Scientific secretariat: Function and job description

Organisation Ordinance to the Human Research Act (OrgO-HRA)

Art. 3 Scientific secretariat

1 Individuals who work in the scientific secretariat must possess the following:

a. a university degree in medicine, pharmacy, natural sciences, psychology or law;
b. adequate training in Good Clinical Practice;
c. knowledge of the scientific methodology of research projects involving humans; and
d. knowledge of the legal preconditions for research on humans.

2 The scientific secretariat's staff resources should be adequate to ensure:

a. they are available to the committee and applicants; and
b. procedural deadlines are observed.

Swissethics

Position

- The organisational structure of the scientific secretariat is laid down in the rules of procedure/regulations of the ethics committee (EC).

Function

- To assist with the provision of instructions relating to the approval procedure (ascertaining the facts, coordination and communication with the parties and authorities and communication between the committee members)
- To conduct an initial review of application documents for obvious deficiencies of a formal or substantive nature (Dispatch[1], 2.9.4; Explanatory report[2], 3.2.11)
- To advise researchers (Dispatch[1], 2.9.4)
- To reduce the members' administrative workload (Dispatch[1], 1.8.3.4)

Obligations

- To conduct the **initial review** of the research projects for compliance with medical/scientific and legal requirements (Human Research Act (HRA), implementing ordinances to the HRA, the rules of Good Clinical Practice according to Annex 1 ClinO, particularly ICH-GCP), with the main focus on GCP conformity and the evaluability of research applications
- To prepare a deficiency list where appropriate
- To conduct an initial review of corrections submitted in response to the deficiency list
- To conduct an initial review of amendments, responses to conditions and other relevant application documents
- To conduct an initial review of the risk category

- To advise applicants on legal/scientific matters
- To reduce the workload of the volunteer ("militia") committee in respect of regulatory and administrative aspects
- To ensure a professional mode of working that follows traceable written processes

Additional obligations, depending on the committee's organisational structure

- To attend and minute meetings of the EC
- To formulate decisions
- To sort and distribute submitted documents to members
- To clarify competencies
- To prepare annual statistics as per the request of Swissethics/FOPH
- To organise and run local basic and continuing training events for investigators and ethics committee members
- Staff responsibilities
- Responsibility for infrastructure and premises, including archives
- To assist the chairperson in various matters, including accounting or policy matters

Competencies (rights)

- When mandated by the committee, and if stipulated in the rules of procedure: to return research applications with formal and substantive shortcomings for improvement
- To advise applicants
- To sort submitted documents by approval process (presidial, simplified or full), and suitable reviewer
- If empowered by the rules of procedure: to sign decisions in a dual signature process with the chairperson

Demarcation from the administrative secretariat

- The demarcation of tasks in relation to the administrative secretariat is set out in separate rules of procedure.
- Anyone acting in this role receives a job description.

References:

1. Dispatch to the Federal Act on Research involving Humans of 21 October 2009
2. Explanatory report on the ordinances to the Human Research Act (draft of 21 Aug. 2013).
3. Organisation Ordinance to the Human Research Act of 20 September 2013 (OrgO-HRA).