Self-regulation in Science
Guidelines for Safeguarding Good Scientific Practice

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Attachments:

For ease of reading, the gender references in this document are masculine.
All personal information, however, applies universally to both men and women.
Preamble

(1) Within its legal mandate, Zeppelin University is responsible for the organization of
  - Research
  - Teaching and
  - Promotion of young researchers

Teaching and promotion of young researchers are inextricably linked with research at the university. Therefore it is of special importance to the university to maintain and foster an atmosphere of openness, creativity and commitment. In the exercise of its responsibility in research, the university must make provisions against scientific wrongdoing.

(2) Therefore Zeppelin University will investigate every definite suspicion of scientific wrongdoing. If the suspicion of wrongdoing is confirmed after clarification of the case circumstances, measures appropriate to the particular case will be taken within the scope of legal possibilities.

(3) With regard to examinations, conferral of academic degrees, engagements and appointments, originality and quality should always take precedence over quantity. This will apply primarily also to performance- and stress-oriented appropriation of funds in research.

Section I
General Principles

§ 1 Obligation to Exhibit Integrity in Science

(1) All persons engaged in scientific activities as well as students at Zeppelin University are bound to observe the rules of good scientific practice pursuant to § 2. The departments, academic program managers as well as advisors must familiarize the students and young scientists with the rules of good scientific practice and prevent them from committing scientific wrongdoing.

(2) Zeppelin University undertakes to create the necessary organizational and personnel structures for safeguarding integrity in science and preventing scientific wrongdoing and to continuously develop these structures according to scientific progress.

(3) The scientists at Zeppelin University are bound in their activity as examiners to check all written examinations, in particular take-home exams, final papers, dissertations and
habilitations for plagiarism. The Study and Examination Center or Zeppelin University Graduate School (ZUGS) must be informed of every strong suspicion.

(4) The rules of good scientific practice should be integrated in academic teaching and in the training of young researchers.

§ 2 Rules of Good Scientific Practice

(1) The rules of good scientific practice include in particular the following general principles of scientific work:

a) Working according to accepted rules (*lege artis*),
b) Documenting research findings,
c) Checking one's own research findings self-critically,
d) Acting honestly with regard to articles from partners, competitors and predecessors,
e) Taking responsibility jointly as authors and ruling out honorary authorship (e.g. advisors/heads of the institute),
f) During projects which include the involvement of subjects, safeguarding their legal assets, in particular the right to informational self-determination and general personal rights,
g) Avoiding and preventing scientific wrongdoing.

(2) Primary data that serves as a basis for publications shall be saved on durable and secure storage facilities in the institution where it is created for ten years.

(3) A quality assurance system should be organized for tests with standardized workflows – in a laboratory, for example, in which quality management at different organization levels is recommendable: While quality management targets and structures of the entire university are defined at university level, responsibility at the work level rests with the respective project manager or person responsible for the laboratory.

(4) Regardless of the university management’s responsibility, every scientific work unit and every leader of a work group is responsible, in their respective area, for an adequate organization which ensures that

a) chairmanship, supervision, quality assurance and conflict settlement duties are clearly assigned and actually observed,
b) cooperation in the work groups is characterized by a climate of exchange and mutual constructive criticism regardless of hierarchy-related consideration,
c) young researchers are correspondingly instructed and supported according to their respective educational status (§ 3).

§ 3 Support of Young Researchers

(1) Young researchers start working scientifically with their bachelor, master and/or doctoral thesis. The goal is to impart to them through the university not only technical skills but also
an ethical attitude toward scientific methods, responsible use of results and cooperation with other scientists.

(2) Young researchers are entitled to regular scientific supervision, counseling and support from advisors or work group leaders.

(3) Young researchers are obligated to render complete documentation. They should regularly be given the opportunity to report on the progress of their research work and to attend internal seminars.

§ 4 Scientific Publications

(1) When research findings are published, all persons who are co-authors within the meaning of § 8 Subsection 1 of the law concerning copyright and related intellectual property right (Copyright Act) of September 9, 1965 (BGBl. (Federal Law Gazette) I page 1273) as amended are entitled to recognition of their co-authorship. It is not permitted to name persons who do not meet the requirements of § 8 Subsection 1 of the Copyright Act as co-authors.

(2) Subject to different customs, as they have found recognition in various disciplines, the following guidelines must always be observed with regard to the composition of scientific publications:

a) Scientific studies must be verifiable. Therefore their publication must contain an exact description of methods and findings.

b) Findings which support or question the author’s hypothesis must be disclosed equally.

c) Findings and ideas from other researchers as well as relevant publications of other authors must be quoted in a proper manner.

d) Fragmentation of studies for the purpose of increasing the number of publications is not permitted.

(3) If several persons are involved in research work or in writing a scientific report, those persons who significantly contributed to the formulation of the question, to the research plan, to the performance of research work, to the analysis or interpretation of the results as well as to the conception or to the critical content-related revision of the manuscript can be named as co-authors. Neither only technical assistance during data collection nor solely the provision of financial resources nor general chairmanship of the department in which the research was performed suffices to justify co-authorship. The same applies to mere reading as well as to individual corrections or suggestions without co-determination of the topic.

§ 5 Acceptance of Third-party Funds

(1) Zeppelin University supports and encourages the acquisition of public and private third-party funds.

(2) Applications for the appropriation of funds which are to be allocated to Zeppelin University gGmbH should be directed to the Board via the “Research Promotion” and/or “Strategic
Partnerships and University Development* departments. The acceptance or refusal of these third-party funds is declared by the Managing Director and binding, and not by the acquisitioning university member. If the Managing Director intends to refuse third-party funds, he must give the Chairman of the Research Council the opportunity to convene a meeting and make representations before his decision.

(3) An offer of third-party funds for Zeppelin University must be refused if the independence of the conducted research is not ensured and/or the acceptance violates legal provisions. In addition, the regulations and principles specified in the Code of Conduct of Zeppelin University apply to all third-party funds in the area of scientific services, contract research and sponsoring.

(4) The acceptance of third-party funds can also be refused or subjected to conditions if the acceptance affects other tasks of Zeppelin University or the rights and obligations of other university members, or if follow-up costs were not suitably considered.

(5) For the sake of transparency and evaluation, the Board as well as the Research Promotion Department or the Department of Strategic Partnerships and University Development must be informed of all relevant correlations pertaining to the third-party fund offer including possible existing types of contractual / business relationships, also within the scope of secondary employment. A complete list must be compiled of all possible service obligations connected to accepting third-party funds.

(6) When acquisitioning and accepting third-party funds, any impression of corruptibility, especially the subjectivity of research findings for the benefit of the third-party funder, as well as the controllability of academic, economic or other decisions of Zeppelin University must be avoided.

§ 6 Instruction of the Rules of Good Scientific Practice and Their Observance

(1) These regulations must be announced to scientific personnel of Zeppelin University by handing it out to them when they are hired or appointed. Furthermore, the scientific personnel must be informed about the existence of the following scientific integrity regulations.

   | Information for students on how to deal with and prevent plagiarism at Zeppelin University
   | Joint Study and Examination Regulations | JSERs for bachelor and master degree courses
   | Doctoral Regulations of Zeppelin University
   | Post-Doctoral Regulations of Zeppelin University

(2) Other young researchers as well as students must be informed of the existence of the regulations named in Sec. 1 by the supporting scientists.

(3) All science professionals as well as students must be intent on observing the rules of good scientific practice and preventing scientific wrongdoing. In cases of doubt, they must consult an experienced scientist or the ombudsperson (§ 7).
§ 7 Officer for Self-regulation in Science (Ombudsperson)

(1) At the suggestion of the President, the Senate shall appoint a professor as Officer for Self-Regulation in Science (hereinafter referred to as: ombudsperson) as well as a deputy. The ombudsperson must not simultaneously be a member of the ethics commission (§ 10). The term of office is three years; re-appointment is permitted.

(2) As a trusted third party, the ombudsperson shall counsel those persons who have informed him about definitely suspected wrongdoing as well as persons who are suspected of scientific wrongdoing. In addition he shall spontaneously pick up on definite indications of scientific wrongdoing which he becomes aware of otherwise.

(3) The ombudsperson shall check every suspicion of scientific wrongdoing for concreteness and significance with regard to plausibility. If he considers the suspicion to be plausible based on this check, he shall inform the responsible panels about it. In doing so, he may disclose the information confided to him by consulters only when and insofar as it is a reasonable suspicion of such scientific wrongdoing which, if not pursued, might incur considerable damage to Zeppelin University, its members or third parties.
Section II
Procedures in case of Suspected Scientific Wrongdoing

§ 8 Scientific Wrongdoing

Scientific wrongdoing is a behavior in a scientific context which violates legal provisions or such written or unwritten rules whose observance is regarded as essential in general, in a specific scientific subject or in a scientific field. Scientific wrongdoing is defined as the intentional and grossly negligent statement of falsehoods in a scientific context, the infringement of intellectual property rights or impeding another person’s research work. A catalog of behaviors considered as scientific wrongdoing is included in attachment 1 of these regulations.

§ 9 Obligation to inform, Confidentiality, Consequences

(1) Zeppelin University will investigate every definite suspicion of wrongdoing (§ 8) without distinction of person.
(2) Until culpable misconduct is proven, strict confidentiality must be observed concerning the parties involved in the procedure as well as any findings/interim results.
(3) If the suspicion of scientific wrongdoing is confirmed after clarification of the case circumstances, measures appropriate for the particular case will be taken within the scope of legal possibilities (cf. attachment 2).

§ 10 Ethics Commission

To safeguard self-regulation in science, Zeppelin University has set up an ethics commission. Duties, formation and procedures are defined by Rules of Procedures.

§ 11 Preliminary Examination in Case of Specific Grounds for Suspicion

(1) The ombudsperson must be informed of a definite suspicion of scientific wrongdoing without delay. The notification of suspected scientific wrongdoing should be made in writing; in case of oral notification, a written note must be made by the ombudsperson. The processes and results of individual phases of the procedure must also be recorded in writing and in an easily comprehensible manner. In case of a lack of impartiality on the part of the ombudsperson, he may assign the preliminary investigation to his deputy.

(2) The person suspected of wrongdoing will be given by the ombudsperson the opportunity to make representations including incriminating facts and evidence; Sec. 1 Clause 2 shall apply accordingly. The period for this is two weeks. The informant’s name shall not be disclosed without his consent to the person concerned. The person suspected of wrongdoing may claim a lack of impartiality on the part of the ombudsperson. In this case the preliminary investigation will be conducted by the deputy ombudsperson.
(3) After receipt of the representations of the party concerned and/or expiry of the period, the ombudsperson shall decide, if possible within a period of two weeks,
   a) whether the preliminary examination procedures should be suspended because the suspicion is not sufficiently confirmed or the suspicion proves to be completely unfounded; the person concerned as well as the informant must be advised of the reasons; the informant must be advised of his right of complaint pursuant to Sec. 4.
   b) whether the institution of a formal inquiry (§ 12) should take place; the ombudsperson shall forward the documents together with his comment to the chairman of the ethics commission.

The Board must be informed of the decision; in case of the termination of the procedures, which must be noted in writing, this is not required.

(4) If the informant disagrees with the suspension of the preliminary examination procedures, he can lodge a complaint in writing, stating the reasons, with the chairman of the ethics commission within two weeks after notification of the reasons pursuant to Sec. 3 Clause 1, a). The ethics commission shall decide whether the suspension of the preliminary examination procedures is final or whether a formal inquiry shall be instituted; the procedure described in Sec. 2 and 3 shall apply to the ethics commission accordingly. A further complaint procedure against ethics commission’s decision to suspend the above-mentioned procedures shall not take place.

§ 12 Formal Inquiry

(1) The ethics commission, which shall review the charge with free consideration of evidence, is responsible for the formal inquiry. It is entitled to take whatever steps are necessary to clarify the case circumstances. For this purpose, it may obtain all necessary information and representations and may in individual cases consult experts specializing in the field of the scientific case circumstances to be judged as well as experts experienced in handling such cases as additional members in an advisory capacity. If a lack of impartiality is determined by one of the members, by the person concerned or the informant, the corresponding deputy members of the Ethics Commission will conduct the formal inquiry.

(2) The person concerned must be informed of the incriminating facts and evidence, if applicable. The person concerned as well as the informant must be given the opportunity to make oral representations; he may also consult a trusted person as an advisor.

(3) If the identity of the informant is unknown to the person concerned, his name must be disclosed to him if the informant consents to the disclosure and if this information is necessary for proper defense, particularly if the credibility of the informant is of primary importance for determining scientific wrongdoing. Without the informant’s prior consent (approval), neither his name nor any information which allows inference to his person may be disclosed at any point in time of the procedures.

(4) The processes and results of individual phases of the procedure must be recorded in writing and in an easily comprehensible manner.
§ 13 Termination of the Formal Inquiry

(1) If the ethics commission regards scientific wrongdoing to be unproven, the procedures shall be suspended. If it regards scientific wrongdoing to be sufficiently proven, it shall deliberate on the further procedure options, particularly on the possible consequences (attachment 2), and shall submit a final report and a recommendation for the further procedure to the Board.

(2) The chairman of the ethics commission must immediately give written notice of the primary reasons which led to the suspension of the procedures or redirection to the Board to the person concerned and the informant. An internal complaints procedure against the commission’s ruling shall not take place.

(3) If scientific wrongdoing was established, the Board shall consider which measures should be taken in order to maintain the university’s scientific standards as well as the rights of all persons concerned directly or indirectly based on the final report and recommendation of the ethics commission. The departments must determine, in cooperation with the Board, whether and to what extent other scientists (former or possible cooperation partners, co-authors), scientific institutions, scientific magazines or publishing houses (in case of publications), scholarships and research communities, professional associations, ministries and the public should or must be informed.

(4) The respectively responsible institutions shall initiate measures pertaining to service law, labor law, civil law, criminal or regulatory law with the corresponding procedures taking into account the circumstances of the particular case.

(5) The Board of Directors shall give written notice of the termination of the formal inquiry and of the measures taken to the ombudsperson and the Senate.

§ 14 Procedures in case of Change of Institutions

(1) If the person suspected of scientific wrongdoing was a member of Zeppelin University at the material time, the provisions of these regulations shall apply even if he is meanwhile no longer a member of the university.

(2) If the person suspected of scientific wrongdoing was still a member of another institution at the material time, the university shall regularly request this institution to take over the inquiry.

§ 15 Supplementary Measures; Storage of Files

(1) After termination of the formal inquiry, the ombudsperson shall determine all university members whose justified interests are affected by the established scientific wrongdoing. He shall advise those university members, particularly young researchers and students who
were involved in scientific wrongdoings through no fault of their own, with regard to safeguarding their personal and scientific integrity.

(2) The formal inquiry files shall be stored for 10 years. University members named in connection with a case of proven scientific wrongdoing shall receive, at the ombudsperson's request, certification of the duration of the storage period according to Clause 1 to their discharge.

Section III
Procedures for the Protection of Legal Assets of Subjects during Research Projects Involving Subjects

§ 16 Filing a Proposal

(1) For the evaluation of a research project involving subjects, the ethics commission shall take action at request of the scientist responsible for the project at Zeppelin University.

(2) The prerequisite for filing a proposal is prior completion of the checklist attached to these guidelines (attachment 3). If all the questions of this checklist are answered with "no", an examination by the commission is not required. If at least one question is answered with "yes", a proposal must be filed to the commission.

(3) The proposal with the documents relevant to the ethics statement must be filed to the Research Promotion Department by the responsible project manager. This department, together with a legal representative, shall verify the formal correctness of the proposal and shall obtain counseling on legal issues if required. If there is still a need for clarification after the counseling, it shall forward the proposal to the commission.

§ 17 Evaluation Process

(1) The ethics commission which examines the documents submitted by the responsible project manager in view of the ethical aspects of planned research projects involving humans is responsible for the evaluation. The responsibility of the responsible scientist shall remain unaffected.

(2) The ethics commission shall examine in particular

- the provisions for minimizing the subject risk,
- the appropriateness of the risk/benefit ratio of a research project,
- the provisions for informing the subjects sufficiently about the methods, aims and risks of the research project,
- the compliance of the project with pertinent statutory regulations, in particular data protection laws.
(3) Members contributing to the research project or whose interests are affected in such a manner that there is reason to doubt their impartiality are barred from the discussion of the resolution.

(4) The commission may reject or approve the proposed project or approve it with restrictions based on the submitted documents and its own investigations. In cases of doubt, it can determine that further evaluation is necessary and remit the proposal to a recognized external, independent ethics commission. The remittal and the vote of this commission are binding.

(5) The proposer must be given written notice of the ethics commission's decision. Reasons for adverse decisions and restrictions must be given in writing.

(6) The evaluation process documents including the commission decisions shall be stored for 10 years.

Section IV
Final Provision

§ 18 Entry into Force

These guidelines shall enter into force on the date following their publication.

Notice of publication
These regulations were approved, issued and made public by the President on 2015-12-02. The effective date is therefore 2015-12-03.

Prof. Dr. Insa Sjurts, President
Attachment 1
Catalog of Behaviors Considered as Scientific Wrongdoing

I. Scientific Wrongdoing
Scientific wrongdoing is defined as the intentional and grossly negligent statement of falsehoods in a scientific context, the infringement of intellectual property rights or impeding another person’s research work. The circumstances of the particular case respectively are ultimately decisive.

In particular the following may be considered as scientific wrongdoing:

1. Misrepresentation by:
   a. fabrication of data;
   b. falsification of data, e.g.
   aa. selecting and rejecting unwanted findings without disclosing such action,
   bb. manipulating representations;
   c. providing incorrect information in an application for employment or for funding (including misrepresentation concerning the means of publication and forthcoming publications);

   Note: In the description of publications in applications for third-party funding, it is recommended to refrain from mentioning papers which have not finally been approved for publication; if this recommendation is not followed for technical reasons, the respective spokesperson of the research proposal concerned must bear the risk for an invalid proposal.

2. Infringement of intellectual property rights:
   a. relating to any pieces of work protected by copyright, primary scientific findings, hypothesis, teachings or approaches established or made by someone else by:
      aa. unauthorized use claiming authorship (plagiarism),
      bb. exploitation of research approaches and ideas, in particular as an expert (theft of ideas),
      cc. undue or unjustified claim to authorship or co-authorship of a scientific publication,
      dd. falsifying the content, or
      ee. unauthorized publication and providing unauthorized information access to third parties before the work, the findings, the hypothesis, the contents of the teaching or the research approach have been published;

   b. by using the (co-)authorship of another person without his/her permission;

3. Impeding another person’s research work by:
   a. sabotage of research work (including damaging, destroying or manipulating the set-up of experiments, devices, documents, hardware, software, chemicals or other objects required by another person to conduct an experiment),
b. elimination of primary data, insofar as this violates statutory regulations or discipline-related, accepted principles of scientific methods.

II. Joint responsibility can, among other things, arise from
1. active involvement in the wrongdoing of others,
2. knowing about falsifications committed by others,
3. co-authorship of falsified publications,
4. gross negligence of duty of supervision
Attachment 2

Catalog of Possible Sanctions and/or Consequences in case of Scientific Wrongdoing

The following catalog of possible sanctions and/or consequences of scientific wrongdoing should be viewed as an initial orientation aid and is not intended to be exhaustive. Because every case is different and diverse aspects of the established scientific wrongdoing play a role, there are no standard guidelines for adequate reactions; on the contrary they depend on the circumstances of the particular case.

I. Service and Labor Law-Related Consequences
Because it is very expectable that in cases of scientific wrongdoing at Zeppelin University the person concerned is simultaneously a university employee, service and/or labor law-related consequences should be examined first:

a. Warning
A warning is a preliminary stage of dismissal, i.e. it comes into question only in cases of minor scientific wrongdoing in which a dismissal is not yet intended. The personnel department should be involved in the process at an early stage.

b. Dismissal
A dismissal presupposes that, according to the circumstances of the particular case and taking both contract parties’ interests into account, the continuation of the employment relationship is no longer reasonable. In more serious cases of scientific wrongdoing, this should apply as a rule. In such a case, the personnel department must be contacted without delay.

c. Contract Termination
In addition to termination of the employment relationship by means of dismissal, it should be attempted to terminate the employment relationship by means of mutually agreed contract termination.

II. Academic Consequences
Academic consequences in the form of a withdrawal of academic degrees can be taken by Zeppelin University itself only if it conferred the academic degree on the person concerned. If the academic degree was conferred by another university, it must be informed of serious scientific wrongdoing if this was connected with the acquisition of an academic qualification.

Possible consequences include in particular withdrawal of academic degrees (bachelor, master, doctoral) or withdrawal of teaching licenses

III. Civil Law-Related Consequences
The following civil law-related consequences may be considered:
1. Banning from the university;
2. Claims for surrender against the concerned person, e.g. to surrender stolen scientific material;
3. Claims for removal and injunctive relief from copyright law, personal rights, patent law and competition law;
4. Claims for restitution, e.g. of scholarships, third-party funds or the like;
5. Damage claims of Zeppelin University or third parties for personal damage, material damage or the like
IV. Criminal Consequences

Criminal consequences are possible whenever it is suspected that a case of scientific wrongdoing simultaneously constitutes an element of offense of the German Penal Code (StGB) and/or other penal provisions or regulatory offences. Investigative authorities should only be called in with the Board’s approval.

Possible elements of offense include:

1. Infringement of personal and private spheres
   § 202a StGB: Data espionage
   § 204 StGB: Use of other persons' secrets

2. Crimes against life and physical integrity
   § 222 StGB: Negligent homicide
   §§ 223, 229 StGB: Malicious injury or physical injury resulting from negligence

3. Offenses against property
   § 242 StGB: Theft
   § 246 StGB: Misappropriation
   § 263 StGB: Fraud
   § 264 StGB: Subsidy fraud
   § 266 StGB: Embezzlement

4. Falsification of documents
   § 267 StGB: Falsification of documents
   § 268 StGB: Falsification of technical records

5. Damage of other people’s property
   § 303 StGB: Damage of other people’s property
   § 303a StGB: Alteration of data

6. Copyright infringement
   § 106 Copyright Law: Unauthorized use of copyrighted works.

V. Revocation of Scientific Publications / Information of the Public / Press

Scientific publications which contain errors due to scientific wrongdoing must be withdrawn, if they are still unpublished, and corrected if they are published (revocation); cooperation partners must be informed in a suitable form if necessary. The authors and involved publishers are generally bound to this; if they do not take action, Zeppelin University shall initiate the possible suitable measures. In cases of serious scientific wrongdoing, Zeppelin University shall inform other affected research institutions and/or research communities. In justified cases, it may also be advisable to inform professional associations.

Zeppelin University may be bound, in order to protect third parties, preserve trust in scientific integrity, redeem its scientific reputation, prevent consequential damage as well as in general public interest, to inform affected third parties and the public.
Attachment 3
Ethics Commission | Fast Facts and Checklist

Studies which are conducted with the involvement of subjects must take into account several aspects, e.g. of data protection. If you note the aspects named below and consistently answer the questions in the checklist with "no", you shall be able to carry out your project without further examination by the ethics commission.

For studies with inclusion of subjects please note the following

- Subjects must always provide written consent to data protection before collection and processing of personal data within the course of a study. Personal data refer to specific data about personal or objective affairs of a specific or specifiable person. This does not include anonymized data. However, anonymization does not exist if inference can be made to the respective person from the data without very great effort (e.g. in a limited group of subjects where specific information, such as special hobbies or external features, etc., may lead to the identification of the person concerned due to its singularity or uniqueness or its combination with other information).

- Basically the subjects must be completely, truthfully and understandably informed in writing about aims and the test procedure and the purpose of data collection or data processing.

- The subjects must be informed in writing about their right to refuse or cancel participation.

- Data anonymization must be ensured in all means of data recording (particularly in sound and video recordings and in computer logs) and data storage.

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<thead>
<tr>
<th>Checklist for studies with inclusion of subjects</th>
<th>yes</th>
<th>no</th>
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<tr>
<td>1. Will personal data allowing inferences to be made to a specific person (e.g. name, e-mail address, etc.) be collected or will video and/or sound recordings of participants be made?</td>
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*The posed question may be answered with "no" regardless of the question content if only the names and addresses of the subjects are collected, stored and communicated to ZU in connection with their payment for its own billing purposes.*

<p>| 2. Will persons belonging to a very vulnerable group or unable to give their consent to participate themselves (e.g. children, people with learning disabilities, clinical populations) participate in the study? |     |    |</p>
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<td>3.</td>
<td>Will hidden observation or other methods where it is not ensured that the participants can give informed consent and/or be informed completely be used in the study?</td>
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<tr>
<td>4.</td>
<td>Will the study contain questions about topics which are of an intimate nature to the respondents (e.g. illegal or deviant behavior or sexual preferences)?</td>
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<tr>
<td>5.</td>
<td>Is it expectable that the study will induce psychological stress, exhaustion, pain or other negative effects beyond an everyday extent in the participants?</td>
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<tr>
<td>6.</td>
<td>Will the study participants be given drugs, placebos or other substances (e.g. food, beverages, vitamin products) or will the participants be subjected to invasive or potentially harmful procedures?</td>
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