1. **PURPOSE**
   To assess the advisability, on the basis of local expertise, facilities, and, most importantly, study participant (SP) safety, of accepting to conduct a given study.

2. **SCOPE**
   All clinical research units in which a study involving human SPs is conducted.

3. **RESPONSIBILITIES**
   The Principal Investigator (PI) is responsible for the conduct of all studies, so the decision as to whether or not to proceed with the conduct of any study is hers/his.

4. **BACKGROUND**

5. **PROCEDURE**
   5.1. **Scientific Design**
      5.1.1. Evaluation of the study protocol to ensure it is scientifically sound and clearly written.
      5.1.2. Protocol should provide nonclinical and clinical information on an investigational product that is adequate to support the proposed clinical trial.

   5.2. **Study Participant Safety**
      5.2.1. SP Safety - the overriding principle applied to the decision to undertake a clinical research study is the assessment of the Risk/Benefit ratio – specifically, the overall safety of the product/procedure/device for human SPs.

   5.3. **Timing**
      5.3.1. There are two activities associated with study initiation that may begin prior to contract completion (no other activities may be initiated until a signed contract is on file):
         5.3.1.1. administrative staff review (SP safety, feasibility, logistics, science, and economics)
         5.3.1.2. preparation for submission to the Institutional Review Board (IRB)
      5.3.2. On occasion, staff may begin study initiation activities (such as protocol notebook and source document creation) with a tentative budget and/or contract on file, but only upon securing PI and research team approval prior to initiating such activities.
5.4. Costs

5.4.1. The PI and the research team will review the protocol for start-up costs, defined as all direct activities that are associated with getting a study ready to enroll subjects (see exceptions below).

5.4.2. Examples of expenses include:

5.4.2.1. Administrative review/assessment
5.4.2.2. IRB preparation and submission fees
5.4.2.3. Attendance at Investigator meetings
5.4.2.4. Off-site education/training of ancillary staff
5.4.2.5. Study termination fee (included in start-up)
5.4.2.6. Record storage and archiving
5.4.2.7. Advertising costs
5.4.2.8. Adequate staff resources
5.4.2.9. Equipment availability

5.4.3. All initiation costs are noted in the contract as a separate, one-time, nonrefundable fee that is not rolled into the overall, or per-patient, reimbursement.

5.4.4. Per-participant, per-visit costs

5.4.4.1. Direct costs (e.g., local labs, diagnostic imaging, etc.)
5.4.4.2. Investigator/coordinator/staff costs

5.5. Pre-contract Activities

5.5.1. Administrative protocol review for feasibility (both logistic and economic), as well as scientific adequacy. An initial review will be done to determine feasibility of execution, including subject, staff, and PI availability and expertise.

5.5.2. Study notification: The study will be routed to all appropriate personnel after administrative review. This will include clinical research staff and the appropriate additional study Investigators.

5.5.3. The Study Coordinator (SC) will notify the sponsor of the correct location for shipping study supplies, investigational product, regulatory documents, and contacts.

5.6. After-contract Activities

5.6.1. The protocol, Investigator’s Brochure (IB), advertising, Informed Consent Form (ICF) and any additional documents deemed necessary can now be forwarded to the approved IRB for review and approval
5.6.1.1. Revisions to essential documents should be returned to the study sponsor for review and approval prior to local IRB submission.

5.6.2. A staff responsibility list will be prepared and presented for review at the study initiation meeting, if required by the study sponsor.

5.6.3. The following documents are created:
   5.6.3.1. Source documents
   5.6.3.2. Study flow sheet/timeline, created as needed or from the sponsor.
   5.6.3.3. Subject packet (if applicable)

5.7. **Feasibility**
   5.7.1. PI meeting
      5.7.1.1. The designated SC and PI generally meet to review the protocol, PI responsibilities, and discuss general operations. The regulatory binders are reviewed at this time.
      5.7.1.2. If an FDA Form 1572 is required for the study, the PI will sign the PI responsibility sheet (1572) and the budget worksheet for PI activities. The original 1572 will be maintained by the sponsor. A copy of the 1572 will be maintained in the regulatory document binder. Copies of both forms are given to the Grants and Contracts coordinator.

5.7.2. Site Initiation visit (may or may not occur at this time).
   5.7.2.1. Initiated by the trial monitor/sponsor, the research facilities are toured and the protocol is reviewed during this visit.

5.7.3. Initiation meeting
   5.7.3.1. The meeting agenda documents team member responsibilities, study-specific training plans and evaluation, planned date of first subject screening/enrollment, patient reimbursement, and study endpoint.
   5.7.3.2. Initiate patient screening/enrollment log, with weekly updates, if required, by the SC to the sponsor and enrollment notebook.

6. **TERMS & ABBREVIATIONS**
   **GCP**  Good Clinical Practice
   **IB**   Investigator Brochure
   **ICH**  The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
   **IRB**  Institutional Review Board
   **PI**   Principal Investigator
   **SC**   Study Coordinator
   **SP**   Study Participant
7. REFERENCES
   7.1. ICG and GCP Guidelines

8. ATTACHMENTS
   None