Antragsformular zur Unterstützung für Forschungsprojekte

Sponsor / Sponsor-Investigator

Study Title:

Short Title / Study ID:

Protocol Version and Date:

Trial registration:

Study category and Rationale

Clinical Phase:

Background and Rationale:

Objective(s):

Outcome(s):

Study design:

Inclusion / Exclusion criteria:

Measurements and procedures:

Study Product / Intervention:

Control Intervention (if applicable):

Number of Participants with Rationale:

Study Duration:

Study Schedule:

Investigator(s):

Study Centre(s):

Statistical Considerations:

GCP Statement: ☐ *read*	This study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki, the ICH-GCP or ISO EN 14155 (as far as applicable) as well as all national legal and regulatory requirements.

Explanation for the Inclusion of vulnerable Subjects (if applicable):

Recruitment Procedure (if applicable : Advice/Flyer have to be submitted ; if applicable, please indicate the Localisation / Medium (which Newspapier)

Study Procedure/Flowchart with Timelines: Study specific Examinations have to be clearly identified

Risks/ Inconveniences, which are Study specific:

Coverage of Damages: Insurance (☐ yes ☐ no)? Sum?

Storage of Data-and Samples for Future Research Aims: ☐ **yes** ☐ **no**
If yes, please indicate in which documents (for ex. study protocol, informed consent) and on which pages you have described this topic).

Ethical Considerations:

1. Please describe the potential gain of new knowledge obtained with this study, and its meaning for patients/society.
2. Please give an assessment of the benefit/risk relationship for the patient.
3. Please explain, why the methodology is also ethically appropriate to gain new generalizable knowledge (for ex. double-blind, placebo, sham, vulnerable subjects, emergency cases, partial information only etc.)

The most relevant References:

Bitte speichern unter "*IhrName_Antragsformular_DMG*" und an info-dmg@email.de senden.