STANDARD OPERATING PROCEDURE 1: HOW TO SCREEN A STUDY FOR A MULTICENTER TRIAL.

SOP 1: How to screen a study for a multicenter trial.

Multicenter trials

A multi-center trial needs the following-

- Needs to assure standardization
- Uniformity of procedures
- High data quality
- Collaboration across sites

Scoring system – FINER

This scoring system will be used to screen the proposals for multi-center trials-

Components and criteria of FINER are as follows:

Components	Criteria
1. Feasibility**	- Ensures adequacy of research design
	- Guarantees adequate funding
	- Recruits target population strategically
	- Aims an achievable sample size
	- Prioritizes measurables outcomes
	- Optimizes human and technical resources
	- Accounts for clinician commitment
	- Procures high adherence to the treatment and low rate of dropouts
	- Opts for appropriate and affordable timeframe
2. Interesting	- Engages the interest of principal investigators
	- Attracts the attention of the readers
	- Presents a unique and relevant perspective of the problem
3. Novel	- Generates new hypothesis
	- Improves methodological flaws of existing studies
	- Resolves a gap in the existing literature
4. Ethical	- Complies with the local ethical committees
	- Safeguards the main principles of ethical research
5. Relevant	- Generates new knowledge
	- Contributes to improve clinical practice
	- Stimulates further research

	- Provides an accurate answer to a specific research question

**Funding: The likelihood of the funding is based on the research funders as well as whether the PI or study team has approached any funding bodies. Also, whether there are any replies from them.

Trial Screening Committee

Steps for screening of a proposal-

No.	Step	Method
1.	Initial screening	Screening by a 3-member team that must include a statistician
2.	Submit a proposal	Concept note/Detailed proposal to be sent to HCC after signing a Non-Disclosure Agreement (NDA) by HCC and Principal Investigator (PI). Refer to Appendix A for elements of concept note.
3.	Feasibility	Study can only be considered further if deemed feasible by the screening committee The PI will be encouraged to identify funding and collaborators.
4.	Selection of a study	If multiple projects are under review, then a FINER score can be used to prioritize the projects. FINER score- 25 points, 5 points per domain. This should be done by a selection committee.
5.	Selection committee	Includes a Statistician Core experts- 2 members Should be at least 7 years in service and have at least 2 first-author/corresponding author publications in that field. Should not have a conflict of interest
6.	Non-disclosure agreement	Must be signed between PI and HCC This also must be signed by all the committee members Template for creating Non-Disclosure Agreement (NDA) is in Appendix B
7.	Limits	Any investigator must not be PI on more than 2 HCC projects ongoing at the same time Any centre must not be the Co-ordinating center of >10 projects at a given time
8.	Turn-around time for decisions	Proposal _ Receipt→ 1 week to check the completeness of the document Screening → selection committee→ 1 month for decision making
9.	Next steps	To proceed if funding is assured or available
10.	Core committee	A core committee must have 5 members that includes- PI of Co-ordinating center PI of 3 other sites, decided by Co-ordinating center
11.	Protocol writing	The core committee must prepare a complete protocol as per the NDCT rules and ICMR rules (as applicable).

		Each member must sign and agree to the final version, but the final responsibility rests with the PI of Co-ordinating center. Turnaround time- 6 weeks.
12.	Approval from HCC executive committee	The protocol must be approved by the HCC executive committee in its final form. Turnaround time- 7 days.
13.	Submission to IEC	The PI of Co-ordinating center must submit to the IEC only the final protocol. Ideally, the next steps must be undertaken only after IEC approval of the Co-ordinating center/s, but will be allowed if other sites are willing to resubmit modified versions depending on what is approved by the Co-ordinating center IEC.
14.	Recruitment of sites	A Site feasibility check to be performed (SOP2) Potentially eligible sites can be identified by the PI of Co-ordinating center Sign an NDA with the sites and then share the protocol

Appendix A: Elements of a Concept note

A concept note must be a 2-page document (500-600 words) covering the following points and explaining them in brief:

1. Title of the study
2. Background and Rationale
3. Aim
4. Study objectives
5. Hypothesis
6. Population and setting
7. Intervention
8. Study design
9. Outcomes and measures
10. Study Procedure
11. Statistical consideration (Including sample size, potential period of recruitment and follow up)

Appendix B: NDA Template

NON - DISCLOSURE AGREEMENT

This NON - DISCOSURE AGREEMENT (the "Agreement") is entered into by and between HEMATOLOGY CANCER CONSORTIUM, TATA MEMORIAL CENTRE, DR. E. BORGES ROAD, PAREL, MUMBAI – 400012 (hereinafter called "HCC") and (which expression shall mean and include unless repugnant to the context, its successors and permitted assigns) represented by its Director, <Name>, and <SITE ADDRESS> (hereinafter called "SITE") and represented by <Sponsor PI Name> (hereinafter called "investigator")

This Agreement shall govern the conditions of disclosure by HCC to SITE of certain confidential information relating to Project "STUDY TITLE" including without limitation, information as specified below (collectively, the "Information"):

"Information" shall mean any and all information including information without limitation, relating to Intellectual Property Rights and "STUDY TITLE" I on _____<dd/mm/yyyy> becoming aware of such information in the process of supporting this project, or even at the preliminary stage of discussions between HCC and SITE while seeking expression of interest from HCC, in the proposed project.

WHEREAS, in consideration for the opportunity to be considered as an investigator, Investigator is willing to receive the Confidential Information subject to abiding by the terms and conditions set forth below;

NOW, THEREFORE, in consideration of the benefits set forth herein, the parties hereby agree as follows:

1) HCC is willing to disclose Confidential Information to Investigator on the following terms and conditions:
    a) Investigator will receive, maintain, and hold the Confidential Information in strict confidence and will NOT use such information at any time for other than the purpose for which it has been provided;
    b) Investigator will treat such information as it would its own proprietary and confidential information and not to disclose such information to any third party;
    c) Investigator will take all precautions to prevent the disclosure of such information to any third party.
    d) Investigator will not use such information at any time for exploiting or causing to exploit it directly or indirectly by the Investigator or through any third party, for any commercial interest or otherwise.
2) The investigator shall be relieved of any and all obligations under the paragraph '1' above, regarding information which
    a) was known to or independently developed by Investigator prior to disclosure of the Confidential Information as demonstrated by written records of the investigator, and it was not acquired directly or indirectly from HCC, or their affiliates;
    b) was generally available to the public through no act or omission or negligence on the part of Investigator;
    c) was furnished to Investigator on a non-confidential basis by any third party having a legal right to do so; or,
    d) was required by law, regulation, government order or judicial order to be disclosed, provided that Investigator promptly notifies HCC of such required disclosure and provides HCC an opportunity to contest the disclosure requirement, by appropriate legal action.

Confidential Information shall not be deemed to be in the public domain merely because it may be derived from one or more items which are publicly known.

3) The investigator shall only disclose the Information to those employees of the investigator who need to know such Information for the above-stated purpose. The investigator shall make all such employees aware of this Agreement and the obligations and restrictions imposed herein, and obtain necessary confidentiality agreements from them, and shall inform HCC accordingly. The investigator shall also ensure that such employees comply with the obligations and restrictions of this Agreement. The investigator shall be held responsible for disclosure of Information by its past employees if such information was acquired by them during tenure of their employment with the investigator.
4) The Confidential Information is the exclusive properly of HCC and neither this Agreement nor any disclosure shall be deemed, by this implication or otherwise, to vest in Investigator any license or other ownership rights to or under any patents, know-how, or trade secrets disclosed to Investigator by HCC, or their affiliates or agents.

5) At any time upon the request of HCC, or immediately if Investigator and/or HCC determine that Investigator will not be participating in the services under discussion Study, Investigator shall return to HCC, or, at HCC's option, destroy,

    a) the Confidential Information, including all copies, and
    b) all other embodiments of the Confidential Information

in the possession of Investigator, including all copies and/or any other form or reproduction and/or description thereof made by Investigator.

6) The investigator recognizes that HCC may suffer irreparable damages if the information or any portion thereof is disclosed or any breach of any of the undertakings given by the investigator herein and accordingly the investigator agrees that HCC shall be entitled to specific performances of investigator's obligations and/or any other remedies available in law or equity.

7) Neither party shall (i) issue a press release or make any other public statement that references this Agreement; or (ii) use the other party's or its affiliates' names or trademarks for publicity or advertising purposes without the prior written consent of the other party.

8) No failure or delay by HCC in exercising any right, power, or privilege under this Agreement shall act as a waiver thereof. This Agreement constitutes the entire understanding of the Parties with respect to the matters contained herein, superseding all prior oral or written understandings or communications between the Parties. Any amendments or modifications to this Agreement must be in writing and signed by both the Investigator and HCC.

9) Correspondence with HCC, respecting this Agreement shall be addressed to<Name>, Director, HCC, Mumbai at the address set forth above, Correspondence with Investigator with respect to this Agreement shall be addressed to <Sponsor PI Name>, Address:

10) This Agreement shall be construed and interpreted in accordance with the laws of the Republic of India.

11) This Confidentiality Agreement is effective from <Date>, Notwithstanding the termination of this Agreement for any reason whatsoever, this Confidentiality Agreement shall survive for 10 years from the date of termination of the Agreement

12) Nothing herein above shall commit or obligate, or be legally binding on either party to agree to any potential business relationship or to enter into any further agreements or negotiations with the other or to refrain from entering into an agreement or negotiations with any third parties.

AGREED TO AND EFFECTIVE AS OF THE DATE LAST SIGNED BELOW:

(Sponsor Principal Investigator)	(HCC)
Signature: _____	Signature: _____
Name:	Name:
Title: _____	Title: _____
Date: _____	Date: _____