ACADEMISCH CENTRUM TANDHEELKUNDE AMSTERDAM

ACTA Institutional Review Board (IRB) Regulations

Introduction

The medical ethics review of scientific medical research on humans is formally regulated in Dutch legislation by the Medical Research (Human Subjects) Act (*WMO, Wet Medisch wetenschappelijk Onderzoek met mensen*). It is carried out by one of the 19 Medical Ethics Review Committees accredited in the Netherlands. Much of the research conducted at ACTA, however, is not covered by the WMO: for example, behavioural research, retrospective research and research on residual material. Scientific journals usually ask for proof of a formal ethics review when an article is submitted.

As well as assessing research, ACTA did not have a recognizable body capable of assessing ethics issues relating to teaching, healthcare and organization.

At the same time, there are frequent changes in university policy and legislation on privacy, data collection and secure data storage. The need to implement Research Data Management (RDM) in line with the FAIR principles (Findable, Accessible, Interoperable and Reusable) – a need which is inextricably linked with transparent registration – also requires a clearly defined structural approach at ACTA.

Aim

The role of the ACTA IRB is to advise ACTA's Director of Research on ethical aspects of scientific research conducted wholly or partly under the responsibility of ACTA. Where appropriate, the Committee can also advise on ethical aspects of teaching, healthcare and organization. This is the responsibility of the members of the management team (MT) within their respective areas. The Dean bears ultimate responsibility and may be involved in the event of escalation or a potential conflict of interests.

<u>Research</u>

Checking for compliance with the legislation on privacy and secure data storage is integral to the above aim, as is the transparent registration of research proposals.

Only a summary assessment of the scientific quality of research is carried out, as this is primarily the responsibility of the principal researcher. If there is evident doubt about the quality of the research design, the IRB will withhold approval.

All research (including Bachelor's and Master's theses) conducted either at ACTA or elsewhere with the involvement of ACTA staff must be submitted to the IRB for approval before the start of the project. An IRB assessment has no legal status. Research proposals are assessed on behalf of the Dean, unless the Dean has mandated or sub-mandated this to another member of the MT.

The Committee may give formal approval for a research project that is NOT subject to the WMO but does comply with the rules under the Medical Treatment Contracts Act (*WGBO, Wet op de*

Geneeskundige Behandelingsovereenkomst), the General Data Protection Regulation (GDPR), Good Clinical Practice (GPC), Good Ethical Conduct, the Good Conduct Code and the Responsible Handling of Body Material for Scientific Research (both drawn up by Federa). The IRB also carries out checks on the observance of the rules on RDM in force at the universities and among scientific journals, including data collection and storage, the use of the correct programmes and software, and compliance with the FAIR principles.

If there is doubt as to whether the research project is subject to the WMO, the Committee will advise the researchers to ask the MERC of Amsterdam UMC to give its verdict on the matter.

Teaching and other issues

Before final approval can be granted and following assessment by the IRB, a research proposal in the field of teaching (e.g. experience of particular teaching methods, the use of particular technologies in teaching, etc.) will be submitted to the Director of Education with a request to grant permission.

As regards ethics relating to teaching, healthcare and organization in general, the aim is to ensure that ethical aspects are always considered by staff and students in their decisions and actions.

Specific duties

Providing solicited and unsolicited assessment and advice on ethical aspects of the following (non-exhaustive list): Research

Non-WMO research
- Research on residual material
- Retrospective file research
- Literature research
- Behavioural research
- Research conducted partly or entirely abroad
- Research into teaching
- Research on students

Healthcare:
- New treatment methods and treatment protocols at ACTA, or dealing with gaps in treatment methods and protocols
- The patient-caregiver relationship

Management/General:

- Assessing the application of new legislation
- Different kinds of partnership with industry and commerce (e.g. sponsorship of research or teaching facilities, or the provision of teaching)
- Activities that could have an impact on the perceived reliability or reputation of ACTA as a healthcare, teaching and research organization
- The handling of sensitive personal information on patients, students and staff
- Behaviour at ACTA in general

Questions relating to scientific integrity that the IRB is asked to consider are submitted to the Dean. Applicants' attention is also drawn to the possibility of submitting their questions to ACTA's confidential counsellor on Scientific Integrity and/or the parent universities' Scientific Integrity Committees. Any cross-faculty integrity issues will be referred to the inter-faculty IRB.

Approach and procedure

All research conducted either at ACTA or elsewhere involving ACTA staff must be submitted to the IRB for approval before the start of the project, using the procedure communicated internally. Proposals are registered in an online records system, and researchers submit them to the IRB by email, accompanied by the correct documentation. All proposals are dealt with in confidence.

The IRB normally meets weekly and aims to inform the applicant of its verdict within one week.

The Committee may decide:

- to approve non-WMO research
- to reserve its verdict and request changes
- to reject the research project (in exceptional cases)

An approved research project is assigned a registration number, which can be communicated to outside organizations and stated in publications. If the verdict is negative, the research project cannot be carried out.

Approved research projects are registered, and the relevant records can be accessed by the Director of Education and/or Dean at any time. Third parties can verify whether research projects have been approved through the secretary of ACTA's IRB, using the registration number. This facility will be posted on the ACTA website.

If it transpires that the research project is subject to the WMO, the proposal will be submitted to the Scientific Research Committee (which includes members of the IRB) so that a declaration of feasibility can be issued. This is followed by formal submission (preferably to the MERC of Amsterdam UMC). Once the researchers have obtained approval from the MERC, they will be expected to notify the ACTA IRB so that their project can be entered in the ACTA records system.

Staff and students who have ethics-related questions or problems that are not covered by the above procedure can report them to the IRB. It will then reach a verdict on the matter and/or suggest an approach, if necessary after obtaining outside expertise.

N.B. The IRB will communicate information on the procedure and the submission format, and any changes, via the familiar forums, in any case including the mailing list of assistant, associate and full professors, and the meeting of associate and full professors. This information will also be shared on the ACTA website and intranet and on the Ethics Committee's IRB Canvas course (which is accessible to students, lecturers and researchers).

Composition

The Committee comprises at least seven members, including the following by virtue of their duties:

- Data Protection Officer (DPO)
- Research Data Management (RDM) Coordinator
- Member of the Professional Conduct (PC) Committee

Also general staff members: general members are appointed for a three-year period, which can be renewed once only for three years. The above-mentioned DPO, RDM and PC are by virtue of their position permanent members of the Committee.

The Committee has a chair, a secretary and administrative assistance.

Appeals

The researcher with ultimate responsibility and the IRB work together closely to bring the research project in line with acceptable standards. Consequently, the IRB does not reject research projects as a rule, but it will draw the researcher's attention to what needs to be improved before approval can be granted. In the exceptional case where the IRB is ultimately unable to approve a research proposal, the researcher with ultimate responsibility can lodge an appeal with the Dean.

The members of the Committee are currently (as of 1 January 2022) as follows:

- Prof. F.R. Rozema, Chair of the IRB
- Dr R.C. Gorter, Interim Secretary of the IRB (Professional Conduct Committee)
- Dr B.J.J. Hattink (Research Institute, Research Data Management)
- Dr M.D. Lagerweij (member of Amsterdam UMC MERC)
- Dr A.R. Ozok (Lecturer)
- M.A. Verkijk LLM (Data Protection Officer)
- Ms A. Visser, secretarial assistant