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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Assessing Protocol Feasibility** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
| **REVIEWED BY** |  |  | |  |
| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

**2.1 Purpose**

To describe the procedures for assessing the feasibility of conducting a study at [INSTITUTION] in compliance with standard protocol.

[INSTITUTION] is committed to maintain the highest scientific, clinical and ethical standards while conducting research at [Institution]. Further, [Institution] is committed to comply with all applicable regulations and guidelines in this regard. In view of the same, before agreeing to participate in a clinical research study, the Principal Investigator (PI) and Institution must agree to the scientific, clinical, and ethical merits of the study; the financial impact to the hospital; compliance with regulations; and the operational feasibility of conducting the study at [Institution]. This standard operating procedure (SOP) describes the steps for assessing the feasibility of conducting a research study at [Institution].

Additionally, Institution and PI considers the potential benefits of proposed studies to Disease control in [Institution] and development of the department’s research portfolio.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory, medical, and ethical requirements for assessing the appropriateness and feasibility of implementing a protocol within the [Institution] research network.

**2.2 Scope**

This SOP applies to the activities involved in assessing protocol feasibility for all research studies conducted at [INSTITUTION] involving human subjects.

This SOP applies to the assessment of protocols and funding for non-investigator initiated studies.

**2.3 Procedure**

**2.3.1 Protocol Assessment**

When a Sponsor/CRO contacts the study site either directly PI or the Dept of Clinical Resarch about a potential study, the Principal Investigator (PI) will assess whether or not it would be feasible to conduct the protocol with the existing staff and facilities. PI can use protocol checklist to ensure if protocol is feasible to conduct at [INSTITUTION] (AX1-V3/SOP 02/V3)

The PI will discuss the protocol with the Dept of Clinical Resarch.

The Investigator, and research staff will review the protocol to ensure the following:

**2.3.1.1 Clinical/Scientific/Ethical Feasibility**

* Clinical importance to [Institution] patients.
* Scientific merit.
* Benefits and risks associated with the protocol.
* Consistency with the priorities of the hospital and the clinical department.

**2.3.1.2 Operational Feasibility**

* Availability of personnel and other resources required to conduct the study.
* Availability of patients meeting the inclusion / exclusion criteria of the study.
* The level of interest expected from the physicians needed to recruit patients into the study.
* The operational complexity of the protocol.
* Whether there are any conflicting studies in progress

**2.3.1.3 Regulatory Feasibility**

The PI/CTC reviews the protocol to determine whether there is anything required that may be problematic when submitting the project to the IEC. As part of the review the CTC can consult with IEC representatives.

The CTC must check the following points before submitting the protocol to the IEC for approval, as IEC determines:

* Research studies have the resources necessary to protect participants:
* Adequate time for the researchers to conduct and complete the research.
* Adequate number of qualified staff
* Adequate facilities
* Access to a population that will allow recruitment of the necessary number of participants.
* Availability of medical or psychosocial resources that participants might need as a consequence of the research.

**2.3.1.4.Financial/ Legal Feasibility**

* A detailed review of the costs, including staff time needed to complete protocol activities and patient visits are determined by the PI and the CTC.
* The PI and CTC prepare the budget worksheet.
* The budget worksheet is compared with the sponsor’s budget.
* The PI and CTC will negotiate with the sponsor to establish a feasible budget. Once an agreement is made, the budget will be signed by the PI and sent to the sponsor.
* If an agreement cannot be reached with the study sponsor to cover all costs of the study, the PI and CTC will work together to determine whether the study will be conducted at [INSTITUTION].
* The Legal expert will facilitate legal review of the contract.

**2.3.2 Decision**

All the above mentioned points (2.3.1.1, 2.3.1.2, 2.3.1.3 & 2.3.1.4) will be discussed in the respective meeting(s).

Decision will be taken by consensus in the dept meeting for the conduct of the protocol at [Institution].

The PI will notify the sponsor (in case of sponsored study) of the site’s decision. In the event that the protocol not meet the above mentioned criteria. The PI will inform the same to the sponsor, allowing the Sponsor the opportunity to make changes in the suggested part of the protocol and have it reassessed.

In case of Investigator initiated studies, PI will make the required changes in the protocol or can provide rational for the same. PI will submit the protocol to IEC for review and approval after incorporating all the changes discussed during the meeting with the dept of clinical research (if any) in the protocol.

**2.4 Applicable Staff**

This SOP applies to all the personnel of the clinical research team and Dept of Clinical Research who may be responsible for making decisions regarding conduct of the research studies at [Institution].

These include the following:

* Investigator
* Legal Expert(s)
* Dept of Clinical Research Team including nurses, fieldworkers, lab staff etc

**2.5 Staff responsible for Implementation**

The Dept of Clinical Research will ensure that the research team involved in the conduct of the study will comply with this site SOP.

The Dept of Clinical Research and PI will ensure that at the time of implementation of the SOP, the research team at [Institution] are trained and in the event that an SOP is modified, provide training regarding the change(s) and ensure their compliance with the changes.

Inform IEC that this site SOP will be implemented within the institution.

**References**

1. 21 CFR 312.21 Phases of an investigation

2. 21 CFR 312.23 IND content and format

3. 21 CFR 312.60 General responsibilities of investigators

4. 21 CFR 56.109 IRB review of research

5. 21 CFR 56.111 Criteria for IRB approval of research

6. International Conference on Harmonization (ICH) Good Clinical Practices

7. Schedule Y

8. SOP of Qbec, Duke University

**Protocol Feasibility Checklist:**

**Factors to consider:**

|  |  |
| --- | --- |
| **1. Population** | |
| Do you have access to the right patient population? |  |
| Will you need to recruit patients from external sources? If so, will  sponsor provide funding? |  |
| Is the proposed enrollment goal realistic? |  |
| Is the proposed enrollment period realistic? |  |
| Will enrollment compete with other studies seeking the same  patients? |  |
| Are inclusion/exclusion criteria overly restrictive? (Consider the likely  screen failure ratio and the number of screen failures) |  |
| Do you expect a significant number of adverse events? (How ill is this  population?) |  |
| **2. Protocol** | |
| Is the protocol well designed? |  |
| Is the protocol ethical? Will the IRB have problems with it? |  |
| Is the study question important? |  |
| Will the subjects benefit from participating in the study? |  |
| Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written? (In case of sponsored  study) |  |
| Can other services (e.g., lab, radiology) meet the protocol  requirements? |  |
| Is necessary equipment available? |  |
| Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls or  postcards? |  |
| Are case report forms complex? |  |
| Are drug or device storage/accountability requirements complicated? |  |
| Will the drug be available for patients at the end of the study? (This  can impact patient satisfaction.) |  |
| **3. Procedures** | |
| Are procedures frequent? |  |
| Are procedures difficult, e.g., elderly patients asked to swallow pills? |  |
| Are procedures painful? |  |
| Is the dosing schedule complex? |  |
| **4. Staff** | |
| Are qualified staff available? |  |
| If needed, is training available? |  |
| Does the PI have adequate time to devote to the protocol? |  |
| Are additional specialists needed? |  |
| Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff will subjects encounter in a given  visit? |  |
| **5. Budgets** | |
| Does preliminary budget appear adequate?( Sponsors or investigator  generated) |  |
| If the study is canceled prior to enrollment, will the sponsor pay for  pre-study activities, e.g., IRB submission, meetings, chart reviews? |  |
| Will sponsor pay for an adequate number of screen failures  (especially important for difficult protocols)? |  |
| Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work  required by protocol? |  |
| Any other protocol required equipments or procedure etc |  |
| **6. Other** | |
| Is adequate space available? |  |
| Will electronic or remote data retrieval systems be used? If so, will  sponsor provide training? |  |
| Does the sponsor/PI expect this study to be audited by the regulatory  bodies? |  |