

FSW nWMO advisory committee - Regulation

Composition of the FSW nWMO Advisory Committee:

The committee consists of at least 3 members: the FSW representatives within the METC and an advisor/policy officer. The membership term is set at 4 years. After each term, the FSW nWMO advisory committee will evaluate with the institute boards whether the membership will continue or if the position will be vacated. The decision regarding (re)appointment is made by the faculty board based on a weighted decision from the institute boards and approval from the Central Committee on Research Involving Human Subjects. After two terms have passed, a well-substantiated explanation must be provided as to why the next extension is advised/why the position is not being vacated (e.g., because personnel planning does not allow for it). The necessary knowledge should be ensured through the selection of members.

Tasks:

The committee's task is to assess whether proposed research falls outside the scope of the WMO (Medical Research Involving Human Subjects Act).

Mandate:

The committee is authorized to declare that research falls outside the scope of the WMO and can be assessed by the internal ethics committee.

Responsibilities:

The committee is responsible for recording and communicating its decisions in a timely manner.

Procedure:

Protocol submission

A request for the evaluation of a study is digitally submitted to the committee. This request can be made by: a) the researchers who wish to conduct the research; b) a member of the internal ETC (if the protocol has already been submitted to this internal ETC) when the internal ETC is uncertain about the WMO applicability of the research.

a) If researchers want to submit their study within the nWMO procedure, they must fill in the "advice form" that has been created for this purpose. Researchers may also submit METC-LDD templates to the FSW nWMO committee for advice instead of the short advice form. If the research is not subject to WMO, researchers can reuse the responses from the advice form/METC-LDD templates for submission to the relevant internal ETC.

b) If a member of the ethics committee submits a request, the secretary of the internal ETC will send all the information already received from the researchers with an explanation as to why nWMO evaluation is needed (i.e., the completed standard form for ethical evaluation with the accompanying attachments and communication).

The submitted documents are presented to all members of the FSW nWMO committee.

Decision making

1. Decision-making takes place based on consensus via email or during a scheduled meeting.
2. If the committee is unable to reach a decision due to uncertainty about the scope of the WMO concerning the proposed research, the committee will ask the chair or executive board of the METC-LDD for advice. For a conclusive decision from the committee, unanimous agreement from all members is required. In exceptional cases (e.g., in the event of illness where no advice can be sought from a third party/substitute), a conclusive decision can be made by two members, at least one of whom is an FSW representative within the METC. The committee can always decide to seek advice/expertise from external parties to reach a decision.
3. The decision is communicated to the applicant via email, preferably within 5 working days after the decision is made. Applicants typically receive the advice within 20 working days from the submission date, depending on the METC executive board's schedule, should this step be necessary, and excluding official holiday periods.