

Rules of Procedure of the Joint Ethics Committee of the Pädagogische Hochschule Heidelberg University of Education and SRH University of Applied Sciences Heidelberg of 17 October 2018

On the basis of Section 19(1) Nos 7 and 10 of the Federal State Higher Education Act [*Landeshochschulgesetz* – LHG], in the version of 1 April 2014 (GBl. [Law Gazette] p. 99), as last amended by Article 1 of the Act of 13 March 2018 (GBl. p. 85), the Senates of the Pädagogische Hochschule Heidelberg University of Education and SRH University Heidelberg established a Joint Ethics Committee by resolutions of 18 July 2018 and 17 October 2018. They provide the Ethics Committee with these Rules of Procedure.

Preamble

Respectful treatment of people who volunteer to participate in research studies is the hallmark of ethically responsible research at the Pädagogische Hochschule Heidelberg University of Education and SRH University of Applied Sciences Heidelberg. The Joint Ethics Committee of the two universities assesses the ethical responsibility of research projects. This cooperation has the following advantages:

- (1) The Committee is made up of members from both universities. This means that decisions are not made by members of the researcher's university alone. This increases the independence and objectivity of the Committee.
- (2) Both universities can bring their expertise to the joint committee. There are both ethical and legal aspects to the issues addressed by the Committee. Equal representation on the Joint Ethics Committee ensures that the professional and legal expertise of both institutions is fully utilised in the ethical assessment of research projects involving human subjects.

Regardless of the opinion of the Ethics Committee, the responsibility for maintaining ethical standards in the research process always lies with the scientists conducting the research. The Ethics Committee can only give a robust opinion if it is well informed about the proposed research procedure and its potential ethical risks. A favourable opinion from the Ethics Committee does not relieve the researcher of the responsibility to ensure that the relevant ethical standards are met at all times.

The procedure of the Joint Ethics Committee of the PH Heidelberg and SRH University of Applied Sciences Heidelberg is based on the Rules of Procedure of the Ethics Committee of the German Psychological Society (DGPs) as amended.

Section 1

Tasks

- (1) The Ethics Committee reviews the ethical aspects of proposed research projects and, where applicable, issues a statement (opinion). This does not affect the responsibility of the scientists conducting the research.
- (2) In medically related areas, assessments are in keeping with the World Medical Association's (WMA) Declaration of Helsinki.

- (3) The Ethics Committee checks, in particular, whether
- a. all precautionary measures have been taken to exclude or minimise the risks to the study participants,
 - b. there is an appropriate balance between the benefits and risks of the project,
 - c. the consent of the study participants or their legal representatives is adequately documented,
 - d. the applications to the Committee contain information on
 - I. the aim and schedule of the project,
 - II. the type and number of study participants, as well as criteria for their selection,
 - III. all steps of the study procedure,
 - IV. burdens and risks to study participants, including potential after-effects and precautionary measures to prevent negative effects,
 - V. mechanisms for providing study participants with (written) information about the procedure of the study that fully and truthfully informs them, in a manner they can understand, about the objectives and procedure of the study,
 - VI. mechanisms for obtaining the participant's (written) consent to participate in the trial,
 - VII. possibilities for participants to refuse participation or withdraw from participation; in the case of participants with limited decision-making powers (e.g. children, legally incapacitated persons): mechanisms for obtaining the consent of custodians for the subject to participate in the study; any intended insurance cover, if applicable,
 - VIII. data processing (particularly in the case of audio and video recordings and computer logs) and data storage from the viewpoint of data anonymisation,
 - IX. reasons for the need to request an opinion (cf. Section 3(2))
 - X. assurance that the application has not already been submitted to another ethics committee (cf. Section 3(5))
- (4) The Committee acts on behalf of the Senates of the two universities.
- (5) The Ethics Committee and its members are independent in the performance of their tasks and are not bound by instructions. They are responsible only to their conscience.

Section 2

Composition and Appointment of Members

- (1) The Joint Ethics Committee shall consist of the following voting members:
- a) a professor from the PH Heidelberg
 - b) an academic staff member from the PH Heidelberg
 - c) a professor from SRH University Heidelberg
 - d) an academic staff member from SRH University Heidelberg
 - e) a doctoral student (PH Heidelberg)
 - f) a Master's student (SRH University Heidelberg)
 - g) a member of the President's Office from each university
- (2) The members referred to in Section 2(1) (a), (b), (c) and (d) shall be appointed by the respective University Senate for four years, and the members referred to in Section 2(1) (e) and (f) for one year.
- (3) In the first two years, the Ethics Committee will be chaired by the member of the President's Office of the PH Heidelberg, in the following two years by the member of the President's

Office of SRH University of Applied Sciences Heidelberg. This rotation shall be maintained in subsequent years.

- (4) The Managing Director of the Research Department of the Pädagogische Hochschule Heidelberg University of Education and the Head of the Institute for Applied Research of SRH University Heidelberg may be involved in decision-making as experts.

Section 3

Submission of Applications

- (1) The Committee shall act at the request of any member or employee of either university.
- (2) An Ethics Committee opinion on a research project can only be requested if this is necessary for third parties (e.g. funding bodies, publishers). In all other cases, advice can be sought from the Ethics Committee.
- (3) The application to the Ethics Committee must be made at least one month before the research proposal is submitted.
- (4) Students are not entitled to submit applications in ethical matters relating to scientific work and may only seek advice via a supervisor in exceptional circumstances.
- (5) Applications will be processed on the condition that the application has not already been submitted to another ethics committee for review. The applicant must include a statement to this effect in the dossier.
- (6) The applicant must send the documents relevant to the opinion or advice of the Ethics Committee to the Chair of the Ethics Committee via their Dean's Office. The Chair will consider the eligibility of the application and, if appropriate, circulate the documents to all members of the Committee.

Section 4

Review Procedure

- (1) Each member of the Committee shall assess the application and give their opinion to the Chair of the Committee. The Chair summarises the opinions received and his or her own assessment in a Committee statement, making it impossible to draw conclusions about the authors. If the opinions are not compatible, the Chair shall submit a draft statement to the members of the Committee for discussion. If the opinions are still irreconcilable, an oral hearing shall be scheduled.
- (2) The Chair may, after consultation within the Committee, request the opinion of one or more additional experts. In this case, the expert consulted shall be sent the entire application.
- (3) The Committee may ask the applicant to give an oral explanation of the research project or to provide additional documentation, information or justification.
- (4) An application must normally be approved within one month. The applicant must be informed in writing of the Ethics Committee's decision. In addition to issuing a favourable or unfavourable opinion, the Committee may return the application to the applicant and request its revision. Reasons for refusal or return must be given in writing.
- (5) If an application is rejected on ethical grounds, the applicant may submit counter-arguments and request a new statement from the Committee once only. If an application is returned to the applicant for revision with conditions, it may be resubmitted once in revised form.
- (6) Decisions of the Ethics Committee require a simple majority of all members. In the event of an equality of votes, the Chair shall have a casting vote. When a decision is taken, it is always a decision taken by the Ethics Committee as a whole.

- (7) In individual cases, members will be excluded from the discussion if they are involved in the research project or if their interests are such that there are concerns about conflicts of interest. Members of the Ethics Committee are required to inform the Chair of any cases of involvement or a conflict of interest. The decision shall be taken by the Chair after consultation with the Committee member. The basis for the assessment of a conflict of interest are the guidelines for dealing with questions of conflict of interest in appointment procedures at the PH Heidelberg.
- (8) The Committee may instruct the Chair to decide alone in cases to be determined by the Committee. He or she shall inform the Committee as soon as possible.
- (9) Multicentre studies that have already been assessed by another committee may be dealt with by the Chair. The Committee must be informed and, in cases of doubt, consulted.
- (10) The Ethics Committee normally meets once a semester. Meetings of the Ethics Committee are not open to the public. Its findings are documented in minutes.
- (11) The Chair shall report annually on the work of the Ethics Committee to the Senates of both universities.

Section 5

Confidentiality of the Procedure

- (1) The subject matter of the procedure and the statements of the Ethics Committee must be kept confidential. Members of the Committee are obliged to maintain confidentiality. The same applies to any assessors or experts consulted in the process. Individual opinions shall be kept confidential.
- (2) At the start of their work, all persons involved in a procedure must be informed of their duty of confidentiality.
- (3) Committee opinions, application documents, minutes of meetings, decisions, reports to the Senates, correspondence, etc. shall be archived. Data protection must be observed when archiving application documents.

Section 6

Entry into Force

The Rules of Procedure shall enter into force on the day following their official publication.

Heidelberg, 17 October 2018

sgd.

Professor Dr Hans-Werner Huneke
President of the
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sgd.

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