

# **REGULATIONS ON ETHICAL ISSUES**

Ethics and Data Committee  
Leiden Law School  
Leiden University

These regulations set out ethical guidelines for research at Leiden Law School, Leiden University. All researchers are expected to apply these guidelines when undertaking their research and to adhere to the substance contained therein. Researchers may consult with the Ethics and Data Committee and request to have research plans reviewed according to these guidelines (see application form on the website). In certain cases this may be required by a third party, such as the Netherlands Organization for Scientific Research (NWO) or ESRC; in other cases the request may be at the researcher's own instigation.

The information below sets out the underlying ethical principles, followed by the practical application of these principles and finally the role and methods of the Committee.

## **General underlying ethical principles related to research**

- (1) Research is set up and undertaken in accordance with the Netherlands Code of Conduct for Academic Practice of the VSNU (Association of Universities in the Netherlands).
- (2) Researchers and their assistants only undertake the tasks for which they have been properly trained and/or instructed.
- (3) Researchers take measures not to violate the rights and the wellbeing of respondents, organizations and other persons who are involved in the research.
- (4) Researchers conduct their activities in academic freedom and independently. To the extent that limitations on this freedom cannot be avoided, this will be made clear in any subsequent publications.

## **Application of underlying ethical principles in research**

### ***Personal data***

- (1) Researchers treat personal data in an appropriate manner, in accordance with the applicable legislation in the Netherlands. See the University's website for clarification on the implementation of the General Data Protection Regulation (GDPR, in Dutch: AVG).
- (2) The privacy of respondents is respected. Personal data is deemed confidential. Personal data that could lead to the identification of the respondent is (if applicable) saved separately from the research data, unless this is not possible such as in the case of interview recordings for example.
- (3) Researchers use personal data exclusively for the purpose(s) it was collected, as formulated by the researcher.
- (4) Researchers pass on no personal data to persons outside the research group without the consent of the respondent (if the data has been collected from the respondent) or without the consent of the organization that provided the data.
- (5) If a researcher maintains a systematic database containing directly identifiable personal data, he or she ensures registration with the Dutch Data Protection Authority in accordance with legislation in the Netherlands.

- (6) Researchers are responsible for drawing up a Data Management Plan.  
This plan sets out how they will create, save, maintain, make available, archive and store research data in the long term.

### ***Recruiting respondents and informed consent***

- (1) Prior to undertaking the research, the researcher informs respondents and/or their legal representatives about what they can expect throughout the period of the research. If possible, this information is provided to the respondent in the form of a letter or folder; if this is not possible or desirable, there must be a well-founded reason for this.
- (2) Researchers inform future respondents that their participation is voluntary and that they may refuse to take part without providing a reason, or stop participating at any given time. Researchers inform respondents about important factors which could possibly influence their participation. Researchers inform respondents about the method that will be used to report back to them.
- (3) The respondent is also given sufficient opportunity to read, consider and ask questions about the information provided as referred to in (1).
- (4) On the basis of the information in the information letter or folder and the information provided verbally by the researcher, the respondent is asked for consent. The consent form states, in addition to the name of the researcher, the specific reference (date/version) of the information folder.
- (5) Children and persons who are not competent to pass judgement, may only be involved in the research if no alternative exists to obtain the data and if the research is aimed at obtaining scientific insights or better treatment for these respondents. In addition, the burden on these respondents will be minimal. Where possible, researchers will provide an appropriate explanation for the situation. In all such cases, informed consent is necessary from legal representatives or from the daily supervisor(s) under whose supervision the data assimilation will be performed.
- (6) In the case of research involving children younger than 12 years of age, the consent form will be signed by the child's legal representative. In the case of research involving children 12 years of age and older, the consent form will be signed by both the child and the legal representative. From 18 years of age, consent is no longer necessary from the legal representative. In the case of decisionally incompetent respondents, consent must be obtained from the legal representative of the person, irrespective of the age of the respondent. In addition, researchers obtain consent from the actual respondent where possible.
- (7) If in the process of recruiting respondents, professional services such as treatment or teaching are offered as counter-performance, researchers must clearly explain the nature of the services and the possible risks, obligations and limitations corresponding to these services.
- (8) Researchers may offer no excessive or inappropriate rewards in order to recruit respondents.

### ***Research procedures***

- (1) Researchers shall apply no methods which could offend the dignity of the respondents or disproportionately affect their private life.
- (2) Researchers avoid being misleading in their research as far as possible, in the sense that participants are provided with incorrect information. Being deceptive in this way can only

be justified by the expected scientific, didactic or applied value of the study. These considerations should be clarified by the researcher.

- (3) Researchers present research data, in whatever form, in a (pseudo) anonymized manner. If the conditions of the provider so require, case descriptions are knowingly changed; the researchers shall make a notification of this in their report.
- (4) Data from the research is customarily saved until after the purpose for which the data was assimilated has been achieved and the reporting has been finalized, in accordance with the applicable statutory regulations. The researcher and the Academic Director shall ensure that the data is stored securely (as stated in the Data Management Plan).
- (5) In the event a respondent, whose data has been collected, objects to his or her data being used, this will be destroyed immediately if the data has not yet been used in publications. An exception to this provision can be made if longitudinal research is involved; in that case the person in question will not be questioned in the subsequent measurements; the previous measurements remain applicable until the conclusion and final report of the research. If data has already been used in publications and the researcher must meet requirements concerning replication, the identifiable personal data will be destroyed and the data will be made anonymous.

#### ***Actions of researchers***

- (1) If researchers discover important mistakes in data they have published, they will take appropriate measures to remedy such mistakes by means of a rectification, recall, erratum, or another appropriate form of publication.
- (2) Researchers may only take responsibility for any work which they actually performed or to which they contributed. Only in that case may they be mentioned as an author and only for the work to which they contributed.
- (3) If a scientific practitioner carries out research requested by a third party, he will be enabled, once the framework has been established, to carry out the assignment independently from the commissioning party. The relationship between the executing party and the commissioning party is clear, for example when advisory work or some other form of relationship exists. Any possible conflict of interests will be avoided at all times or mentioned in publications. The researcher bears responsibility for the conclusions of the research.
- (4) Agreements with external financing parties will at all times contain the provision that the researcher retains the freedom to publish findings within a reasonable, specified, period of time.

## **THE ETHICS AND DATA COMMITTEE**

### ***Objective, scope and mandate/authority***

- (1) The objective of the Ethics and Data Committee is to guarantee that scientific research undertaken at Leiden Law School is conducted in an ethically responsible manner.
- (2) To this end the Committee reviews any research proposed.
- (3) The Committee provides advice to the principal investigator or researcher on the ethical admissibility of the research. This advice is not binding.
- (4) Researchers themselves are at all times responsible for their research meeting the ethical standards.
- (5) The Committee reviews research that is proposed by researchers working at Leiden Law School, Leiden University. Researchers at Leiden Law School may also submit research proposals involving students and external PhD candidates; the researcher in question is then responsible for the proposal.
- (6) Where research is carried out in collaboration with external researchers, a request to the Committee for advice is only possible if the principal investigator is employed by Leiden law School, Leiden University.

### ***Composition***

- (1) The Committee has three members. Each proposal is assessed by at least two members of the Committee, one of which is the chairman.
- (2) Members are appointed by the Faculty Board. The term of office for members is three years.

### ***Working procedure for proposed research***

- (1) It is the responsibility of researchers to determine themselves on the basis of the Regulations on Ethical Issues whether research for which they are responsible should be submitted to the Committee.
- (2) In carrying out its tasks, the Committee will take account of the ethical principles as set out in these Regulations. The Faculty Board will notify all staff and the respondents involved of these principles (via e.g. the Programme Coordinators and publication on the faculty website).
- (3) The Committee reviews all research that involves respondents.
- (4) The Committee meets every six weeks. Requests for a review are discussed at ordinary meetings. Such a request must be received at least two weeks before the scheduled meetings. The Committee will draw up its advice no later than two weeks following a meeting and the applicant will be notified of the outcome by email.
- (5) The Committee is supported in its work by an administrative office whose tasks include the administration of the documents to be assessed and forwarding the final advice to the person who submitted the research proposal.
- (6) If necessary, the Committee can consult with independent experts in the process of its review.
- (7) To apply for a review the application form drawn up by the Committee and made available on the Committee's website should be completed by the applicant. This form contains all elements which the Committee requires to be able to provide advice. The application forms can be submitted to the Committee's administrative office: [ethiekendatacie@law.leidenuniv.nl](mailto:ethiekendatacie@law.leidenuniv.nl). The application form also states which other additional documents are required.