**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\(^3\), 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