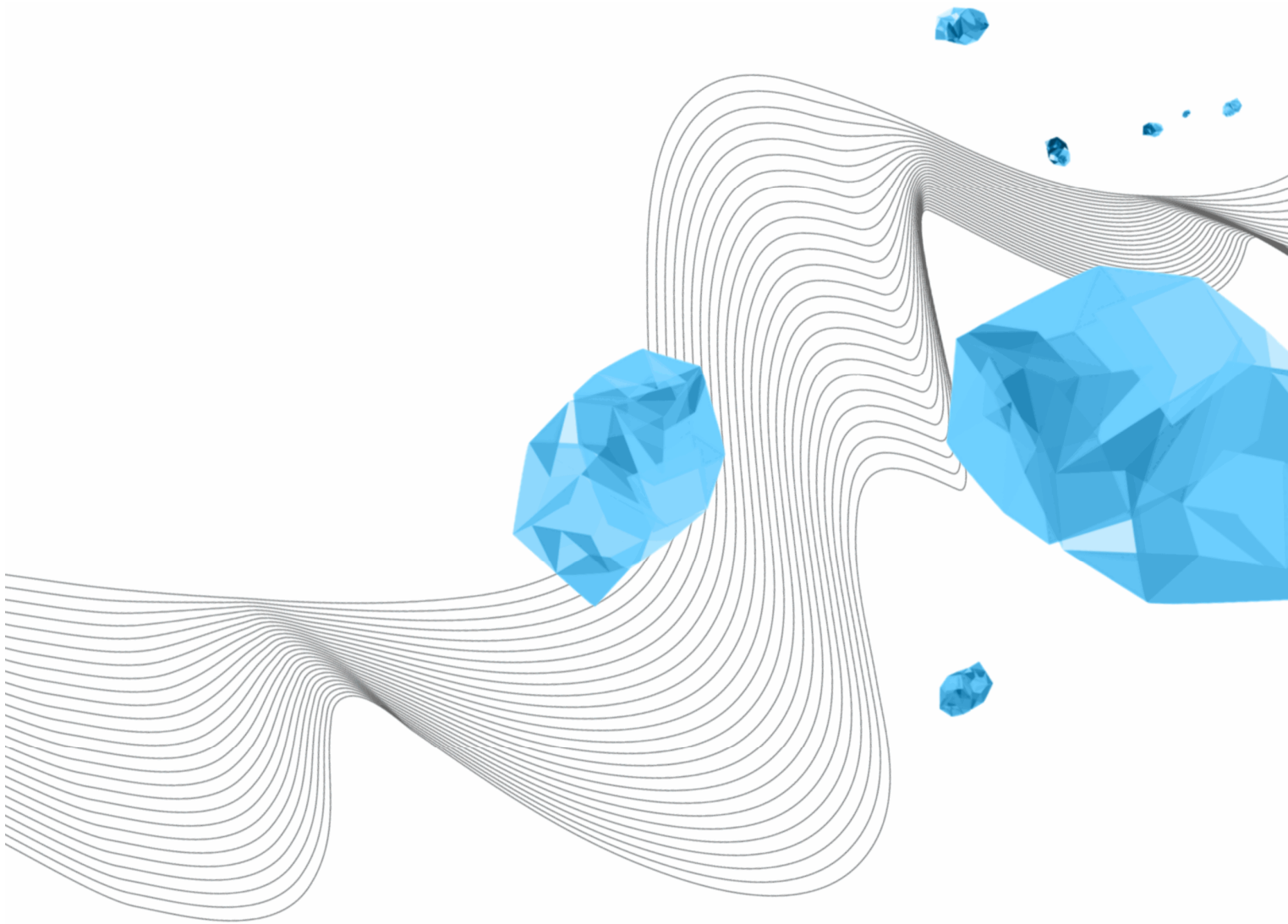


UNIVERSITEIT TWENTE.

RESEARCH ETHICS POLICY



APPROVED BY THE EXECUTIVE BOARD OF THE UNIVERSITY OF TWENTE: 07 OCTOBER 2019

Executive Summary

The University of Twente is committed to conducting research in a responsible manner and considers ethical review of research as common and good practice for all researchers including MSc/BSc/PhD students. To that end the university encourages ethical awareness and reflection of researchers and students during research. Ethical review of research facilitates researchers and students in taking – within reasonable limits - responsibility in respecting and caring for the legitimate interests of their research subjects, their research collaborators and of the environment, groups and individuals in society that might be affected by the results of the research. The ethical review is conducted and facilitated by 4 domain-specific committees: Natural Sciences & Engineering Sciences, Computer & Information Sciences, Humanities & Social Sciences, Geo-Information Sciences. The committees are installed and supported by the Faculties of the University of Twente. For complex and controversial cases, objections and quality assurance a university-wide committee is installed.

In the review process, researchers, including MSc/BSc/PhD students start with submitting their anticipated research/research proposals or substantial amendments of ongoing research for ethical review by one of the domain-specific ethical committees before commencing or continuing with their research. The self-assessment tools offered by the ethical committees support the researchers in identifying and assessing potential ethical issues of their research. Review of research involving human subjects or personal data is considered as common practice and mandatory. For other types of research it is recommended to identify the existence of possible ethical issues related to for instance the environment, dual-use aspects, low-income countries or artificial intelligence.

The research is reviewed at a level of detail proportionate to the level of ethical risk involved. To that end the review follows a three-step procedure. First the researcher conducts a quick self-assessment to identify and assess possible ethical risks. In case of possible risks or doubts, the self-assessment is evaluated by a member of the ethical committee to which the research has been submitted. In case of potential moderate to high ethical risks the ethics committee will review the research. The outcome of the review process is a statement, an advice to the researcher/researchers who have filed their research for review whether their work is compliant with ethics standards and policies.

Ethical review of research involves a learning process for researchers, assessors and the organization at large. To facilitate learning and continuous improvement of the review process the research ethics policy includes a set of quality assurance measures.

Policy statement

The University of Twente is committed to the advancement of academic research and to ensuring that research subjects, be they human, animal, cultural, biological, environmental or physical, are respected and taken care of according to legal regulations and ethical standards in the respective research fields.

The university expects that all employees, students and others involved in research at the premises of the university or on behalf of the university at other locations, act according to good scientific practice and take – within reasonable limits – responsibility in respecting and caring for the legitimate interests of their research subjects, their research collaborators and of the environment, groups and individuals in society that might be affected by the results of the research.

In accordance with Section 1.7 of the Higher Education and Scientific Research Act (Wet op het hoger onderwijs en wetenschappelijk onderzoek), the European Code of Conduct for Research Integrity¹ and the Netherlands code of conduct for scientific integrity², the University of Twente has taken a set of measures to facilitate researchers to take responsibility:

- An independent ethical review process that assesses research at the University of Twente at a level of detail proportionate to the level of ethical risk involved.
- An infrastructure consisting of ethics committees and tooling to support the review process.
- A set of guidelines to structure and facilitate the assessment.
- A governance structure to embed, guard and uphold the review process across the University and evaluate the review process in order to improve and modify it where needed.

These measures are further described in this policy document. This policy should be read in conjunction with the University of Twente code of ethics³ and the integrity codes mentioned above.

¹ <https://www.allea.org/publications/joint-publications/european-code-conduct-research-integrity/>

² <http://www.vsnu.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf>

³ <https://www.utwente.nl/en/organization/structure/management/scientific-integrity/>

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1. SCOPE AND APPLICABILITY

1.1 Scope

The University of Twente is committed to conducting research in a responsible manner and considers ethical review of research as common and good practice for all researchers including MSc/BSc/PhD students. The University stimulates ethical awareness and reflection of researchers and students during research. Ethical review of research facilitates researchers and students in this process. The aim of the ethical review is to assess practices, products and (anticipated) use of research as specified in a research proposal or plan. The outcome of the review process is a statement, an advice to the researcher/researchers who have filed their research for review whether their work is compliant with ethics standards and policies.

The form and extent of the review is proportionate to the level of ethical risks involved. In practice this means that the review starts with a light self-assessment which in some cases may lead to a more extensive ethical review by a committee. Ethical review of research involves the assessment of research proposals in terms of their ethical acceptance based on a set of generic principles and field-specific principles

In this policy, research is understood as the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes. The definition of research encompasses experimental and observational research, fundamental and applied research, and desk or literature research. Research may involve study of and/or interaction with research subjects, be they human, animal, cultural, biological, environmental or physical. Data to perform research may be from public sources or internet data bases, or be obtained by experiments or observations. Research activities with published data sources such as studies which are commonly understood in a field as literature research or desk research are generally not considered as research in need of ethical review. However when such studies (are expected to) contain conclusions and results that are socially or environmentally irresponsible, it is strongly recommended to offer the anticipated research for ethical review.

Research which falls under the Medical Research involving Human Subjects Act (WMO) needs to be reviewed by an accredited Medical Research Ethics Committee (MREC) in the Netherlands. Medical research carried out by the Techmed Centre or at other research units of the University may fall under the WMO act. The University of Twente collaborates with an accredited MREC for WMO regulated research. The ethics committees of the University of Twente do not assess research which falls under the WMO; non-WMO medical research will be assessed by the ethics committees.

The use of animals in research is regulated under the Experiments with Animals Act (Wet op Dierproeven, WoD). The Central Authority for Scientific Procedures on Animals (Centrale Commissie Dierproeven, CCD) evaluates whether a license can be granted for a project proposal. The CCD bases its decision on a recommendation by an Animal Experiments Committee (Dierexperimentencommissie, DEC). The Animal Welfare Body (Instantie voor Dierenwelzijn, IvD) of the University of Twente deals with issues such as animal welfare, alternatives to animal experiments, procedures, registration and supervision and communication with the CCD. The University of Twente collaborates with other universities regarding the ethical

review of the use of animals in research projects. The ethics committees of the University of Twente do not assess this type of research.

The ethical review process as described in this document does not include a complete assessment of compliance with legislation or other University procedures which are relevant for research such as the GDPR, WMO and University of Twente research data management policy.⁴ For assessment of compliance with WMO regulated research, researchers preferably contact the MREC the University of Twente collaborates with. For GDPR issues the researchers may contact the Data Protection Officer team at the University of Twente or the privacy contact person of the Faculty.

1.2 Applicability, compliance and policy commencing date

This policy is applicable to all employees of the University of Twente, BSc/MSc/PhD students preparing their thesis and guests (such as visiting scientists, external postdocs or PhDs) conducting research at the university's premises or on behalf of the University of Twente at other locations.

Submission of research for ethical review is voluntary, but not without obligation as researchers have a responsibility – within reasonable limits - in respecting and caring for the legitimate interests of their research subjects, their research collaborators and of the environment, groups and individuals in society that might be affected by the results of the research.

Submission of research for ethical review is mandatory in case of research involving human subjects or potentially sensitive data about or from individuals, groups or organizations.

In accordance with national and international practices, the University of Twente considers the review of research involving human subjects or personal data as common and good practice. For other types of research it is recommended to identify the existence of possible ethical issues related to for instance the environment, dual-use aspects, low-income countries or artificial intelligence. The self-assessment tools offered by the ethical committees support the researchers in identifying and assessing potential ethical issues involved with their research. Faculties may formulate additional policies which require their staff, BSc/MSc/PhD students preparing their thesis and guests to submit all research for review.

This policy takes effect on 7 October 2019 and replaces all previous research ethics policies at the University of Twente.

⁴ For an overview of legislation relevant for research, see Netherlands code of conduct for scientific practice (2018).

2. ORGANIZATION OF ETHICAL REVIEW

The ethical review is conducted and facilitated by 4 independent domain-specific committees. For complex and controversial cases, objections and quality assurance a university-wide committee is installed. The organization of ethical review is illustrated in figure 1. In sections 2.1 – 2.4, tasks and responsibilities of researchers, committees, Faculties and the Executive Board are described.

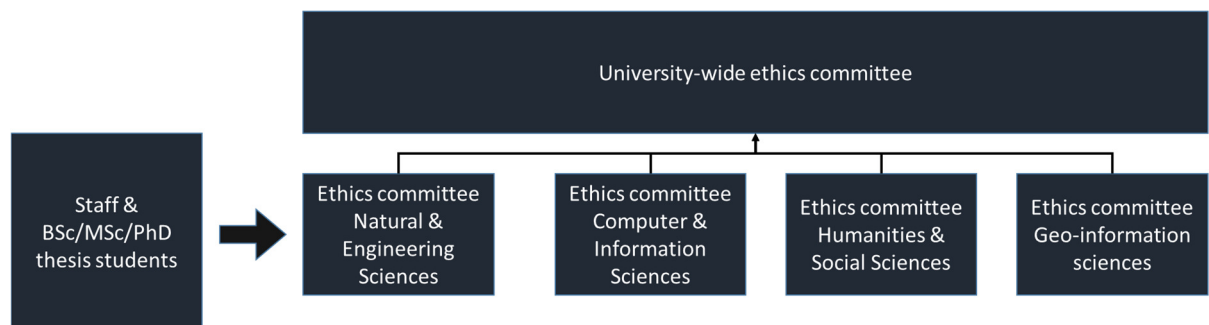


FIGURE 1: SCHEMATIC OVERVIEW ORGANIZATION ETHICAL REVIEW

2.1 Responsibilities of researchers

Scientific staff, supervisors of students preparing their theses, henceforth called researchers, are responsible for conducting an ethical review of their research where deemed necessary (see section 1.2). Researchers submit their research to one of the domain-specific committees at the University of Twente. Researchers are expected to have informed themselves about ethical principles relevant to their research and submit their research to the domain-specific committee best suited to evaluate their research. Depending on the research area, researchers may submit their research plans to the committee installed by their own faculty, or to a committee installed by another faculty. Researchers will supply information relevant for the review to the best of their knowledge. Supervisors of MSc/BSc/PhD students are co-responsible for submitting the research proposal.

2.2 Tasks, composition and responsibilities of domain-specific committees

Ethical review of research falling within the scope of this policy will be conducted by one of the domain-specific committees:

- Natural Sciences & Engineering Sciences.
- Computer & Information Sciences.
- Humanities & Social Sciences.
- Geo-Information Sciences.

The ethics committees are tasked with reviewing research proposals falling within the scope of the ethical review policy. This includes the self-assessment and provision of information to researchers regarding the review procedure. The committees will keep records of the reviews and archive the reviews according to legal provisions and applicable policies of the University of Twente. The Faculty Board of the researcher or in case of multiple researchers, the Faculty Board of the leading researcher, will periodically be informed about the advice by the committee. To assure the quality of the ethical review process, the committees are responsible for establishing quality assurance procedures, see also chapter 5.

The ethics committee consists of a minimum of 5 members including a chairman and vice-chairman, elected by the members; together they should be able to review all research proposals in the domain of the committee. This may also include for example expertise in the field of medical research which does not fall under the Dutch law regarding medical research involving human subjects (WMO). Members of the ethics committee are appointed for a period of 4 years after an appointment procedure has taken place. Extension of appointment is possible.

Members of the ethics committees:

- are active researchers who have scientific or technical expertise related to the domain of the committee;
- have preferably knowledge of, or experience with ethical assessment;
- are able to identify potential ethical risks and assess the research projects proportionate to the ethical risks involved;
- have no apparent conflicts of interest.

The committee includes preferably a member with ethical or legal training. The committee is supported by a secretary.

2.3 Task, composition and responsibilities of the university-wide committee

The university-wide committee consists of the chairmen and vice-chairmen of the domain-specific committees. This central committee will be supported by a secretary. The committee elects a chairman from its members.

This central committee has four tasks:

1. It is responsible for quality assurance of the ethical review policy and functions as a platform for coordination between the ethics committees. See also section 5.1 on quality assurance.
2. It facilitates ethical review of complex research proposals related to two or more domain-specific committees (see also section 4.1).
3. It acts as a review committee in case of objections of researchers or Faculty Boards regarding the advice of one of the domain-specific committees. See also section 4.3 on objections.
4. It collects and moderates solutions of possible complaints from participants in research projects when these complaints involve ethical issues related to the research. One of the members of central committee will act as a contact person for complaints. See also section 4.5

When needed the central committee consults experts for the execution of its tasks.

2.4 Tasks and responsibilities of the Faculty Boards

The Faculty Boards appoint the members of the domain-specific committees. In principle, members of a committee can originate from all Faculties to assure that committees have sufficient knowledge and expertise to review research submitted to the committee. The appointment procedure guarantees the quality of the committees. The Faculty boards will appoint a secretary to support the committee.

- The Faculty of Engineering Technology, together with the Faculty of Science and Technology establishes the committee Natural Sciences & Engineering Sciences.
- The Faculty of Electrical Engineering, Mathematics and Computer Science establishes the committee Computer & Information Sciences.

- The Faculty of Behavioural, Management and Social Sciences establishes the committee Humanities & Social Sciences.
- The Faculty of Geo-Information Science and Earth Observation establishes the committee Geo-Information Sciences.

In order to facilitate the formation of domain-specific committees and the execution of their tasks, committee members will receive compensation in the form of hours allocated to this task as part of their appointment at the University of Twente. Members can be discharged on request of the member itself, or by the Faculty Board in case of dysfunction. In case of the latter the Faculty Board will hear the committee and the member of the committee allegedly dysfunctioning.

The Faculties are responsible for providing sufficient information and training to stimulate researchers' awareness and reflection of ethical issues and to support them in submitting proposals and conducting self-assessments. To that end, Faculty Boards:

- Stimulate discussion on ethical issues during meetings with senior staff members, at the level of research groups and facilitate training of staff members to become more competent in research ethics.
- Stimulate the inclusion of research ethics aspects in educational programmes, both at the bachelor, master and PhD level.
- Appoint ethical advisors, i.e. researchers or support staff tasked with supporting and counseling researchers regarding research ethics, at the level of departments or groups of departments if deemed appropriate by the Faculty Board. The advisors function as the first person to consult if a researcher has questions regarding ethics of research or the self-assessment which is part of the procedure (see section 4). The ethical advisors also stimulate attention for research ethics within the Faculty. They inform the relevant committees about research developments and ethical discussions in their field and group.

The Faculty Boards are responsible for assuring that research conducted within their Faculty is compliant with relevant (ethical) principles, norms and standards. Faculties may decide to make ethical review mandatory and require their staff, BSc/MSc/PhD students preparing their thesis and guests to submit all research for review. Alternatively, Faculty Boards may require specific research projects to be submitted for review, such as research involving human subjects or personal data. Faculty Boards may consult the domain-specific committees for advice regarding ethical issues related to research projects.

2.5 Tasks and responsibilities of the Executive Board

The Executive Board bears final responsibility for the provision of an ethical review infrastructure at the university in accordance with the duties of care as specified in the Netherlands code of conduct for research integrity. The Executive Board decides on changes in the ethics policy, after consultation with the Faculty boards, represented by the Deans. The Executive Board may consult the central committee regarding matters involving the ethical review policy and procedures.

3. GUIDING PRINCIPLES ETHICAL REVIEW

The ethics committees assess the research proposals on their ethical acceptance based on a set of generic principles and field-specific principles. This chapter describes these principles. In addition the committees take into account the Dutch and European Codes of Conduct for research integrity⁵ and commonly accepted national and international guidelines regarding ethical research review (see the list of references in Appendix A).

3.1 General guidelines for all ethics committees

All ethics committees shall consider the following aspects:

General considerations

- Assess whether ethical awareness is demonstrated by i) active reflection on the ethical issues that may arise during, or as a consequence of, the aims, procedures and setting of their research, ii) initiating a proper assessment of the potential harms and other drawbacks of the research for individuals, communities and society, and iii) monitoring for any developments that may impact upon ethical aspects of the research.

Human research participants

- Ensure that informed consent procedures are followed towards research participants.
- For children and adults incapable of giving informed consent, ensure that informed consent will be obtained from parents or legal guardians.
- Ensure that research participants are treated with respect and dignity and that they are not exposed to serious physical or psychological harm or strain as a result of the research.

Personal data

- Ensure that the collection and use of personal data is based on informed consent, is necessary for the research, is stored securely, and is stored no longer than necessary.
- Ensure that secondary use of personal data is based on informed consent or proper justification if consent cannot be maintained.
- Take special precautions for the processing of sensitive personal data (race, sexual orientation, political opinions, medical data, etc.), research involving tracking and surveillance, and further processing and merging of data sets.

Social responsibility and sustainability

- Assess whether the research can be anticipated to provide knowledge, products, or practical applications that may negatively affect the interests of groups or individuals in society, including increased risks to health and safety, well-being, opportunities and rights, and enhanced risks of unequal treatment and discrimination. If so, take actions to prevent or mitigate these risks, and include relevant stakeholders in the research if possible.
- Assess whether the research can be reasonably anticipated to provide products, technologies or practical applications that are not environmentally sustainable and/or that have negative impact on the environment, animals and/or plants. If so, a justification is

⁵ <http://www.vsnul.nl/files/documents/Netherlands%20Code%20of%20Conduct%20for%20Research%20Integrity%202018.pdf>
<https://www.allea.org/publications/joint-publications/european-code-conduct-research-integrity/>

needed and efforts need to be taken to mitigate negative environmental effects and promote sustainability.

- Assess whether the research will be conducted, in part or in whole, in lower- and lower-middle income countries or areas. If so assess special risks for researchers and research subjects, include benefit-sharing actions, and arrange for harmonizing University of Twente and local ethics review.

Animals

- If animals are involved in research, ensure that there is a justification and that the researcher has contacted the Animal Welfare Body (IvD) of the University of Twente to verify that the research does not fall under the Animal Experiments Act.

Medical research

- If the research involves medical research, ensure that the researcher has verified whether the research does not fall under the Medical Research involving Human Subjects Act (WMO) and whether a non-WMO declaration is needed.

Potential conflicts of interest

- Assess whether any of the parties involved in overseeing or carrying out the research have a potential conflict of interest that could affect or seem to affect the ethical conduct, review or oversight of the research, including financial interests, conflicts of commitment, and conflicts of conscience.

3.2 Additional guidelines committee for the Humanities & Social Sciences

Due to the type of research in the social and behavioural sciences, and the humanities specific themes arise related to both the topics of research and the research methods applied for its execution. The main ethical challenges are related to sufficiently safeguarding the interests of human research participants, as well as other individuals and groups affected by the research and its results. The following themes and principles apply, but are not limited to (see also the Dutch Code of ethics for research in the social and behavioural sciences involving human participants):

- The researcher respects the dignity of humans and their environment by avoiding exploitation, treating participants and their communities with respect and care, and protecting those with diminished autonomy. This means that asking for informed consent of participants (or their proxies) is default, unless the research cannot be effective if people are fully informed in advance. It also implies that the privacy of participants is respected and personal data are stored and processed with special care.
- Researchers strive towards a minimization of harm, and a just distribution of benefits and burdens, with respect for the potentially conflicting interests of diverse (groups of) participants, communities, and society. Researchers adopt an ethical attitude in which they are mindful of the meaning, implications and consequences of the research and its results, for anyone affected by these.
- When investigating communities and social groups, researchers show proper respect for all groups involved: respect for the values and views of research participants, including those that deviate from those generally accepted by society; avoid using classifications or designations that allow for unreasonable generalizations; acquire knowledge of local

traditions, traditional knowledge and social matters, and enter, as far as possible, into a dialogue with local inhabitants, representatives of the culture and local authorities, especially with respect to research in other countries or in minority cultures.

- Ensure that the research does not contribute to, and if possible diminishes, unequal treatment, stigmatization, discrimination, and other inequalities in society, and does not contain biases in the research design that could contribute to such consequences.

3.3 Additional guidelines committee for the Geo-Information Sciences

Due to the type of research covered in the area of geo-information sciences specific ethical themes arise which need ethical assessment in addition to the generic principles discussed in section 3.1. These themes include, but are not limited to:

- Research in the field of geo-information sciences may target less developed countries with concerns on typical issues such as security and legal order, sexual and reproductive health and rights and equality of women. Countries may lack human rights; they may be in war and/or may have oppressive regimes. Ensure that the research does not contribute to, and if possible diminishes, unequal treatment, stigmatization, discrimination, and other inequalities in society, and does not contain biases in the research design that could contribute to such consequences.
- Research often has to deal with problems that relate to human life and livelihood by trying to find socio-economic solutions compatible with a respect for the environment and the protection of nature and land. As such a critical analysis must be performed on the management and possible misuse of geo-information resources including remote sensing data. When investigating communities and social groups, show proper respect for all groups involved: show respect for the values and views of research participants, including those that deviate from those generally accepted by society; avoid using classifications or designations that allow for unreasonable generalizations; acquire knowledge of local traditions, traditional knowledge and social matters, and enter, as far as possible, into a dialogue with local inhabitants, representatives of the culture and local authorities, especially with respect to research in other countries or in minority cultures.
- Research will pay attention on adverse aspects of applications in geo-information technology by considering the ethical, cultural and economic repercussions that applications may have on society. Consider how the research could contribute to a better understanding of, and better protections for, basic human rights, such as freedom, autonomy, human dignity, and privacy, and strike an appropriate balance between the recognition of cultural differences and the recognition of basic human rights.
- Research in the field of geo-information sciences needs to respects ethical principles underlying research and capacity building projects and sees to adequate descriptions on the roles and responsibilities of the various parties involved.

3.4 Additional guidelines committee for the Natural Sciences & Engineering Sciences

Research in the area of Natural Sciences and Engineering Sciences involves the use of materials and/or devices and may be oriented towards their development, their use as tools to reach another goal, or both. Due to this type of research, specific ethical themes arise which need ethical assessment in addition to the generic principles discussed in section 3.1. These themes include, but are not limited to:

- When developing materials and devices, attention must be paid to the (material or social) environment. Research should take into account: sustainability, use of materials and energy; enhancement of equality; potentially undesirable and / or unintended use.
- Avoid the misuse of research materials and results by considering whether the materials, methods, technologies, and knowledge involved in or generated during the research or innovation could serve, or easily be modified or enhanced to serve, alternative, unethical or ethically questionable purposes that could harm individuals, animals, society and or the environment;
- Take special precautions to prevent or counter the effects of potential misuse of security-sensitive chemical, radiological, or nuclear materials and knowledge (e.g. the appointment of a security advisor, limiting dissemination, classification, training for staff).
- Safety of persons who are in contact with developed materials and devices (researchers, research subjects, or any others) must be safeguarded by appropriate safety measures and risk analyses. Potential risks must be weighed against foreseeable benefits
- Studies with persons are to be carried out in a manner that respects their personal integrity, autonomy, privacy and dignity. Voluntary basis for participation must be ensured, and participants must be explicitly informed about procedures and potential risks, and asked for their consent. Similar caution regarding voluntary basis and consent must be observed in obtaining human cells, tissue or other materials.
- Anticipate and assess potential risks of harm to the urbanised or natural environment as a result of the applications or uses of the technology, and take appropriate measures to address them during the innovation process;
 - Optimize the technology for effective and cost-efficient resource recovery (recycling);
 - Take responsibility to search for technological solutions that lower the potential consumption of raw materials and energy;
 - Take responsibility to search for technological solutions that lower the production of environmentally harmful wastes and lessen environmental pollution;
- Consider whether technology that is developed could have adverse effects of the following kinds, and if so, consider mitigating actions:
 - immediate or long-term risks of harm to public health and safety;
 - a disproportionately negative impact on certain groups of users or non-users, for example people of a certain age, gender, sexual orientation, social class, race, ethnicity, religion, culture or disability;
 - negative impacts on individual freedom, individual choice, privacy, human dignity, or the integrity of the human body
 - risks of harm to well-being and interests of users and non-users, for example, risks of increased stress, hardship, anxiety, social isolation, or harm to self-esteem
- Consider whether the technology that is developed could be developed so as to have larger social benefits, such as contributing to social equality and nondiscrimination, protection and inclusion of vulnerable groups, supporting cultural diversity, and protecting democratic institutions.

3.5 Additional guidelines committee Computer & Information Sciences

Due to the type of research covered in the area of computer & information sciences specific ethical themes arise which need ethical assessment in addition to the generic principles discussed in section 3.1. These themes include, but are not limited to:

- Some methods of research can lead to accidental discoveries that may be of vital importance to the subject, such as an irregular heartbeat on an ECG or malicious behavior on the Internet. If researchers anticipate such findings from the start of the research, a clause should be included in the proposal explaining the procedure to be followed in such a case. Ensure that new research concepts and innovations, by themselves or through their use in a system, do not pose inherent direct or long-term risks of harm to public health and safety
- Research involving interviewing research participants about illegal activities they may have performed or may be involved in, requires a specific informed consent procedure leaving the research participant unidentified to assure participation. Ensure that new research concepts and innovations offer reasonable protection against any potential unauthorized disclosure, manipulation or deletion of information and against potential denial of service attacks, e.g. protection against hacking, cracking, cyber vandalism, software piracy, computer fraud, ransom attacks, disruption of service;
- Treat with extreme caution the dissemination of research involving the identification of undiscovered security weaknesses in existing systems; Avoid practical experiments with computer viruses or perform them in a controlled environment, and exercise extreme caution in the dissemination of the results of paper-based (theoretical) computer virus experiments;
- Ensure that new research concepts and innovations do not pose any unjustified inherent risks to the right of individuals to control the disclosure of their personal data. If research concepts and innovations involve the combination of multiple data sources, carefully consider the effects on (informational) privacy.
- If research concepts and innovations involve the development of capabilities for, or the use of, data surveillance or human subject monitoring or surveillance, then invoke the requirement for informed consent, if appropriate. Strike an appropriate balance between the need to monitor and control personal information and the right of individuals to (informational) privacy and other human rights.
- Ensure that decisions made by information systems that have significant social impact take into account the rights, values and interests of stakeholders, including users, and make efforts to ensure that the reasons for decisions made by information systems can be retrieved, so as to make the systems accountable.

4. ETHICAL REVIEW PROCEDURE

4.1 Procedures at domain-specific committees

Ethical review of research consists of a three-step procedure, see figure 2.

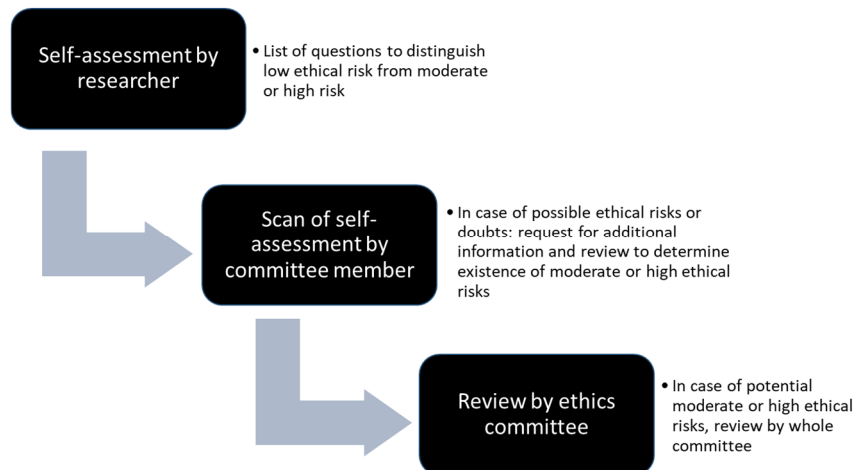


FIGURE 2: ETHICAL REVIEW PROCEDURE

1. Researchers select one of the domain-specific committees to which they submit a self-assessment. The research can only be submitted to one ethics committee. If two or more domains are equally covered, the research may be reviewed by the central committee. The self-assessment is composed of administrative questions, a summary of the intended study, general ethical questions and research domain-specific questions. Answers are restricted to 'yes'/'no'/'maybe' plus text fields to address specifics regarding the answer. Additional information regarding the specific questions in the self-assessment may be offered by the domain-specific committee via a FAQ, further explanation and/or example cases. When all questions in the self-assessment are answered with 'no', no further ethical review is necessary. A positive opinion, specifically mentioning that it is based on the given answers, is issued to the applicant and (periodically) the Dean of the leading Faculty of the research project. When one or more questions are answered with 'yes' or 'maybe', further review is necessary and the self-assessment is sent to the committee (the second step in the procedure).
2. In this second step the committee will request a description of the research approach, methodology or protocol from the submitting researcher or request additional explanation for the responses in the self-assessment. One of the committee members will receive the self-assessment and/or the research approach, methodology or protocol digitally to review as first assessor. The domain-specific committees may choose to develop specific procedures in line with the ethical review policy for the organization and execution of this review. To guarantee an independent review, the committee member (first assessor) cannot be involved in the submitted research, or be related to the submitting researcher. When in doubt the first assessor can consult another committee member for a second opinion. Again, no relations can exist between the second assessor and the researcher or research project. In case of

complex research proposals which may be related in terms of contents with the domain of another committee the first assessor may consult a member of another domain-specific committee. The first assessor will assess whether the anticipated research (as evident from a research proposal or plan) is compliant with the guidelines of the ethics review policy. The opinion, based on the submitted documents and communication with the researcher, is reported to the applicant and (periodically) the Dean of the leading Faculty of the research project.

3. In case of controversial cases, e.g. when first and second assessor have diverging opinions, or if they are both in doubt, or if casuistry for an application is lacking because the methods used are novel, the application will be submitted to the whole committee for discussion during a meeting. This is the third step in the procedure. In case of cases which i) relate to two or more domains, ii) are considered to have potential moderate or high risks and iii) are deemed too complex by the assessors in step 2 to be evaluated by one specific domain-committee, the research may be submitted to the university-wide committee. The domain-specific or, if applicable, the university-wide committee will endeavor to meet at the latest three weeks after the information is forwarded. The submitting researcher can be invited for further explanation and/or to address questions. For a committee's conclusion to be valid, a quorum of at least 75% of the members needs to be present. If the committee cannot reach a uniform opinion, voting is needed. The decision regarding the opinion is taken by majority of vote. If there is a tie vote, the chairman shall have the casting vote. A positive or negative opinion is issued. Those outvoted will write a minority statement that will be fed back to the researcher with the decision. The secretary will take minutes of the meeting.

Each application will be stored in a central university database according to legal provisions and the University's archiving policy, which enables reporting and analysis of the ethical review process at the University of Twente.

4.2 Procedure university-wide committee

The university-wide committee meets at least three times per year to evaluate the operations of the domain-specific committees. It is recommended that some of the meetings of the central committee include as guest the chairman or a delegated member of a medical-ethical assessment committee (MREC) to ensure proper collaboration between the ethics committees and the MREC.

Meetings for the university-wide committee are prepared by the chairman of the committee. The agenda may include the following items:

- New developments in research ethics (including developments at the national and international level).
- Regulations for the University of Twente ethics committees (proposition, implementation and monitoring of standards and regulations that apply to all ethics committees).
- Operation of the University of Twente ethics committees (problems and issues with one or more committees other than those having to do with joint standards and regulations).
- Ethical review of a complex or controversial research project related to two or more domain-specific committees. See section 4.1.

Minutes are made for distribution amongst the central committee, as well as amongst the domain-specific committees.

When necessary, the central committee meets incidentally to discuss and decide on appeals of the submitting researcher against the opinion of the domain-specific committees (see section 4.4).

4.3 Procedure in case of an appeal against the opinion of the domain-specific committee

The domain-specific committees offer a non-binding advice to the researcher. In case of disagreement with this opinion, the researcher can appeal against it with the central committee. The central committee discusses the case and offers an advice to the submitting researcher and the Executive Board.

The committee will endeavor to meet at the latest three weeks after an appeal is made, and issues its decision at most four weeks after the appeal is made. For a quorum, at least four members need to be present, representing three committees. Members of the domain-specific committee of which the opinion is appealed should not be present. For an appeal, the central committee collects (i) the original submission from the appellant; (ii) the recommendation from the domain-specific committee, (iii) a statement of appeal by the appellant with reasons for objecting to the recommendations; (iv) a response to the statement of appeal by the chairman of the domain-specific committee.

4.4 Complaints regarding the ethical review process

In case of suspicions or observations of irregularities in the ethical review process, members of the ethics committees, researchers submitting research proposals or other employees of the university are asked to contact a confidential advisor or submit a complaint (general University of Twente complaints procedure or University of Twente whistleblower procedure).

4.5 Complaints procedure for participants in research projects

During research projects ethical issues may arise, foreseen or unforeseen. The University of Twente considers it as its responsibility to take care of such issues. Also from the viewpoint of quality assurance it is important to evaluate such issues in order to identify improvements in the ethical review procedure. Research participants who wish to file a complaint can do so by contacting the leading researcher. In case the complaint is not resolved, research participants may send their complaint to the contact person for complaints at the central committee. The contact person will examine whether the complaint is admissible by verifying whether the complaint relates to research projects of the University of Twente, includes research ethics aspects, whether it is sufficiently founded and whether it is of significance. In case of an admissible complaint the contact person of the central committee will ensure the complaint is addressed and ensures that any improvement points are fed back to the involved researchers, committee and/or procedures.

5. QUALITY ASSURANCE

5.1 Quality assurance of the review processes

The organization and execution of ethical review of research can be characterized as a learning process of both individual researchers and the organization more broadly. To ensure that the ethical review process at the University of Twente satisfies and meets requirements and expectations formulated by the Executive Board, Faculty Boards, researchers and external stakeholders including funders of research, this policy stipulates a set of quality assurance processes at the level of the domain-specific committees and the central committee.

At the level of the domain-specific committees:

- For quality assurance the domain-specific committees may regularly perform random checks on self-assessments with only 'no' answers. This random check consists of a review of the submitted summary and text fields by one or more of the committee members to assess whether the positive opinion is indeed applicable. If consistency is lacking or if the information is inconclusive, the submitting researcher may be contacted by the secretary of the committee for further information. Researchers are clearly informed about this possibility when submitting their research for review.
- The committees regularly review whether the necessary knowledge and competences to execute their task is present in the committee. The committees establish a mechanism to regularly discuss a sample of the assessment and opinions issued by members. This is to serve consistency between committee members' assessments, and to stimulate mutual learning within the committee. When deemed useful or necessary members of the committee receive additional education and training to fulfill their tasks as assessors. The committees document information relevant as evidence for their competences.
- To improve the ethical review procedure, ethics committees discuss with researchers the procedure and consider where improvements are needed regarding information and support for researchers submitting research plans for review.

At the level of the central committee:

- The committee drafts an annual report for the Executive Board and Faculty Boards where she reports on the activities of the domain-specific ethics committees and its own. The report will not disclose confidential information of the research projects, researchers and research subjects. The annual report contains at least: number of ethical reviews per research domain, rejections, complaints, specific ethical issues, quality of the reviews and review process, and composition of the ethics committees. The report is sent to the Executive Board and Faculty Boards.
- As part of the annual report, a section is included which reflects on the ethical review process at the University of Twente and a brief improvement and action plan. The evaluation and improvement action process will be structured as a Plan-Do-Check-Act cycle.

5.2 Policy review

As part of the quality assurance of the ethical review, this ethical review policy will be reviewed every five years or upon request by the Executive Board or Faculty Boards. For the review, the Executive Board may consult two external experts who are asked for their evaluation and recommendations regarding policies, procedures and practices. The review will take place under the responsibility of the Executive Board in consultation with the Faculty Boards.

APPENDIX A: NATIONAL AND INTERNATIONAL ETHICAL GUIDELINES

CEN Workshop Agreement (2017). Ethics assessment for research and innovation - Part 1: Ethics committee. CWA 17145-1.

CEN Workshop Agreement (2017). Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework. CWA 17145-2

Code of ethics for research in the social and behavioural sciences involving human participants (2018)

World Health Organization (2011). Standards and operational guidance for ethics review of health-related research with human participants

World Medical Association (2018). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

Council for International Organizations of Medical Sciences (CIOMS) (2002) - International Ethical Guidelines for Biomedical Research Involving Human Subjects

European Commission. Horizon 2020 ethics review