Guideline for Clinical Trials/Studies for SFB 829

1. Writing a rough, first concept (understandable for non-professionals of the research field), including:
   - Involved people, institutes, external partners, distribution of responsibilities (main responsibility, project management, monitoring, etc)
   - Aim of the study/scientific aim
   - Study design including a schedule and details for implementation, recruitment of test persons, description of instruments, medical products, etc.
   - Statistical Analysis for calculation of the sample size (this should be done in collaboration with a statistician e.g. https://imsieweb.uni-koeln.de)
   - Planed operations and burden(s) to the test persons
   - Selection of test persons (what criteria should be fulfilled, which criteria disqualifies a person?)
   - Description of study mode
   - Method of data analysis
   - Listing of not approved drugs (if applicable)
   - Possible complications and risks
   - Risk-benefit analysis and safety management
   - Overview of expected costs and funding

   Please also use this description (B. Studienbeschreibung) as orientation for your concept: http://medfak.uni-koeln.de/19696.html

2. Counsel by the ZKS (optional)
   An initial counselling "Erstberatung" with the ZKS provides a very helpful estimate of the regulatory classification, costs, effort and tasks of your study. The first counselling is charge-free for members of the medical faculty.
   The ZKS further offers professional fee-based services for every step of the study. For an overview of the service portfolio Please visit: http://zks.uni-koeln.de/ctcc_studymanagement.html

3. Review of contracts (if applicable)
   In case of external partners legal claims relating to results, publications, time frames, patents, etc. should be agreed by contract. For revision please contact the DFS-administration (in case the study is third-party-funded). This step should be done as early as possible as this can require some time.

4. Counsel by the ethics commission of the UKK (optional)
   Each clinical study requires an approval by the ethics commission. The extent and format of an application is dependent on the regulatory classification of the study, whereas the commission ultimately decides how the study is classified.

5. Writing the application for the ethics commission
   For templates, checklists and attachments please visit the following links according to the type of study:

- Antragstellung gemäß Arzneimittelgesetz (AMG): http://medfak.uni-koeln.de/19698.html
- Antragstellung gemäß Medizinprodukteges etz (MPG): http://medfak.uni-koeln.de/19697.html
- Non-AMG/ non-MPG (only study type for which point 6 does not apply): http://medfak.uni-koeln.de/19694.html

6. Submission to Competent Authority
   - Medical product: https://www.bfarm.de/DE/Arzneimittel/Arzneimittelzulassung/KlinischePruefung/_node.html
   - Medical device: https://www.bfarm.de/DE/Medizinprodukte/KlinischePruefung/AntragAufGenehmigung/_node.html
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7. Registration

According to article 35 of the WMA Declaration of Helsinki "Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject".

Please register here:
https://www.drks.de/drks_web/navigate.do?navigationId=edit&messageDE=Studien%20registrieren&messageEN=Register%20trials
or
https://clinicaltrials.gov

8. Initiation

The initiation is the starting point of a study. The complete team meets to finally distribute and determine tasks before the measurements begin .

Helpful Links:

http://zks.uni-koeln.de

http://medfak.uni-koeln.de/19685.html

http://www.ak-med-ethik-komm.de/index.php?lang=de

https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/