Clarification of responsibility of multicenter projects with human subjects, dates and/or samples

The submission of documents for clarification of responsibility is optional and only recommended in cases when responsibility of EC is not clear or a letter of the position of the EC is mandatory for publication.

**Procedure**

1. Applicant submits documents to a first EC (=‘leadEC’): synopsis (template www.swissethics.ch), questionnaires, CRF, ev. interview guideline. If necessary, the EC will ask for additional documents.

2. LeadEC reviews documents and decides, if project falls under the scope of HRA, and informs the ECs concerned about the project by sending the documents and its opinion (responsible/not responsible).

3. ECs concerned inform leadEC about their opinion.

4. LeadEC writes letter of decision listing ECs concerned. If one EC has another position because of special cantonal laws this will be mentioned.

**Correspondence**

- In paperform and/or electronically (dependent of EC selected)
- Per e-mail
- Per e-mail
- Per Mail to the applicant, Copy per e-mail to ECs concerned

**Fees:** according to table (www.swissethics.ch)

- e.g. sponsor from industry:
  - Simplified procedure: 4500.-- (Tarifkode 4.2.3)
  - Presidential decision: 2000.-- (Tarifkode 4.3.3)

**Deadlines:** <45 days