Please complete all fields. In addition, supplementary or supportive information may be provided as attachments (please indicate in the latter to what point in the below fields you are referring to).

Text in curly brackets should be adjusted to meet the proposal requirements.

Text in *blue italics* is guidance text and should be deleted before the template is submitted.

Lines can be deleted or added to meet the needs of the proposed study.

|  |
| --- |
| **Study title** |
| {Insert title which should include the key design features} |
| **MAIN APPLICANT** (Requestor) **NAME** |
| {Insert the name, address including country and full contact details including telephone number, email etc}  *The requestor is the person responsible for the conduct of the research*  *For investigator-initiated studies, the requestor is the sponsor-investigator as per the Guideline for good clinical practice E6(R2)(EMA/CHMP/ICH/135/1995, June 2017)*. |
| **MAIN APPLICANT qualifications & experience** |
| {Summarize the requestor qualifications & experience}  *Attach curriculum vitae and/or other relevant documents confirming the requestor qualifications & experience. This documentation should include any previous training in principles of GCP, relevant ICH guidance, and relevant experience, e.g., with work with clinical studies, and/or with the planned type of research* |
| **MAIN APPLICANT affiliation** |
| {If the requestor is acting as an employee of an institution (e.g., academic institution), insert the requestor role at the institution, the institution name and address including country.} |
| **co-applicant name** (if any) |
|  |
| **Co-APPLICANT qualifications & experience** |
|  |
| **CO-APPLICANT affiliation** |
|  |
| **Conflicts of interest** |
| {List all conflicts of interest} |
| **Proposed Study Sponsor - Investigator name and affiliation** (if not the requestor)**:** |
| {Insert if applicable} |
| **Research background** |
| {Insert a detailed description of the background to the planned research including any hypotheses to be tested, value to patients and understanding of the product or disease if applicable } |
| **Study rationale** |
| *The importance of the research question should be clarified and the need of the research in context of available evidence should be demonstrated* |
| **Study design** |
| {Please insert details on e.g., randomization, blinding, parallel, placebo controlled or uncontrolled, brief description of the sequence and duration of the study period, indication and overall purpose, single or multi-site} |
| **Study objectives** |
| {Insert} |
| **Brief description of the course of the study** |
| {Insert}  *Give a concise description of the study procedures. Give a chronological (i.e., visit to visit) description of all procedures and investigations. Consider including a flow diagram summary of the study and/or tabular schedule of events.* |
| **Study subjects/sample size** |
| {Insert n = } |
| **inclusion criteria** |
| {Insert}  *Inclusion criteria may be divided into general and study-specific criteria* |
| **exclusion criteria** |
| {Insert}  *Exclusion criteria may be divided into general and study-specific criteria*  *List also excluded concomitant medications if applicable* |
| **Primary endpoint(s)** |
| {Insert} |
| **secondary endpoint(s)** |
| {Insert} |
| **study medication** |
| {Insert}  Please list all medications you plan to use in the planned study; when applicable list rescue medications etc |
| **safety reporting** |
| {Insert}  *Solicited reporting? Spontaneous stimulated reporting?* |
| **Planned study site(s)** |
| {Insert} |
| **Planned statistical analyses** |
| {Insert a brief description and if applicable add info on :  \* the number and timing of statistical analyses to be performed in study  \* sample size and the rationale  \* main analysis populations  \* Focus on the analysis of the primary endpoint(s)  \* interim analyses : yes/no} |
| **Publication and posting plan** |
| {Insert a description of the planned publication and posting plan (for ex on website). Indicate whether the study results will be published as an abstract, a manuscript, a poster or other. Also and if possible, please inform about when and where the study results will be submitted for publication}  *Posting refers to clinical trial registries, publication refers to sharing the results of the investigation* |
| **Data protection** |
| {Insert a description of the measures planned to protect patient privacy and shared data}  *Insert additional info in case of use of social security database(s)* |
| **Concurrent (potentially competing) projects** |
| {Insert if applicable}  *Pertains to competing projects from the requestor that might interfere with the successful initiation, conduct or completion of this project* |
| **Requested support** |
| {Insert if applicable}  *Can include material, financial or other support (e.g. intellectual)* |
| **funding sources** |
| {Insert if applicable }  *Include also planned or obtained funding sources other than Averitas e.g. charity funding* |
| **study budget plan** |
| {Insert details of the planned plan; the plausibility of the budget plan needs to be clear}  *Be precise as possible e.g. request for study medicinal product/samples including specific packaging requirements such as blinded study medication with randomization list, , provide an itemized overview of the requested financial support and if milestone payments are requested, ensure justified tabular overview is provided.* |