and methods) and which institutions may only collect/ process (bound by instructions) data on behalf of the decision-makers.

**1.4 Scientific and professional competence of the investigators for the realization of the project**

**2. General Project Information:**

**2.1 Title:**

**2.2 Subject area:**

**2.3 Project duration and schedule:**

*2.3.1 Start*

*2.3.2 Estimated completion*

**2.4 Project funded by:**

**2.5 Project history:**

It is a

new application ( )

resubmission\* ( ) Please state application number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

extension\* ( ) Please state application number \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

amendment/supplementary application\* ( ) Please state application number \_\_\_\_\_\_\_\_\_\_\_\_\_\_

(\*In case of resubmission, amendments or supplementary applications, clearly mark the changes compared to the previous application!)

Has the application already been assessed by another ethics commission?
 (yes) (no)

If yes, where, when and under which identification number?

**2.6 Insurance**

The subjects are insured by:

(Enclose a copy of the insurance policy.)

If no insurance has been procured, add a justification why insurance is not necessary/ cannot be financed.

**3. Purpose, Short Description and Classification of the Project**

**3.1 Purpose**

(Please describe the research question and goal in two sentences and in generally understandable language!)

**3.2 Project description**

*3.2.1 Background*

*3.2.2 Research question*

*3.2.3 Test description*

Please describe in detail and in generally understandable language, what will be done with the subjects/patients. Consider the following points:

- appropriateness of the research plan to answering the research question,

- necessity and benefits of the procedure,

- adequacy of methods and goal,

- a list of all abbreviations used!

- presentation of all steps of the examination procedure, incl. listing all

test methods (e.g. psychological tests, experiments, questionnaires, neurophysiological procedures, blood sampling, imaging techniques;

- for technical procedures, information on the device and manufacturer information, declaration of conformity, approval!

*3.2.4 Exposure assessment*

Please describe in detail possible burdens, risks, and damages to the subjects and define precautionary measures to avoid such risks (termination criteria). Explain why these burdens are ethically justifiable in light of the expected gain in knowledge.

**3.3 Formal classification of the project**

*3.3.1 Description of the subjects*

3.3.1.1 Are the subjects explicitly recruited for this study?

3.3.1.2 Description of recruiting procedure

3.3.1.3 Description of inclusion and exclusion criteria

3.3.1.4 Evidence of adequate size of subject groups (biometrical planning, power analysis)

3.3.1.5 Are the subjects patients?

3.3.1.6 Are the subjects especially vulnerable (e.g. children or patients unable to give consent, patients with cognitive or mental impairments or socio-economically disadvantaged patients)?

If yes,

Description of the subjects:

Explain why the study must be conducted with this population:

Which special measures will you take to protect the subjects from this population?

Information and consent of minors: Confirmation that the consent of all persons having care and custody of the child and the consent of minors able to give consent are obtained.

3.3.1.7 Are students or staff among the group of subjects who are in a dependent relationship with the person(s) conducting the study?

If yes: How do you make sure that the subjects will not suffer any disadvantages (e.g. when discontinuing their studies) or are under pressure to participate?

3.3.1.8 How do you inform the subjects? How much time do they have between information and signing the consent form?

3.3.1.9 Will subjects be remunerated?

e.g. extent of financial compensation or promise of other benefits; reimbursement of travel expenses; financing

*3.3.2 Classification of the study*

3.3.2.1 Is it a multi-center study?

If so, which other institutions are involved and which other ethics commissions are dealing with the study? What is the exact part of the applicant?

3.3.2.2 Will the study use procedures that may assist diagnostics?

If yes:

* What expertise do you have in medical diagnostics and, if necessary, counseling?
* How will you deal with incidental findings? Will you inform the subjects (e.g. about anatomical abnormalities in MRI, abnormalities in the EEG, ECG, in clinical tests such as depression tests, etc.) or
* Is medical diagnostics explicitly excluded? Will you exclude subjects who do not want to be informed about incidental findings (recommended procedure)?
* If information about incidental findings is provided, what kind of guidance and counseling services will be available?

3.3.2.3 Are the subjects deliberately deceived in the study?

If yes:

Describe the type of deception.

Explain what points of information remain deliberately incomplete or intentionally false.

Rate the stress caused to the subjects/patients by the deception.

Explain your way of debriefing (time, extent, type), possibly with the text about subsequent information!

3.3.2.4 Does the study include medically not indicated invasive procedures on the subjects/ patients?

If yes:

Describe the intervention.

Rate the stress caused to the subjects by the intervention.

Who will do the intervention? (qualification)?

How do you ensure medical care for the subjects during and after the intervention?

Separate risk assessment of the intervention including possible complications and their frequency; guideline-compliant classification as to whether the risk is justified.

If no: Is the study based on questionnaires with questions that are possibly confrontational?

3.3.2.5 Will you obtain samples/ material during the study?

If yes:

* Where will you store the material?
* Further plans for the material, including the possibility of their further use for other purposes (consent)
* Ownership rights to the samples.

3.3.2.6 Is it a clinical study (intervention study with the goal to treat diseases)?

**4 Data Collection, Safety and Protection**

**4.1 Which data will be collected?**

List the relevant data (contact details/ research details) that you will collect from the subjects.

**4.2 Is the data collected anonymously from the outset so that it will be impossible to trace the research data back to the subjects at any time?**

It is conceivable in those cases when data is collected exclusively online via questionnaires without storing name, e-mail address, or IP address and when the subjects cannot be re-identified on the basis of the research data collected without disproportionate expenditure of time, money, and manpower. Please indicate the reasons why it can be assumed that the research data is processed only anonymously.

**4.3 How and where will the data be stored?**

Please describe which data will be stored on what kind of data carrier!

**4.4 How long will the data be stored?**

**4.5 Will the data be pseudonymized?**

1. If yes, at what point of the study?
2. Where will you store the list of real names?

How long will you keep the list of real names?

Possible dates for deleting the list are:

* end of the survey phase
* end of the evaluation phase
* end of the storage phase.

State the reason (e.g. necessity of follow-up surveys) if the list of real names is to be stored after the end of the survey phase.

Will you produce image or sound material that may not be completely anonymised/ pseudonymised? How is it handled (e.g. blurring); where and how is it stored? Will such data be published?

**4.6 How do you ensure compliance with data protection requirements in your project?**

Particularly specify the technical and organizational measures taken to protect personal data:

1. If necessary, encryption of data
2. Measures to ensure the confidentiality of data, including limited access to the list of real names
3. Measures to ensure that it is possible to verify and establish retrospectively whether and by whom data has been entered, changed, or deleted
4. Raising the awareness of the persons involved in the processing of data.

**4.7 Name and address of the person(s) in charge of data protection for the study**

**4.8 Was the data protection concept coordinated with the Data Protection Officer of the University of Potsdam?**

**5 Conflicts of interests**

**Disclosure of potential conflicts of interest, also regarding the funding of the study**

**6 Final statement and signatures**

**6.1 Statement of the applicant whether assessment has already been applied to from another office/ authority/ commission.**

**6.2 Statement of the applicant about good scientific practice and compliance with data protection.**

**6.3 Signatures**

Date and place

*6.3.1 Applicant*

*6.3.2 Principal investigator*

*6.3.3 Approval of the responsible professor*

**6.4 Attachments**

6.1 Please attach the following documents to the application:

* sample form - information sheet for the subjects
* sample form - consent of the subjects

6.2 Instructions for information sheets and declarations of consent:

If necessary, separate information sheets and declarations of consent in generally understandable language must be provided for subjects of different ages or types of intervention. This may also apply to non-native speakers.

Text to inform the subjects about their participation (written informed consent) including publication plans of the results

Ability of subjects to refuse participation or to terminate participation prematurely; text informing the subjects about this possibility

How much time do subjects have for their decision?

If possible, specify independent contact person for further inquiries.