TU Delft Regulations on Human Trials[1]

THE EXECUTIVE BOARD OF DELFT UNIVERSITY OF TECHNOLOGY

Whereas:

In the university's research, it is permitted to use people for demonstrations or experiments; it is of great importance that the university's research is utterly reliable and honest, and therefore any risk for the test subjects must be deemed to be in proportion to the importance of the research;

members of the university community who use people as test subjects as part of scientific research and teaching are expected to have a full understanding of their responsibilities and high standards of care with regard to the test subjects;

it is desirable to set rules partly with a view to protecting the physical and mental integrity of the test subjects;

it is desirable for the existing TU Delft assessment procedure regulations on human trials to no longer be regulations of the Scientific Integrity Committee and the subcommittee on human trials to no longer be a subcommittee of the Scientific Integrity Committee, but instead for them to become regulations and a committee of the Executive Board, in view of the increased number and importance of human trials;

and to that end, in view of Section 1.7 of the Higher Education and Scientific Research Act (*Wet op het hoger onderwijs en wetenschappelijk onderzoek*, WHW), agrees the following regulations.

GENERAL

Article 1 Definitions

The following definitions apply in these regulations:

a. human trial: any activity in which research is conducted on persons or their behaviour or opinions in a situation determined by a trial coordinator;
b. trial coordinator: a member of the academic staff or a student of TU Delft or another institution with direct authority over the implementation of a human trial taking place under the auspices of TU Delft;
c. test subject: a person who takes part in a human trial;
d. checklist: the checklist referred to in Articles 5 and 6 of these regulations;
e. form: the research application form referred to in Articles 5 and 7 of these regulations;
f. informed consent: a voluntary decision by a competent person to agree to take part in a human trial or permission to participate from the legal representative(s) of a competent person;
g. committee: the TU Delft Human Research Ethics Committee referred to in Article 3 of these regulations.

Article 2 Assessment of human trials

If, within the framework of research conducted by TU Delft or teaching at TU Delft, it is desirable to conduct a human trial, this will only be permitted once the study has been assessed and approved by the TU Delft Human Research Ethics Committee, its (vice-)chairperson or the faculty committee, as described in Articles 6 to 9 of these regulations.

[1] *This is a translation of the Dutch version of the Regulations. In case of a conflict between the English and Dutch version of the Regulations, the Dutch version will prevail and will be binding.*

COMMITTEE

Article 3 TU Delft Human Research Ethics Committee

The Executive Board will establish the TU Delft Human Research Ethics Committee, abbreviated to HREC, which carries out the duties and assumes the powers set out in these regulations.

Article 4 Composition and appointment of the committee

1. The committee will consist of a chairperson member, a vice-chairperson member and at least two members, who will be appointed by the Executive Board for a four-year term. Re-appointment is permitted.
2. In appointing members, efforts will be made to achieve a balanced representation of the university's disciplines that engage in human trials.
3. Committee membership may be terminated prematurely: a) at the member's own request or b) as a result of poor performance as a member of the committee or if other compelling reasons justify this in the judgement of the Executive Board, but only after the individual concerned has been given a hearing by the committee.
4. The committee will also be supported by a secretary, to be designated by the Executive Board after consulting with the committee.

Article 5 Duties and powers of the committee

1. The committee is tasked with assessing human trials in terms of ethical acceptability, with particular emphasis on informed consent. Each assessment will be conducted by at least three members of the committee, including the chairperson or vice-chairperson.
2. For this purpose, the committee will draw up a checklist for human trials, to be used by every trial coordinator when submitting a study to the committee. The checklist will provide an indication of whether the risk to participants of taking part in the study (the human trial) is minimal or more than minimal. For studies that exceed a minimal level of risk, the committee will compile a research application form for human trials (Research Ethics Application).
3. The committee will advise the Executive Board and the faculties on the development of policy concerning human trials, and will focus in particular on developing proposals for guidelines and specific codes of conduct concerning the duty of care to be observed in human trials.
4. The committee will issue the Executive Board with an annual report on its activities. In its report, the committee will also include its assessment of the operation of the regulations and, where necessary, will propose improvements to the Executive Board.

PROCEDURE

Article 6 Research checklist

1. Before any human trial, the researcher will complete a checklist recording what will happen during the research, how test subjects will be treated and details of how the research data will be dealt with if research results will be recorded. If the checklist indicates the need, the researcher will also append any additional information requested. The checklist will be sent to the committee.
2. The checklist will cover the following matters as a minimum:

a. the department, working group or research institute involved (if possible: the research group/section involved) responsible for the study and the research coordinator;
b. the location where the trial will be conducted;
c. the context of the trial in the study and/or study programme;
d. the aim and justification of the trial and a description of the expected results;
e. a description of the trial scenario and the actions to be taken;
f. the duration of the study and any recalls, and the corresponding period of validity of the protocol;
g. details of how informed consent is obtained and the information provided to the test subject in advance;
h. details of how test subjects' personal data will be handled in relation to confidentiality requirements;

i. the advice that a test subject is free to terminate his/her participation in the trial at any time without undergoing any negative consequences as a result;
j. the compensation and/or expenses payments payable to the test subject;
k. any risks to the test subject (and his/her health) and details of how the test subject is insured against any negative consequences during or following the trial;
l. the way in which the safety of equipment used for the study will be guaranteed.

Article 7 Assessment by the chairperson

1. The (vice-)chairperson will use the checklist to decide whether there is minimal risk to participants in taking part in the study (the human trial). If the (vice-)chairperson considers the level of risk to be minimal, he/she will approve the study and, in doing so, will as far as possible apply the assessment outlined in Article 8, paragraph 1.
2. If the (vice-)chairperson judges that there is more than minimal risk, the application will be assessed by the full committee, in accordance with Article 8. As a follow-up to the checklist, the trial coordinator must submit a detailed research request in accordance with the form provided by the committee.

Article 8 Assessment by the committee

1. The committee will assess applications for human trials in terms of their ethical acceptability based on the criteria set out in Article 6 and will also take account of any (international) standards relating to human trials. The committee's assessment will express a view in particular on the issue of whether:
   a. the test, in the committee's view, could be damaging for the test subjects;
   b. the information provided in advance to the test person is accurate and truthful and sufficiently comprehensive to ensure that it can serve as the basis for a decision to participate in the human trial to be made by the person involved or his/her legal representative or carer;
   c. whether the information provided in advance to the test subject concerning possible risks involved in the human trial is sufficiently comprehensive and clear to the extent that consent provided on that basis by the test subject involved or his/her legal representative or carer can be deemed to constitute sufficient guarantee of informed consent;
   d. whether a responsible weighing of the evidence has occurred in deciding to disclose the exact purpose of the trial to the test subject in retrospect only because explanation in advance would prejudice the trial;
   e. the protection of the test subject's physical and mental integrity and personal life have been guaranteed;
   f. the privacy of the test subject has been sufficiently guaranteed;
   g. the safety of the test subject has been sufficiently guaranteed;
   h. the test subject's after-care, the way in which results are discussed and the handling of any complaints and problems have been arranged to the committee's satisfaction.

2. The committee can provide the trial coordinator with the opportunity, either at its own initiative or at the coordinator's request, to provide further information to the committee.
3. The committee can also call on a third party expert in the relevant research field, from within or outside TU Delft, to give his/her assessment of the intended human trial.
4. If the committee agrees to the content of the application and the ethical safeguarding of the human trial, it will approve the research proposal.
5. If the committee has doubts about the design of the human trial, it can make recommendations to the trial coordinator for modifications to the study and will give the trial coordinator an opportunity to implement these recommendations; or it will give the trial coordinator an opportunity to suggest improvements of his/her own. If the recommendations for improvement are accepted or the improvements are to the satisfaction of the committee, it will approve the research proposal.
6. If the trial coordinator refuses to apply the recommendations for improvement or to do so in full, or refuses to make any improvements, a consultation will take place between the trial coordinator and the committee. If these consultations result in agreement, the committee will approve the research proposal.
7. If the consultations do not result in agreement and the recommendations for improvement are not applied by the trial coordinator, the human trial will not be approved by the committee and not performed by the trial coordinator. The trial coordinator may then follow the objection procedure outlined in Article 10.

8. If the committee judges that the study involves a medical trial, instead of issuing or withholding approval of the study, it may refer the request to a Medical Committee. If the trial coordinator disagrees with this assessment, he/she can follow the objection procedure outlined in Article 10.

Article 9 Faculty-level assessment of student research

1. In the case of human trials to be conducted by Bachelor's or Master's students, the assessment will be made by a committee from the faculty concerned, in accordance with conditions set by the committee (HREC), including those guaranteeing the protection of the physical and mental integrity of test subjects. Articles 6, 7 and 8 will apply to this *mutatis mutandis*, in which case '(vice-)chairperson of the committee' should read: '(vice-)chairperson of the faculty committee'.
2. If requested, the faculty committee will be accountable to the committee (HREC). Members of the committee (HREC) will serve as members of the committee in their own faculty or be otherwise linked to the faculty committee.
3. By way of exception to Article 8, paragraphs 5 to 7, the faculty committee can refer the case to the committee (HREC), which will then conduct the assessment in accordance with Article 8.

Article 10 Objections

1. In the event of continued objections following appropriate consultation, as referred to in Article 8, paragraph 7, or a referral to a Medical Committee, as referred to in Article 8, paragraph 8, the trial coordinator may put the application before the Executive Board within two weeks after rejection by the committee.
2. In the event of objections as referred to in the previous paragraph, the Executive Board will give both the trial coordinator submitting the study for approval and the committee an opportunity to explain their positions.
3. The Executive Board will then make a decision on whether to approve the study.

Article 11 Independence of the committee and confidentiality

1. The committee will be independent in making its assessments. A member of the committee who is in any way involved in a human trial put before it will not participate in assessing that trial.
2. The committee members must observe confidentiality with regard to information of which they become aware during the procedure.

Article 12 Cooperation and confidentiality from staff members

1. Every TU Delft employee is obliged to cooperate fully with any request that the committee may reasonably make in exercising its powers and to do so by the reasonable deadline it sets.
2. All employees involved in dealing with a case must observe confidentiality with regard to information of which they becomes aware during the procedure.

Article 13 Transitional provisions

1. On the day on which these regulations are signed, the existing members of the subcommittee on human trials will be appointed as members of the Human Trials Ethics Committee, i.e.:
   a. Prof. Dr. S. Roeser, chairperson, TPM faculty
   b. Dr. W-P. Brinkman, vice-chairperson, EEMCS faculty
   c. Dr. J. van den Dobbelsteen, member, 3mE faculty
   d. Dr. R. Mugge, member, IDE faculty
   e. Dr. D. Pool, member, AE faculty
   f. Dr. C. van Oel, member, A+BE faculty
   g. Dr. Haneen Farah, member, CEG faculty

   The following person will be designated as secretary: Dr J. Groot Kormelink.

2. With effect from the date of these regulations, the Ethics Review Checklist and Research Ethics Application included as appendices to these regulations will be adopted as the

applicable checklist and form respectively. The committee is entitled to make amendments to these documents.

Article 14 Entry into force

These regulations enter into force on the first day after the date of the edition of the TU Delft newsletter in which they are announced.

Article 15 Official title

These regulations will be referred to as the TU Delft Regulations on Human Trials (*Regeling Mensproeven TU Delft*).

These regulations will be posted on the TU Delft website.
An announcement of these regulations and of their publication on the website will be made in the TU Delft digital newsletter *TU News*.

This was agreed in the meeting of 14 June 2016.

Prof. T. van der Hagen
President

Appendices:

- *Checklist*
- *Application Form*