

Regulations nWMO committees

Introduction

METC approval or a declaration of no objection (also known as a non-WMO statement) is a condition set by the Executive Board of the LUMC before research can be started.¹ The mandate for conducting a due diligence review and the associated statement of no objection was previously given by the Executive Board to the METC-LDD, but with the establishment of nWMO committees it is now brought within the research organisation, in accordance with and following the Executive Board decision taken on 8/9/2021.

These nWMO committees will advise whether proposed research falls *outside* the scope of the Medical Research Involving Human Subjects Act (WMO).^{2,3} These regulations describe the tasks, powers and responsibilities of these so-called divisional nWMO committees.

Abbreviations and Definitions

In these regulations, the following definitions apply:

Committee	nWMO committee of a division
Members	committee members
Research	scientific research
Secretary	Secretary of the divisional nWMO committees
Chairman	chairman of the divisional nWMO committees
WMO	Medical Research Involving Human Subjects Act
nWMO	Research not covered by the scope of the WMO

Tasks, Powers, Responsibilities

Duties of committees:

1. The committees have the task of assessing whether proposed research falls outside the scope of the WMO.

¹ LUMC research code (in Dutch) <https://www.lumc.nl/res/att/1023658/LUMC-Research-Code-NL-mei-2019>

² See also <https://wetten.overheid.nl/BWBR0009408/2021-07-01>

³ The role of (ethical) review for nWMO research was further elaborated in a report commissioned by the Ministry of Health, Welfare and Sport. <https://bit.ly/3nlgmFN>

2. Identify whether the proposed research deserves additional attention from research support bodies in terms of the MDR and GDPR and further relevant adjacent laws and regulations.⁴

Powers of committees:

1. The committees are authorised to declare, conditionally or unconditionally⁵, that research falls outside the scope of the WMO, by issuing a statement of no objection.

Responsibilities of committees:

1. Record and communicate their findings in a timely manner.

The chairman of the committee is responsible for:

1. Determining and coordinating the modus operandi of the various nWMO committees.
2. Securing the necessary knowledge within the committee.
3. Leading the meetings.

The committee secretary is responsible for:

1. Receiving submitted research protocols.
2. Preparing the meetings.
3. Giving timely notice of the meetings.
4. Designating a pre-processor for each research protocol submitted.
5. Correctly sending the documents that will be discussed in accordance with the agenda.
6. Reporting of the meeting.
7. Notification of decision on research protocol to investigator.
8. Archiving of committee records.
9. Monitoring the turnaround time of submitted research proposals.

Committee members are responsible for:

1. Contributing to the tasks of the committee, including with focused knowledge in the field of laws and regulations, GDPR.
2. Preparing opinions/decisions based on submitted research protocols.

Working Method / Content

General

1. Each division has its own committee.
2. The division where the principal investigator is appointed is leading in the submission of the research protocol.

⁴ It is worth noting that splitting these two tasks ostensibly creates scope for issuing a statement of no objection without eliminating a number of general standards (such as voluntariness, proportionality and safeguards for maintaining the privacy of participants) that were previously part of this test. However, these elements are still part of the procedure were it not for the fact that they have been operationalised by SOPs and checklists where it is possible to issue the statement of no objection under the condition that a researcher still seeks advice from research support bodies. If necessary, the protocol has to be rewritten in accordance with advice before the research can start.

⁵ See note 4

Submission protocol

1. A research review request is submitted digitally to the committee secretary.
2. In principle, submitters receive the recommendation within 15 working days of the submission date.

Preparation

1. The secretary shall assign investigation protocols to individual members with the request to prepare them.
2. The secretary prepares the meeting.
3. The secretary shall consult with the chair on the agenda.
4. The secretary shall ensure the timely announcement of meetings and send members the documents that will be discussed in accordance with the agenda.
5. If necessary, investigators shall be invited to the meeting to explain the investigation.

Implementation

1. Each committee shall meet preferably once every fortnight. If necessary, the schedule may be deviated from on the initiative of the secretary if too few members can attend or if an extra meeting is deemed necessary.
2. At these meetings, in addition to the chairman and secretary, at least two ordinary members of the relevant committee shall be present.
3. A report shall be made of what is discussed at the meeting by the secretary of the relevant committee.

Decision-making

1. Decision-making shall take place on the basis of consensus and, in the absence of consensus, by roll-call vote.
2. If any of the committees cannot reach a decision because of
 - a. Inadequate description of the proposed research in the research protocol, the committee refers the investigator to the Research Support Desk, with a copy to the relevant departments science committee.
 - b. Uncertainty about the scope of the WMO with regard to the proposed research, the committee refers the investigator to the METC-LDD for advice or further consideration of the file.
3. The decision will be communicated to the applicant by e-mail, preferably within 5 working days of the decision being made.

Report

1. The committees periodically draw up a report reflecting on their working methods and functioning, both collectively and for each committee separately. This report is shared with the research board with copies for information to the Research Council, METC and the divisional boards of committees.

Composition Committee / Appointment of Members

1. The committees consist of a minimum of 4 members including a chairperson.
2. The Executive Board appoints the chairman and members;
 - a. Candidates for the chair are nominated by the divisional boards.
 - b. Candidates for membership are nominated by the chairman.
 - c. The necessary knowledge should be secured with the selection of members.
4. The membership term for membership is set at 4 years, with a maximum of two terms.
5. The committee may invite others to attend the meeting as advisors.

Final Provision

The chairpersons decide in cases not provided for in the regulations, after consultation with the relevant divisional board.

Contact

Correspondence to the committee may be addressed to the secretary of the relevant committee(s).