Samarth Institutional Ethics Committee (IEC)

Policies and Standard Operating Procedures
August 2015

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Chennai
Tamil Nadu
India

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General Information

The policies and standard operating systems of the Institutional Ethics Committee (IEC) of Samarth were revised in July 2015 to include updated information and to ensure Samarth's IEC complies with Indian regulatory norms and the guiding principles of the institution. The revised document reflects the changes made and approved by the ethics committee members in August 2015.

This document is organized in three sections:

Section I details the Standard Operating Procedures of the Institutional Ethics Committee of Samarth, Chennai.

Section II details the policies for specific situations adapted from the ICMR Ethical Guidelines for Biomedical Research on Human Participants (2006) and Schedule Y of the Drugs and Cosmetics Act (1940) and Rules (1945) as amended up to 30 June 2005 and further revised in October 2008 (Further revisions that have been published in the Gazette of India become applicable as notified by the Government of India). It also includes policies adopted by Samarth that are covered in other international guidelines or by administrative approval that are specific for the institution.

Section III provides forms to be used for IEC research proposal submissions and for providing interim reports, final reports, adverse events reports and other relevant forms.

This document will be available for download from the Samarth website www.samarthngo.org

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Section I: Standard Operating Procedures

Standard Operating Procedures of the Institutional Ethics Committee of Samarth

1. Background

Samarth was established in January 2007 and registered as a society under the Tamil Nadu Societies Registration Act, 1956 on 24th May 2007. It is made up of a group of epidemiologists, social scientists, psychologists, and biostatisticians who share a common vision in advocating for health research. The main objectives of the organization are to conduct research to inform policy; build capacity in epidemiology, social science, and biostatistics; and to build partnerships with the government and private sector in health promotion.

The Samarth Governing Body is the highest body that represents this society and is responsible for the formation of institutional policies. Research is an integral part of the vision and the mission of Samarth. Research has been oriented to areas of need and emphasizes application of knowledge to relevant problems. The inculcation of an attitude of inquiry, acquisition of knowledge of the mechanisms of research and the conduct of research at various levels of involvement in health, are encouraged amongst employees. Research relevant to the country's needs is encouraged, and the organization answers calls for proposals to national projects.

In the interest of conducting scientifically sound research, the Samarth Governing Body has constituted an independent Scientific Review Board that is separate from the institution’s IEC. This board reviews protocols - evaluating the scientific question and appropriateness of the methods planned to answer the scientific question. Through this, the board also assesses the justification of inclusion of human subjects in the research project and the risk-benefit ratio involved.

2. Institutional Authority

The Governing Body of Samarth recommended and authorized the setting up of the "Samarth Institutional Ethics Committee (IEC)" on the 5th of July 2014.

2.1 Samarth Institutional Ethics Committee (IEC): Purpose

Constituted on the 5th of September 2015, the Samarth Institutional Ethics Committee (IEC) reviews projects in the social, educational, behavioural and medical fields. The basic responsibility of the IEC of Samarth is to protect the dignity, rights, and well being of potential research participants. This will be ensured through a competent review of all ethical aspects of project proposals received free from any bias and influence that could affect their objectivity. The IEC will provide advice to researchers on all aspects of the welfare and safety of the research participants after ensuring the ethical soundness of the proposed research.

Scientific aspects of the research will be reviewed and approved by the Scientific Review Board, though IEC members may seek clarification in this regard, if needed.

2.2 Purpose of the Policies and Standard Operating Procedures of the IEC

The objective of the Policies and Standard Operating Procedures (SOP) document is to protect the rights, dignity, welfare and privacy of human research participants and to contribute to the effective functioning of the IEC. The IEC must function such that a responsible and consistent ethical review mechanism for health and biomedical research is put in place for all proposals dealt by it, as prescribed by the Ethical Guidelines for Biomedical Research on Human Subjects of ICMR and the Drugs and Cosmetics Act and Rules, Government of India. The mechanism is also in keeping with the ICH-GCP, and the National Institutes of Health Office for Human Research Protection guidelines.

2.3 Terms of Reference

The IEC will review all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research participants. The IEC will review all research projects involving human participants to be conducted at Samarth, irrespective of the funding agency, approve them if all ethical considerations are met, and monitor ongoing studies.

The IEC of Samarth has the mandate to

i. Require that all research conducted in the institution be presented to the IEC for assessment in the prescribed format. The IEC can also review research that is conducted off-site at institutions where no IEC exists and the researcher is a member of Samarth.

ii. Provide competent and timely review of all research proposals submitted to ensure the ethical conduct of all such research falls within the ethical norms laid down by the latest revisions of the Ethical Guidelines for Biomedical Research on Human Subjects of the Indian Council for Medical Research (ICMR) and other relevant guidelines. In addition it will ensure that all research it approves will also conform to applicable central, state, and local laws and regulations.

iii. Evaluate the informed consent process and documentation; assess the risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations, wherever required.

iv. Suggest strategies to improve research proposals that fall short of the expected ethical standards.

v. Refuse approval of research proposals that do not meet the expected ethical standards.

vi. Provide ongoing monitoring of all research that it approves, including site visits and audits of procedures and documentation. One site visit per year per study is recommended (preferably during data collection/field work), but may be more frequent if directed by the IEC.

vii. Require periodic reports and final reports of all research that it approves.

viii. Work towards facilitating the collaborative and multidisciplinary nature of scientific research, maintaining the integrity of the research process, detecting and declaring all conflicts of interest in research conduct and research review, reporting research misconduct, and ensuring research is driven by relevance to local needs and the interests of patient care and scientific advancement over personal motives.

ix. To assist in the development and the education of a research community responsive to local health care requirements.

3. Composition and Responsibilities of the IEC

The composition of Samarth's IEC is multidisciplinary, comprising of individuals with varied expertise. Independence and competence are the two hallmarks of this IEC. The Chairperson of the IEC will necessarily be a person of stature with a scientific background and adequate familiarity with the principles of ethics and related issues. The Member Secretary who belongs to Samarth will conduct the business of the Committee. The composition of the IEC shall reflect that recommended by the ICMR's guidelines and Schedule Y of the Drugs and Cosmetics Act, and members will include a mix of medical, non-medical, scientific, and non-scientific persons including community representatives. Each member will bring in his or her perspective, thereby ensuring a comprehensive review of research proposals. The composition of the committee is as follows:

i. Chairperson

ii. One-two basic medical scientists

iii. One-two clinicians from various institutes

iv. One legal expert or retired judge

v. One social scientist/representative of non-governmental voluntary agency

vi. One lay person from the community

vii. Member Secretary

The ethical committee can have as its members, individuals from other institutions or communities if required. Adequate representation for age, gender, community, etc to safeguard the interests and welfare of all sections of the community/society are to be provided for. Members will be required to be aware of local, social, and cultural norms, as this is the most important social control mechanism.

The IEC members will be made aware of their roles and responsibilities as committee members. Any change in regulatory requirements will be brought to their attention. They will be kept abreast of all national and international developments in this regard.

3.1 Terms of Appointment, Resignation, and Replacement/ Removal of Members

i. The President of Samarth in consultation with the governing body invites and appoints qualified members to serve on the IEC.

ii. New appointees can be recommended by current/past IEC members.

iii. The duration of appointment for invited members is usually for a period of five years.

iv. Members may be re-appointed for as many terms as deemed by the President.

v. At the end of the term of a member or members, new member(s) are appointed such that at least 50% of the members will remain in the committee to provide continuity.

vi. A member can be replaced in the event of resignation or non-attendance for three consecutive IEC meetings (unless this was intimated in advance to the member secretary on sufficient grounds), or for any action not commensurate with the responsibilities laid down in the guidelines. Disqualification of members for any reason is communicated in writing by the Chairperson.

vii. A member who is unable to attend three consecutive meetings and informs the member secretary in advance may be temporarily replaced by another member selected by the Chairperson.

viii. A member can tender his/her resignation from the committee, with approval from the Chairperson.

ix. Membership of the IEC is a position of responsibility. Members will be paid an honorarium for attending meetings.

3.2 Current Members of the Institutional Ethics Committee

S. No	Name	Designation	Qualification	Affiliation	Term as Member
1.	Dr. B.W.C. Sathiyasekaran	Chairperson	MBBS, BSSc, MD (Comm.Med), MS (Clin.Epi)	Prof. of Community Medicine SRMCI	2017 – 2022
2.	Dr. R. Padmavati	Member	MBBS, DPM, MD (Psyc.Med)	Joint Director-SCARF-Psychiatrist	2014 – 2019
3.	Dr. T.P. Jayanthi	Member	MBBS, MD (Comm.Med), MIH, PhD	Community Medicine - KMC	2014 – 2019
4.	Dr. G. Srinivas	Member	MBBS, MD (Comm.Med), MIPH	Professor & HoD, The TN Dr MGR Medical	2014 – 2019
5.	Dr. S.Y. Jagannathan	Member	MBBS, PGDip (Pub.Health), MD (Path)	Sr. Asst. Prof. of Pathology- KMC	2014 – 2019
6.	Dr. Visali Jeyaseelan	Member	MSc, MPH, PhD (Biostatistics)	Biostatistician, CMC- Vellore	2014 – 2019
7.	Ms. Ranjini Murthy	Member	BSc, PGDip (Rural Mgmt), MPhil (Devpt. Studies)	Social Scientist	2014 – 2019
8.	Ms. Savitha Sriram	Member	Higher Secondary	Community Representative	2014 – 2019
9.	Ms.Sumitra	Member	BL, LLM (Intl Law, Trade, Finance) -Partner	BC & Associates	2014 – 2019
10.	Mr.Karthik Ram Mohan	Member	BL Advocate	Ramasubramaniam and Associates	2015 – 2020
11.	Ms.Neha Lamech	Member Secretary	MSP Public Health	Research Associate in SCARF	2015 – 2020

3.3 Independent Consultants

The IEC may call upon independent consultants who may provide special expertise to the IEC on proposed research protocols. These consultants may be specialists in ethical or legal aspects, specific diseases or methodologies, or they may be representatives of communities, patients, or special interest groups. They are required to give their specialized views and may be required to attend convened IEC meetings but do not take part in the decision making process, which is conducted by members of the IEC.

3.4 Training of IEC Members

i. IEC members will be provided a training pack consisting of relevant guidelines regarding the science and ethics of biomedical research.

ii. IEC members will also be provided with a copy of the Policies and Standard Operating Procedures of the Samarth IEC.

iii. All members must have attended basic training in the ethics of human research participants' protection and be conversant with the ICMR guidelines for research involving human participants, Schedule Y of the Drugs and Cosmetics Act, the Declaration of Helsinki and ICH-GCP guidelines.

iv. IEC members will be offered ongoing opportunities for enhancing their capacity for ethical review by Samarth.

v. A record will be maintained of the training obtained by IEC members and updated annually.

3.5 Responsibilities of IEC Members

i. Membership of the IEC is a position of responsibility and IEC members are expected to approach this position with the seriousness and professionalism befitting their role in aiding the advancement of science and protection of research participants.

ii. IEC members are expected to show interest and motivation, commitment and availability, experience with or education regarding the science and ethics of research, respect for divergent opinions and ability to work as a team, integrity, diplomacy and ability to maintain confidentiality.

iii. Information should be provided as early as possible if a member is unable to attend an IEC meeting. IEC members should not miss three consecutive meetings without good cause, and should inform the Member Secretary if they foresee being unavailable for months at a time.

iv. IEC members should assess in detail the proposals allotted to them as primary or secondary assessors and come to convened meetings with their prepared report. Reports by IEC members should be succinct but sufficiently detailed so as to highlight deficiencies and suggested improvements in design or execution of the study. IEC members function as facilitators of sound and ethical research, not primarily as regulators of research.

v. All IEC members are expected to declare competing conflicts of interest with respect to research proposals or investigators, if any, before commencement of each meeting.

vi. IEC members are expected to agree to not be present during presentation of proposals in which they are co-investigators, unless requested to answer clarifications; they may present proposals if they are Principal Investigators (PIs), but in both situations should leave the room before IEC discussions and decisions. It is the duty of IEC members to adhere to this without being reminded of this duty.

vii. IEC members are required to sign a confidentiality agreement on joining and this will be renewed with every extension.

viii. Members should submit an updated CV on joining the IEC and with each extension.

ix. Members should not make copies of any material provided to them and ensure destruction or return of all materials sent for review after the IEC meetings.

x. The IEC will meet as required based on research projects generated.

3.6 Dissolving of the IEC

i. At any point of time, should Samarth cease to exist, the Samarth IEC is automatically dissolved.

ii. The Samarth IEC may also be dissolved at any time by the President of Samarth, following written notification to each of the members.

4. Research Protocol Submission Process

All research proposals should have been reviewed and cleared by the Scientific Review Board before being submitted to the IEC. All research proposals are to be submitted to the IEC on prescribed application forms, failing which applications will not be accepted.

4.1 Application

i. All research proposals will be submitted by the Principal Investigator (PI) to the Member Secretary on specific forms. These forms can be obtained from the Member Secretary and will be available for download from the Samarth website.

ii. All relevant documents should accompany the application.

iii. Researchers submitting proposals funded by other funding agencies or pharmaceutical agencies that have other kinds of application formats need to submit the agency-specific format as well as the relevant IEC application forms. Failure to do this is likely to result in rejection of the application.

iv. Submission procedure (10 hard copies and a soft copy of the following need to be submitted to the Member Secretary)

v. Research protocol submission form-signed and dated by all investigators

vi. Detailed project proposal

vii. Curriculum vitae of all investigators

viii. Informed consent forms

ix. Translated versions of informed consent forms if appropriate

x. Any other forms appropriate to the nature of the study

xi. The proposal along with all supporting documents should reach the Member Secretary at least one month prior to the IEC meeting

xii. Incomplete submissions will be returned.

xiii. If the application is complete and accepted, the date and time of the IEC meeting that will review the proposal will be intimated to the Principal Investigator in writing. He/she or one of the co-investigators will be required to be present to offer clarifications. If none of the investigators are able to be present for discussion of the proposal, it will not be taken up for review.

xiv. All communications to the IEC are to be made only by the Principal Investigator to the Member Secretary

xv. Applications will be received throughout the year

xvi. Address for communication:
Samarth IEC
New no. 100 (Old no. 11), Warren Road,
Mylapore, Chennai – 600 004

4.2 Documentation

i. The researcher should submit an application of the study protocol in the prescribed format (see section III). The protocol should include the following:

ii. The title of the project with affiliation and signatures of Principal Investigator (PI) and all co-investigators as attestation for agreement to conduct the study. If co-investigators are not available for signature at the time of submission of the protocol, a signed letter with the title of the study with names of all authors should accompany the proposal and stating that the co- investigator has read the protocol as submitted, approves the submission and the role of all investigators and agrees to the terms of participation.

iii. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.

iv. Recent curriculum vitae of the investigators indicating qualification and experience.

v. Subject recruitment procedures.

vi. Inclusion and exclusion criteria for entry of subjects.

vii. Precise description of methodology of the proposed research, including sample size (with justification), type of study design, intended intervention, dosages of drugs if any, route of administration, duration of treatment and details of invasive procedures, as appropriate.

viii. Plan to withdraw or withhold standard therapies in the course of research.

ix. Plan for statistical analysis of the study.

x. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English and all local languages of expected participants.

xi. Safety of proposed intervention and any drug/device or vaccine to be tested, including results of relevant laboratory, animal and human research.

xii. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over dosage should be included.

xiii. Proposed compensation and reimbursement of incidental expenses and management of research related injury/ illness during and after research period.

xiv. If applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants and copy of insurance documents from an Indian insurance agency.

xv. If applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other regulatory authorities for the proposed study (whether in or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

xvi. An account of storage and maintenance of all data collected during the study.

xvii. Plans for publication of results, whether positive or negative, while maintaining the privacy and confidentiality of the study participants, with names of proposed authors and their expected contributions.

xviii. A statement on probable ethical issues and steps taken to address these.

xix. All other relevant documents related to the study protocol including regulatory clearances.

xx. Any material used for advertisement to recruit participants to the study- this may include flyers, posters, radio and TV advertisements.

xxi. Details of funding agency/sponsors and fund allocation for the proposed work.

xxii. For international collaborative studies, details about foreign collaborators and documents for review of Health Ministry's Screening Committee (HMSC) or appropriate Committees under other agencies such as Drug Controller General of India (DCGI).

xxiii. For exchange of biological material in international collaborative studies, an MoU/ Material Transfer Agreement between the collaborating partners, as well as documentation of clearance of the same by ICMR and relevant ministries.

xxiv. A statement on conflict of interest (COI), if any.

xxv. For clinical trials in humans, agreement to prospectively register the trial in the Clinical Trials Register- India (www.ctri.in) and/or other clinical trial registries as required by Indian regulatory authorities.

xxvi. Agreement to report adverse events as required by institutional policy.

xxvii. Agreement to inform the IEC in writing of any deviations to the approved protocol.

xxviii. Agreement to submit progress reports, if applicable or requested, and a final report (for institutionally sponsored as well as externally funded research) within three months of completion of the study, unless an extension is granted by the Chairperson.

5. Review Procedure

The IEC will review every research proposal involving human subjects. The Principal Investigator needs to ensure that a scientific evaluation has been completed by the Scientific Review Board before ethical review is taken up. The Committee will evaluate the possible risks to the subjects with proper justification, expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues. The ethical review will be done through formal meetings and will not resort to decisions through circulation of proposals.

i. Each application will be screened by the Member Secretary for its completeness

ii. Following a request from the Principal Investigator regarding the nature of review required, the Chairperson will advise the Member Secretary (depending on the risk involved) on the categorisation of the application into one of three types: exemption from review, expedited review and full review (see below for explanation).

iii. An investigator cannot decide that her/his protocol falls in the exempted category without approval from the IEC. All proposals will be scrutinised to decide under which of the three categories it will be considered.

5.1 Exemption from Review

i. A study with minimal risk would be defined as one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life.

ii. Proposals which present less than minimal risk fall under this category as in situations such as research on educational practices such as instructional strategies or effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exceptions:

i. When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

ii. When interviews involve direct approach or access to private papers.

5.2 Expedited Review

Research activities that present no more than minimal risk to human participants, and involve only procedures listed in one or more of the categories listed below may be reviewed by the Chairperson and primary and secondary reviewers through the expedited review procedure.

Proposals requesting expedited review should provide sufficient detail to enable a decision to be made in this regard. In the case of minor protocol amendments of approved research studies, the application should clearly specify the amendments that need expedited review.

Categories of Research considered for expedited review

i. Minor deviations from originally approved research during the period of approval (usually of one year duration).

ii. Revised proposal previously approved through full review by the IEC or continuing review of IEC approved proposals where there is no additional risk or activity is limited to data analysis.

iii. Research activities that involve only procedures listed in one or more of the following categories

iv. Clinical studies of drugs and medical devices only when research is on already approved drugs (except when studying drug interaction or conducting trials on vulnerable populations or for new indications)

v. Research involving clinical materials (data, documents, records, or specimens) that will be collected solely for non-research (clinical) purposes.

vi. Collection of data from voice, video, digital, or image recordings made for research purposes.

vii. Research on individual or group characteristics or behaviour not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

viii. All projects, whether internally or externally funded, are expected to submit a report to the IEC annually for monitoring. In approved and ongoing studies, the report will undergo expedited review by the Chairperson, primary and secondary reviewer assigned to the study. Currently used informed consent forms must be submitted for ongoing review, along with an update on the study and any relevant new information that may affect the conduct of the study.

ix. A brief summary and all review decisions will be placed before the IEC members in the next meeting.

x. The expedited review procedure may not be used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

xi. The expedited review procedure may not be used for fresh applications with prospective data collection or interventions involving human participants. The expedited review cannot be given to overseas investigators.

xii. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review, expedited or convened, utilized by the IEC.

5.3 **Full Review**

All research presenting with more than minimal risk, proposals/ protocols which do not qualify for exempted or expedited review and projects that involve vulnerable populations and special groups shall be subjected to full review by all the members.

6. IEC meetings

All decisions will be taken at convened meetings and not solely by circulation of project proposals.

6.1 Distribution of Proposals to Members and Preparation for the IEC Meeting

i. The Member Secretary shall prepare an agenda and send this to the members of the IEC at least two weeks before the meeting.

ii. Each member of the IEC shall receive soft and hard copies of all proposals with all submitted documents including feedback and response to feedback from the scientific review board along with the agenda.

iii. Each member of the IEC will be allotted primary or secondary reviewer status for each proposal by the Member Secretary in rotation. Thus each proposal will be reviewed in detail by two members of the Ethics Committee for ethical review.

iv. Members are expected to indicate at the earliest their participation at the scheduled IEC meeting.

v. If there are potential conflicts of interest in reviewing their allotted proposals, they shall inform the Member Secretary sufficiently early so that these may be re-allotted or be encouraged to review with the nature of the declared conflict recorded in the minutes of the IEC meeting.

vi. IEC members are encouraged to seek clarification about the proposal **only through** the Member Secretary before the IEC meeting so that conclusive decisions can be facilitated.

vii. IEC members will prepare brief assessment reports for the assigned proposals.

viii. If expert opinion is thought necessary, members are free to seek this directly from a suitable person but confidentiality of the proposal should be ensured. The name, affiliation and nature of expertise and the opinion of the expert should be submitted with the review report.

ix. While designated proposals will be the primary responsibility of IEC members, they are encouraged to review all proposals, if possible, and share their views at the meetings.

6.2 Quorum

i. The quorum for IEC review will be half the total number of members plus one.

ii. The quorum should fulfil the following composition (as prescribed by Schedule Y):

   a. One basic medical scientist

   b. One clinician

   c. One legal expert or retired judge

   d. One social scientist/representative of non-governmental organisation/ philosopher/ ethicist/ theologian or a similar person

   e. One lay person from the community

iii. The quorum should be maintained throughout the meeting and the names of members present during each proposal should be recorded to ensure compliance with Schedule Y of the Drugs and Cosmetics Act.

6.3 Conduct of Meeting

i. The principal investigator will present the study in brief, highlighting key points. If the principal investigator is not available, a co-investigator may present.

ii. Investigator(s) will be invited to offer clarifications if required to do so; they may also volunteer clarifications or additional information. Investigator (s) will be requested to leave the room while the committee deliberates, but will be required to be available should more clarification be required.

iii. The members with responsibility for primary and secondary review shall summarise the proposal and present their reports.

iv. Independent consultants/experts will be invited to offer their opinion on specific research proposals, if needed. When invited for consultation, the consultant/expert will be expected to follow the provided IEC SOP and sign a letter stating that they understand the terms of reference and a confidentiality agreement.

6.4 Elements of Review

The committee will consider the following:

Care and Protection of Research Participants

i. The suitability of the investigator's qualifications and experience for the proposed study.

ii. Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action.

iii. The medical care to be provided to research participants during and after the course of the research.

iv. The adequacy of medical supervision and psycho-social support for the research participants.

v. Steps to be taken if research participants voluntarily withdraw during the course of the research.

vi. The criteria for extended access to, the emergency use of, and/or the compassionate use of study products.

vii. The arrangements, if appropriate, for informing the research participant's general practitioner or consultant, including procedures for seeking the participant's consent to do so.

viii. A description of any plans to make the study product available to the research participants following the research.

ix. A description of any financial costs to research participants; the rewards and compensations for research participants (including money, services, and/or gifts).

x. The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research.

xi. The insurance and indemnity arrangements if any.

Protection of Research Participant Confidentiality

i. A description of the persons who will have access to personal data of the research participants, including medical records and biological samples.

ii. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

Informed Consent Process

i. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.

ii. The adequacy, completeness, and understand-ability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s).

iii. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

iv. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being.

v. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

Community Considerations

i. The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.

ii. The steps taken to consult with the concerned communities during the course of designing the research.

iii. The influence of the community on the consent of individuals.

iv. Proposed community consultation during the course of the research.

v. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs.

vi. A description of the availability and affordability of any successful study product to the concerned communities following the research.

vii. The manner in which the results of the research will be made available to the research participants and the concerned communities.

Recruitment of Research Participants

i. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity).

ii. The means by which initial contact and recruitment is to be conducted.

iii. The means by which full information is to be conveyed to potential research participants or their representatives.

iv. The inclusion and exclusion criteria for research participants.

6.5 Decision Making

i. The IEC will provide complete and adequate review of the research proposals submitted to them. It will meet periodically to review new proposals, evaluate annual progress of ongoing ones and assess final reports of all research activities involving human beings through a previously scheduled agenda, amended wherever appropriate. In making decisions the IEC will take the following into consideration:

ii. A member will withdraw from the meeting during the decision procedure concerning an application where there is a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

iii. Decisions may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator and independent consultants) from the meeting, with the exception of IEC staff.

iv. Decisions will only be made at meetings where a quorum is present and maintained for each proposal.

v. Only members who participate in the review will participate in the decision.

vi. Decisions will be arrived at through consensus, where possible; when a consensus is not possible, the IEC will vote.

vii. In the event of a vote, although the names of members who voted for and against the project may be recorded, this information will not be made public knowledge to avoid coercion and inducements.

viii. If one of the members has her/his own proposal for review or has any conflict of interest then s/he should withdraw from the IEC while the project is being discussed.

ix. The decision must be to recommend / reject / suggest modification for a repeat review or advise appropriate steps.

x. The record of the discussion will serve as the minutes and will be approved and signed by the Chairperson. Review reports of primary and secondary IEC members will be filed along with details of the resolution of any concerns raised, outstanding issues and final decisions. Any advice that is non-binding will be appended to the decision.

xi. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed will be specified.

xii. A negative decision on an application will be supported by clearly stated reasons.

xiii. The IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit/risk ratio.

xiv. The discontinuation of a trial will be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

xv. In case of premature termination of a study, notification will include the reasons for termination along with the summary of results conducted till date.

xvi. The following circumstances will require the matter to be brought to the attention of the IEC:

a. any amendment to the protocol from the originally approved protocol with proper justification

b. serious and unexpected adverse events and remedial steps taken to tackle them

c. any new information that may influence the conduct of the study.

xvii. The applicant/investigator will be invited to present the protocol and may offer clarifications during the meeting. Representative of patient groups or interest groups can be invited during deliberations to offer their viewpoint.

xviii. Subject experts may be invited to offer their views, but should not take part in the decision making process. However, her/his opinions will be recorded.

6.6 Communicating IEC Decisions

i. A decision will be communicated in writing to the applicant, preferably within two weeks time of the meeting at which the decision was made.

ii. The IEC communication of the decision will include, but is not limited to, the following:

a. The exact title of the research proposal reviewed;

b. The clear identification of the protocol of the proposed research or amendment, date and version number (if applicable).

c. The names and specific identification number version numbers/dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form and local translations.

d. In case of a conditional decision, any requirements by the IEC, including suggestions for revision and the procedure for having the application re-reviewed;

e. In the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the IEC; submission of progress report(s); the need to notify the IEC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the IEC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other IECs or the Drug Controller General if India; the information the IEC expects to receive in order to perform ongoing review; the final summary or final report; and the need to store soft copy documents for at least 10 years after the end of the study, and hard copy documents for at least 5 years.

f. In the case of a negative decision, clearly stated reason(s) for the negative decision; Signature (dated) of the chairperson (or other authorized person) of the IEC.

7. Follow up and Monitoring

i. The IEC may nominate, when necessary, a subcommittee of one or more persons to oversee the day to day conduct of a trial.

ii. The follow-up review intervals will be determined by the nature and the events of research projects, though each protocol will undergo a follow-up review at least once in six months.

iii. Reports should be submitted at prescribed intervals for review. This should be no less frequent than an annual report.

iv. Final report should be submitted at the end of the study (including externally funded studies).

v. All SAEs and the interventions undertaken should be intimated to the IEC, in the prescribed format (see section 3) with a copy of the report to the study sponsor, if any.

vi. Protocol deviations, if any, should be recorded and reported with adequate justifications.

vii. Any amendment to the protocol should be resubmitted for renewed approval. If these are minor and do not alter the risk-benefit ratio, expedited clearance may be requested.

viii. Any new information related to the study should be communicated to the IEC and the participants, particularly those that pose additional risks or may warrant premature stopping of the trial.

ix. Premature termination of study should be notified, with reasons for termination, as well as a summary of the data obtained up to the point of termination.

x. Change of investigators / sites should be communicated.

xi. In case of voluntary withdrawal from studies, the reasons for participant withdrawal need to be recorded and submitted to the IEC along with the monitoring and final reports.

8. Continuing Review

Any research activity involving the use of human participants that has received initial review and approval by the IEC is subject to continuing review and approval. Time intervals for such reviews shall be made at the discretion of committee but shall occur no less than once in six months.

Amendments to Protocols

i. Amendments to protocols or consent forms must be requested in writing, and reviewed and approved by the IEC prior to making any changes in study procedures.

ii. Requests must describe what modifications are desired, why changes are required, and if the changes pose any additional risks to the participants.

iii. Minor changes (those that do not increase the risk or decrease the potential benefit to participants) may be administratively approved, notified to the IEC at the next convened meeting. Investigators need not be present for this meeting.

iv. Changes considered to be more than minor must be reviewed at a convened meeting of the IEC and the investigator must be available to answer any queries.

v. All amendments are reported to, discussed and approved by the IEC at a convened meeting.

Serious Adverse Event Reporting

i. When a participant who is participating in a research study experiences an unexpected or serious adverse event, the PI must promptly report the incident to the Samarth IEC.

ii. If the research study is being supported by an industry sponsor, the PI is also responsible for notifying the sponsor. The sponsor must then notify the regulatory authorities within a designated time period.

iii. If the PI holds the Investigational New Drug (IND) or Investigational New Device Exemption (IDE) in his/her name, he/she is required to notify the regulatory authorities of the adverse event or reaction within 24 hours

iv. Within 10 working days, the PI must submit a detailed written report of the adverse event or reaction to the IEC in the specified format.

v. Receipt of adverse events reported must be acknowledged in writing and communicated to IEC members at the next convened meeting. If thought

necessary, the IEC may request the PI to be present at that meeting or a subsequent meeting to review the risk-benefit ratio in the light of the new information.

9. Record Keeping and Archiving

All documentation and communications of the IEC will be dated, filed and preserved according to written procedures. Strict confidentiality will be maintained during access and retrieval procedures. The following records will be archived and maintained by the Member Secretary.

i. Constitution and composition of the IEC

ii. Curriculum Vitae (CVs) of all members of IEC.

iii. Standard Operating Procedures of the IEC

iv. One hard copy and one electronic copy of all study protocols with enclosed documents, progress reports, amendments and SAE reports.

v. Minutes of all meetings, duly signed by the Chairperson, or deputed signatory.

vi. Agenda of all IEC meetings

vii. Copies of all existing relevant national and international guidelines on research ethics and all relevant laws, along with amendments.

viii. Copy of all correspondence with members, researchers and other regulatory bodies regarding application, decisions made, and follow up.

ix. Interim reports and final report of the approved projects.

x. Records of all notifications issued for premature termination of a study with a summary of the reasons

xi. All documents should be archived for 10 years (if not permanently) in soft copy and 5 years in hard copy after a study is closed, and will be available for an audit, if required.

10. Special Considerations

While all the above requirements are applicable for biomedical research as a whole, irrespective of the specialty of research, there are certain specific concerns pertaining to specialized areas of research which require additional safe guards/protection and specific considerations for the IEC to take note of. The observations and suggestions of the IEC will be given in writing in clear, unambiguous terms in such cases.

Pregnant or nursing women : Pregnant or nursing women should in no circumstances be the participant of any research unless the research carries no more than minimal risk to the fetus or nursing infant and the object of the research is to obtain new knowledge about the foetus, pregnancy and lactation. As a general rule, pregnant or nursing women should not be participants of any clinical trial except such trials as are designed to protect or advance the health of pregnant or nursing women or foetuses or nursing infants, and for which women who are not pregnant or nursing would not be suitable participants.

The justification of participation of these women in clinical trials would be that they should not be deprived arbitrarily of the opportunity to benefit from investigations, drugs, vaccines or other agents that promise therapeutic or preventive benefits. Example of such trials are, to test the efficacy and safety of a drug for reducing perinatal transmission of HIV infection from mother to child, trials for detecting foetal abnormalities and for conditions associated with or aggravated by pregnancy etc. Women should not be encouraged to discontinue nursing for the sake of participation in research and in case she decides to do so, harm of cessation of breast-feeding to the nursing child should be properly assessed except in those studies where breast feeding is harmful to the infant. Compensation in terms of supplying supplementary food such as milk formula should be considered in such instances.

Research related to termination of pregnancy: Pregnant women who desire to undergo Medical Termination of Pregnancy (MTP) could be made participants for such research as per The Medical Termination of Pregnancy Act, GOI, 1971.

Research related to pre-natal diagnostic techniques: In pregnant women such research should be limited to detect the foetal abnormalities or genetic disorders as per the Prenatal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, GOI, 1994 and not for sex determination of the foetus.

Children: Before undertaking trial in children the investigator must ensure that:

i. children will not be involved in research that could be carried out equally well with adults;

ii. the purpose of the research is to obtain knowledge relevant to health needs of children. For clinical evaluation of a new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of the children;

iii. a parent or legal guardian of each child has given proxy consent;

iv. the assent of the child should be obtained to the extent of the child's capabilities such as in the case of mature minors from the age of seven years up to the age of 18 years.;

v. research should be conducted in settings in which the child and parent can obtain adequate medical and psychological support;

vi. interventions intended to provide direct diagnostic, therapeutic or preventive benefit for the individual child participant must be justified in relation to anticipated risks involved in the study and anticipated benefits to society;

vii. the child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/ tested, provided the consent has been obtained from parents / guardian;

viii. interventions that are intended to provide therapeutic benefit are likely to be at least as advantageous to the individual child participant as any available alternative interventions;

ix. the risk presented by interventions not intended to benefit the individual child participant is low when compared to the importance of the knowledge that is to be gained.

Vulnerable Groups: Effort may be made to ensure that individuals or communities invited for research be selected in such a way that the burdens and benefits of the research are equally distributed:

i. Research on genetics should not lead to racial inequalities.

ii. Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

iii. Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected. Appropriate proxy consent from the legal guardian should be taken after the person is well informed about the study, need for participation, risks and benefits involved and the privacy and confidentiality procedures. The entire consent process should be properly documented.

iv. Adequate justification is required for the involvement of participants such as prisoners, students, subordinates, employees, service personnel etc. who have reduced autonomy as research participants, since the consent provided may be under duress or various other compelling reasons.

11. Prospective Registration of Clinical Trials

i. The ICMR and the WHO require prospective registration of all clinical trials before enrolment of the first participant in a Primary Register of the WHO International Clinical Trials Registry Platform. Further, prior registration is now a condition of publishing clinical trials for many journals. From 1st July 2005 the International Committee of Medical Journal Editors (ICMJE) has declared that their journals will not publish the results of any clinical trials not included on an authorized register.

ii. The ICMR requires all trials conducted in India to be prospectively registered in the Clinical Trials Registry-India (CTRI; www.ctri.in). Schedule Y requires that all ICMR guidelines be followed for clinical trials. The CTRI is a Primary Register of the WHO International Clinical Trials Registry Platform and trials fully registered here will fulfil the ICMJE criteria of prospective trials registration.

iii. All interventional clinical trials conducted in India and involving Indian participants need to be registered.

iv. An interventional clinical trial is any research study that prospectively assigns people to one or more health-related interventions (e.g., preventive care, drugs, surgical procedures, behavioral treatments, etc.) to evaluate their effects on health-related outcomes. Thus trials of marketed or non-marketed products, randomized or non-randomized trials should all be registered.

v. The CTRI currently is accepting completed and initiated trials, but it is a requirement for Samarth investigators to ensure registration prior to recruitment. As of January 2010, the other major website for the database registering clinical trials (www.clinicaltrials.gov) offers the following guidance 'Multi-site trials and multi-sponsor trials are susceptible to duplicate registration, thus care must be taken in how the trials are registered. For multi-sponsor trials it is the lead sponsor who should take responsibility for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered once and only once.' Registration in both these registers is free.

vi. The "Responsible Registrant" for a trial is either the principal investigator (PI) or the primary sponsor, to be decided by an agreement between the parties. The primary sponsor is ultimately accountable for ensuring that the trial is properly registered. For multi-center and multi- sponsor trials, it is the lead PI or lead sponsor who should take responsibility for registration.

vii. The CTRI requires, in addition to the entry of the WHO 20-item dataset, contact details of IEC and a copy of the IEC approval (and DCGI approval, if applicable).

viii. The IEC of Samarth will only grant provisional approval for clinical trials in humans till the permanent registration number and a copy of the registration document is submitted to the Office of Research. Researchers may not commence recruitment until the final clearance is received.

Section II: Policies for Research Conducted at Samarth

1. Training of New and Existing Ethics Committee Members

All members of the IEC, whether new or existing, should seek to periodically up-date themselves on national and international developments in ethics so as to be able to best fulfil their roles and responsibilities. This should be done through completing recognized courses (on-line or otherwise), and keeping abreast of latest guidelines released.

i. Members will receive copies of and be required to be competent and updated in the following areas:

   a. 'Ethical Guidelines for Biomedical Research on Human Participants', Indian Council of Medical Research, India, 2006, or its revisions as and when available

   b. Declaration of Helsinki and its revisions

   c. Indian 'Good Clinical Practices' guidelines for clinical trials on pharmacological products or its revisions as and when available

   d. 'Schedule Y' of the Drugs and Cosmetics (III amendment) Rules 2013, or its revisions as and when available

   e. Standard Operating Procedures of Samarth IEC, or its revisions as and when available,

ii. All members of the IEC will be required to complete a course in Good Clinical Practices/Protecting Human Research Participants and submit certificates of completion to the Member Secretary within the first three months of initiation as a member into the Samarth IEC, if not already completed.

iii. Certification in similar training courses which cover the relevant topics may also be accepted by the Member Secretary.

iv. The IEC will sponsor training for all members who have not yet completed such a course, and subsequent renewal training as required.

v. Each member will be required to track the expiration of their certification and will be required to renew certification within three months of expiration of the previous certificate.

vi. The Member Secretary will keep members informed of new developments / publications and upcoming workshops / meetings / conferences etc related to ethics.

vii. The Member Secretary will also keep members informed of any changes in regulatory requirements.

2. Monitoring and Prevention of Conflict of Interest (COI)

The IEC recognizes that it is possible for a member(s) to find themselves in a position of conflict of interest with one or more of the studies submitted for ethical clearance to the committee.

i. All members of the IEC are required to peruse meeting agendas carefully and identify studies in which they have a conflict of interest.

ii. Examples of COI cases may be any of the following:

   a. A member is involved in a potentially competing research program.

   b. Access to funding or intellectual information may provide an unfair competitive advantage.

   c. A member's personal biases may interfere with his or her impartial judgment.

iii. Once such a study is identified, members are required to sign the declaration of conflict of interest form (see Section III) and submit this to the Chairperson in writing at the start of the meeting.

iv. The member will then be disqualified from participating in discussions and decision making in which he/she has a COI, except to provide information as requested by the Samarth IEC

v. All COI declarations will be filed along with minutes of the meeting by the Member Secretary.

3. Research Participant Recruitment

i. Participant recruitment for all protocols especially with regard to women with childbearing potential, minority groups and children will be reviewed carefully by the IEC. Exclusion of minorities, women and children will be recommended or approved when inclusion is inappropriate with respect to the health of the participants or the purpose of the research.

ii. Individuals may be identified as potential research participants through direct contact of the PI, collaboration with consultants, posted written notices, flyers, or other IEC approved methods.

iii. For more than minimal risk research or any research bearing directly upon a specific diagnosis or treatment, the participant's personal physician/consultant should be notified before enrolling the participant.

iv. If the potential research participant is a minor, then contact must be via a parent or legal guardian.

4. Getting Informed Consent from Research Participants

Informed consent is "consent given voluntarily by a competent individual who has received the necessary information, has adequately understood the information and after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation". Taking informed consent is a process between the researcher and the participant and starts before the research is initiated and continues throughout the duration of the study.

i. The investigator has to communicate to prospective participants all the information necessary for informed consent. Any restriction on participant's right to ask any questions related to the study will undermine the validity of informed consent. Participants must receive a written information sheet containing all relevant information in simple, non-technical language in the participant's vernacular.

   a. The investigator should not give any unjustifiable assurances to prospective participant, which may influence her/his decision to participate.

   b. The investigator must assure prospective participants that their decision to participate or not will not affect the patient-clinician relationship or any other benefits to which they are entitled.

   c. The investigator should exclude the possibility of unjustified deception, undue influence and intimidation. Although deception is not permissible, if sometimes such information would jeopardize the validity of research it can be withheld till the completion of the project, for instance, study on abortion practices.

   d. Adequate time must be provided for the participant to decide on participation.

ii. The investigator must obtain from each prospective participant a signed form as an evidence of informed consent (written informed consent) preferably witnessed by a person not related to the trial, and in case the participant is not competent to do so, a legal guardian or other duly authorised representative

a. Verbal consent can be taken when the participant refuses to sign or give thumb impression or cannot do so. This can then be documented through audio or video means.

b. Surrogate consent can be taken from the authorized relative or legal custodian or the institutional head in the case of abandoned institutionalized individuals or wards under judicial custody.

c. If participant loses consciousness or competence to consent during the research period as in Alzheimer's Disease or psychiatric conditions, surrogate consent may be taken from the authorized person or legal custodian.

d. In case of illiterate participants, a witness is crucial and thumb impressions are allowed. All signatures should be dated by the witness.

e. In the case of minors, proxy consent from a parent/responsible guardian is permitted and only the parent/responsible guardian may sign the informed consent form. However, it is mandatory that the minor, if over 7 years of age and considered capable of understanding the study procedures, provides assent (permission) to participate and, if possible, this should be recorded in a separate assent form. If the participant is incompetent to provide valid informed consent and it is deemed ethically justified to include this person in research, then the proxy consent of a responsible family member/legal guardian and a witness must be taken.

iii. A signed copy of the informed consent form must be given to each prospective research participant.

iv. Informed consent must be obtained from participants before performing the research activity and using only an IEC approved consent form.

v. Obtaining consent from an authorized third party via the telephone is not acceptable.

vi. Written requests for amendments to an existing consent form must be approved by the IEC prior to implementation.

vii. Upon receipt of an IEC approved consent form, all old versions should be discarded to prevent inadvertent use of an outdated consent form. Copies of the most recently approved consent form may be made and should be used until superseded by an amended consent form.

viii. The original consent form should be filed in such a manner as to insure immediate retrieval when required by auditing entities, IEC, or sponsor monitors.

Re-consent must be taken for the following conditions:

i. Availability of new information which would necessitate deviation of protocol.

ii. When a research participant regains consciousness from unconscious state or is mentally competent to understand the study. If such an event is expected then procedures to address it should be spelt out in the informed consent form.

iii. When long term follow-up or study extension is planned later.

iv. When there is change in treatment modality, procedures, site visits.

v. Before publication if there is possibility of disclosure of identity through data presentation or photographs (this should be camouflaged adequately).

Waiver of Consent

The need for consent can be waived if it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations. If such studies have protections in place for both privacy and confidentiality, and do not violate the rights of the participants then the IEC may waive off the requirement for informed consent in following instances:

i. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as may be required by the sensitivity of the research objective, e.g., study on disease burden of HIV/AIDS.

ii. Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

iii. Research on anonymised biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognised institutions or qualified investigators, samples or data from repositories or registries etc.

iv. In emergency situations when no surrogate consent can be taken

v. The IEC will consider written requests for waiver or alteration of the process when accompanied by sufficient justification along with a copy of the research proposal.

5. Compensation for Research Participants

i. If a research participant may have to bear any costs, which would be unnecessary if the participant had declined to participate in the research, all potential participants must be fully informed of the nature and estimated extent of these costs when obtaining consent. Examples of additional research costs include:

   a. Prolongation of treatment or hospitalization.

   b. Extra diagnostic tests necessary for the research.

   c. Extra clinical or laboratory assessments to evaluate research treatment outcome.

   d. A research treatment (whether randomly assigned or not) which may be more costly that a standard treatment.

   e. Other substantial costs associated with participating in the research.

ii. Participants may be paid for the inconvenience and time spent, and should be reimbursed for expenses incurred, in connection with their participation in research.

iii. They may also receive free medical services when reasonable and cannot be termed as benefit.

iv. Payments should not be so large or the medical services so extensive as to make prospective participants consent readily to enrol in research against their better judgment, which would then be treated as undue inducement. All payments, reimbursement and medical services to be provided to research participants should be approved by the IEC.

v. During the period of research if the participant requires treatment for complaints other than the one being studied necessary free ancillary care or appropriate referrals may be provided.

Care should be taken:

i. When a guardian is asked to give consent on behalf of an incompetent person, no remuneration should be offered except a refund of out of pocket expenses;

ii. When a participant is withdrawn from research for medical reasons related to the study the participant should get the benefit for full participation

iii. When a participant withdraws for any other reasons s/he should be paid an amount proportionate to the amount of participation.

iv. Research participants who suffer physical injury as a result of their participation are entitled to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, their dependents are entitled to material compensation.

Obligation of the sponsor to pay: The sponsor whether a pharmaceutical company, a government, or an institution, should agree, before the research begins, in the *a priori* agreement to provide compensation for any physical or psychological injury or provide insurance coverage for an unforeseen injury.

6. Authorship of Publications

The International Committee of Medical Journal Editors has recommended the following criteria for authorship; these criteria are still appropriate for those journals that distinguish authors from other contributors.

i. Authorship credit should be based on all of the following:

   a. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data

   b. drafting the article or revising it critically for important intellectual content

   c. final approval of the version to be published.

ii. When a large, multi-centre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributor ship defined above and editors will ask these individuals to complete journal-specific author and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgements.

iii. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript

iv. Acquisition of funding, collection of data, or general supervision of the research group, alone, do not justify authorship.

v. All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

vi. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

vii. Some journals now also request that one or more authors, referred to as "guarantors," be identified as the persons who take responsibility for the integrity of the work as a whole, from inception to published article, and publish that information.

viii. Increasingly, authorship of multi-centre trials is attributed to a group. All members of the group who are named as authors should fully meet the above criteria for authorship/contributor-ship.

ix. The group should jointly make decisions about contributors/authors before submitting the manuscript for publication. The corresponding author/guarantor should be prepared to explain the presence and order of these individuals. It is not the role of editors to make authorship/contributor ship decisions or to arbitrate conflicts related to authorship.

7. Research Misconduct

i. Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

   a. Fabrication is the will full making up data or results and recording or reporting them.

   b. Falsification is the will full manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research report.

   c. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

ii. Research misconduct does not include honest error or differences of opinion.

iii. Disputes about authorship do not normally come under the scope of research misconduct. In some instances, failure to include a researcher, who contributed significantly to the research, as an author or to acknowledge his/her contribution could amount to plagiarism.

iv. Allegations of research misconduct will be entertained against a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with Samarth.

v. The IEC will view all allegations of research misconduct seriously and review evidence in a careful, non-biased manner. Final decisions and disciplinary action will be put to a vote and ratified by the Chairperson.

8. Research using Stored Biological Products

A bio bank/repository is a collection of resources that can be accessed to retrieve human biological material and data. Human Tissue Repositories collect, store, and distribute human tissue materials for research purposes. As tissue banking concerns research at a later time, the ethical issues pertain to consent requirements for the banking and further uses of tissue and DNA samples, their control and ownership, and the benefit sharing to the individual or community.

Primary use: By primary use it is meant that the biological material will be used for the intended purpose as described in the protocol submitted for approval from the IEC. Ownership of the sample lies with the individual, family or community as the case may be.

The IEC should consider following points for approving primary use:

i. Consent should be written, given voluntarily by the donor who has the capacity to do so. The use of the samples shall be reserved for the defined purpose only.

ii. Participants have the right to withdraw at any time. This does not apply to anonymous samples.

iii. If sample is inadequate or contaminated and re-contact is likely to be necessary for fresh samples, then this should be incorporated in the consent form, or fresh consent obtained.

iv. While obtaining data/samples from vulnerable subgroups with reduced autonomy, the IEC should ensure that informed consent be obtained from legally authorized representatives in the presence of an impartial witness. The risks and benefits should be adequately explained.

v. When samples have to be obtained for specific research from participants belonging to specified communities, permission of the group leader/local leader/authorities must also be obtained. However individual consent should never be compromised even if permission of the gatekeepers/village Panchayat has been obtained.

vi. Group consent of the population/community should be obtained through its culturally appropriate authorities before sampling starts, particularly for group specific research like genetic research.

Secondary Use: Consent forms for the primary use of biological material should specify the details of what will be done with the material in the future. If any future use is foreseen, primary research consent forms should include provision for participant to consent to storage and later use of biological material. Every request for secondary use shall be examined by the IEC to ensure that:

i. The proposed use does not transgress the original consent given for the earlier study and the validity of the objectives of the new study;

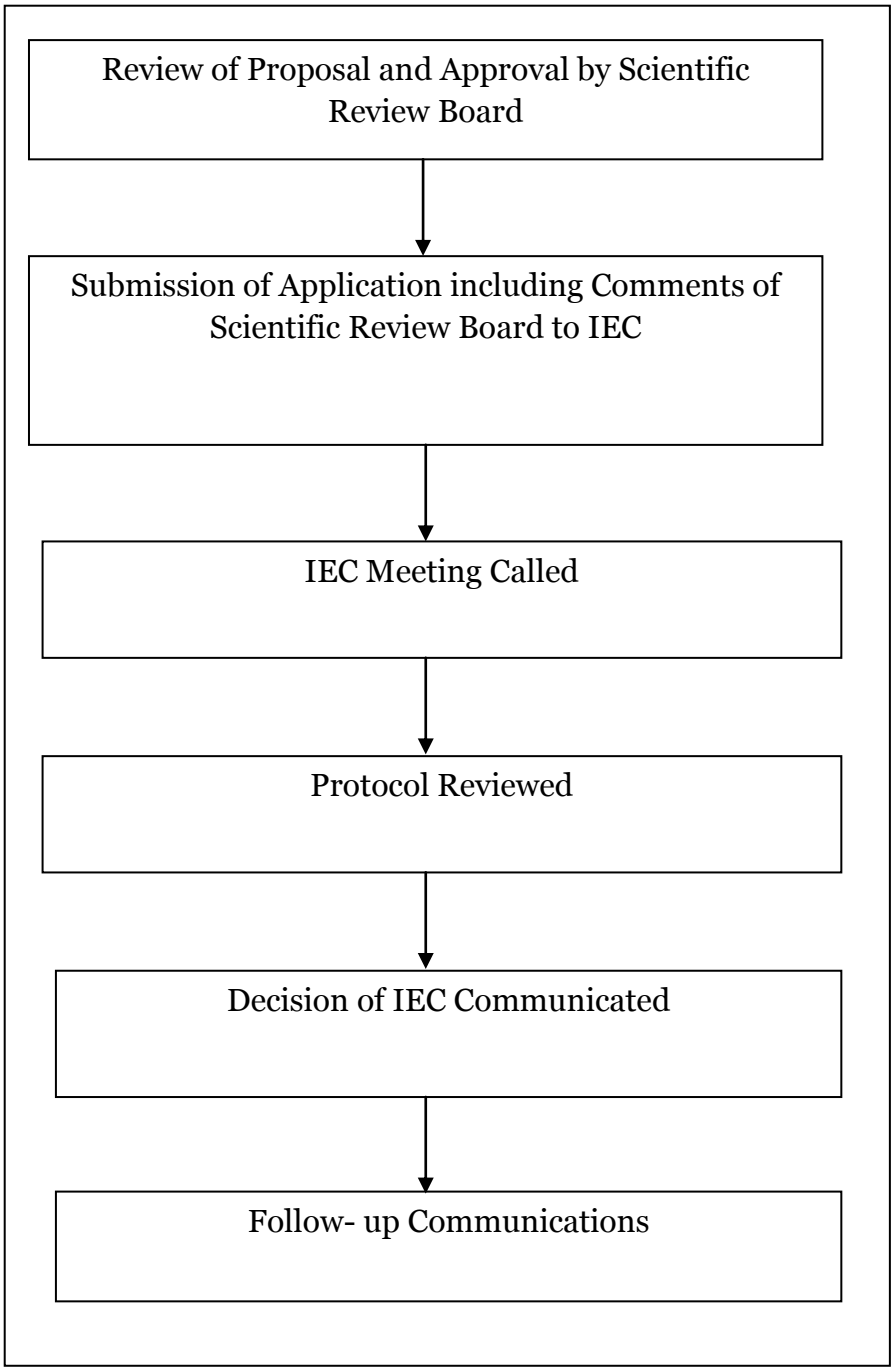
ii. Provisions for ensuring anonymity of the samples for secondary use are stated; after anonymization of a sample, results are not communicated to the donor;

iii. For post-mortem uses of samples the permission of the next of kin, legally authorized representative should be obtained; and

iv. Waiver of consent is given whenever the donor is not traceable or the sample is anonymised.

Section III: IEC Flowchart and Forms

1. IEC Process Flowchart



2. Research Protocol Submission/Re-Submission Form

1. Proposal ID No. (e.g. 001/01/2015)	
2. Research title (with version no.)	
3. Date of submission	
4. If re-submission, number of re-submission, with date of previous submissions	Resubmission no. Date(s) of previous submission
5. Name of Principal Investigator (PI), with qualification, designation, and department	
6. Name of Co-PI/Co-Investigator(s), with qualification, designation and department	
7. Expected duration of the research	
8. Name of funding agency 8.1 Allocation	
9. Name of institution(s) where research is to be conducted	
10. Has proposal been reviewed and approved by the Scientific Review Board of Samarth?	

10.1 If yes, month and year of approval	
11. Nature of IEC clearance requested (tick)	a. Full Board Review b. Expedited Review c. Exempt from Review
12. List of documents enclosed for review (with version number and date)	
13. Research proposal background information (precise yet relevant)	
14. Research proposal main objectives	
15. Hypothesis if any	
16. Research design	
17. If clinical trial, plan to prospectively register in CTRI registry	
18. Data analysis plan	
19. Sample size	
20. Participant recruitment process	
21. Sample inclusion and exclusion criteria	
22. Methodology (in brief; provide references to relevant page in proposal for more details)	
23. Usefulness of the research	
24. Expected 'benefits' to volunteer/community	

25. Explain all anticipated risks of the research (adverse events, injury, discomfort)	
26. Steps to minimize risks	
27. Plans to maintain confidentiality of records/data	
28. Whether compensation for travel and incidental expenses to the research participants are provided?	
29. Describe the Informed Consent Process Mention: written/oral/audio-visual	
30. Special ethical issues as identified by the investigating team (for e.g. vulnerability; storage of biological samples etc)	
31. Disclose Conflict of Interest if any	
32. Plans for publication of results	
33. Signature of Principal Investigator with date	
34. Signature of Co-Investigator (s) with date	

3. Research Study Progress Report Form

Please submit one soft copy and one hard copy of this form along with all supporting documents to the Member Secretary.

1. Research Protocol ID No.:
2. Title of Research:
3. IEC approval date:
4. Name and Designation of Principal Investigator and Address for communication (including telephone and fax numbers and email id):
5. Study Design:
6. Clinical Trial Registry- India (CTRI) Registration Number: (if applicable)
7. Start Date:
8. Expected date of completion:
9. Aims, Objectives and Scope of research:
10. Summary of the work done to date: (state numbers of participants recruited, number completed, interim analyses etc):
11. Protocol deviations: (Report deviations from the study protocol with reasons)
12. Adverse events (All important adverse events or side effects recorded so far):
13. Special concerns: (are there any concerns such as low recruitment rates, difficulties with standardizing procedures or tests, safety issues, or other problems that are likely to impede research?).
14. Signature of Principal Investigator

4. Research Study Final Report Form

Please submit one soft copy and one hard copy of this form along with all supporting documents to the Member Secretary.

1. Research Protocol ID No.:
2. Title of Research:
3. IEC approval date:
4. Name and Designation of Principal Investigator and Address for communication (including telephone and fax numbers and email id):
5. Name and Designation of Co-Investigator(s), and Address:
6. Date, Month and Year of starting the research:
7. Date, Month and Year of completing the research:
8. Aims, Objectives and Scope of research:
9. Summary of the methods used (including details of participants recruited and procedures done):
10. Results: (including main results, subgroup and ancillary analyses)
11. What are the applications and limitations of the findings?
12. Title of papers published or sent for publication based on the reported work. (If not, please describe plans for publication):
13. Has this work been presented at any scientific Conference/Meeting/Seminar?
14. Is the research being continued or extended?
15. Abstract (Structured abstract- one page)
16. Signature of Principal Investigator

5. Unanticipated/Serious Adverse Events Reporting Form

Terminology:

Serious Adverse Event (SAE): A serious adverse event (SAE) in human drug trials is defined as:

1. Any untoward medical occurrence that at any dose results in
2. Death
3. Is life-threatening
4. Requires inpatient hospitalization or prolongation of existing hospitalization
5. Results in persistent or significant disability/incapacity, or
6. Is a congenital anomaly/birth defect.

Procedure for reporting:

All interventional trials approved by the IEC of Samarth will come under the purview of this policy (drugs, devices, and behavioral or educational interventions; single or multiple armed trials, randomized or non-randomized).

For all SAE reports: Within 24 hours of learning about an unanticipated or serious adverse event, the principal investigator is responsible for notifying the DCGI, the Study Sponsor (if external), the **Ethics Committee (samarthethics@gmail.com).** A hard copy of this document must also be sent to the IEC Member Secretary, 100 Warren Road, Mylapore, Chennai – 600004, Tamil Nadu.

Within 10 days the principal investigator is to submit a follow up report to the same list of people as above.

SERIOUS ADVERSE EVENT FORM

PROTOCOL TITLE:	Protocol ID No.:	Centre:

Subject's Study No.	Investigation Product:	Report type 1.0 = Initial 2.1 = follow up 1 2.2 = follow up 2 etc
Occupation:		

Patient Initials:	Date of birth dd/mm/yy	Age Years	Sex	Height (cm)	Weight (Kg)

Event onset (dd/mm/yy)	Adverse Event in MEDICAL TERMS:

Tick ✓ all appropriate to the Event

Patient Died Date: dd/mm/yy	Life Threatening	Prolonged Hospitalization	Significant Disability	Congenital Abnormality	Other SAE

Description:

Suspected Product(s):	Daily Dose at onset of event:	Route of Administration:

Indication for use:

Therapy dates (from/to), dd/mm/yy):

Therapy duration until onset of SAE

Was the product stopped? Yes / No
If yes, did the event abate after stopping the product? Yes / No/ Not Applicable

Were Relevant Concomitant Drugs administered? Yes / No
If Yes, give names and details:

Drug Name	Dose & Route	Date Started (dd/mm/yy)	Continued Y or N	Date Discontinued (dd/mm/yy)	Reason For use

Other Relevant History, laboratory findings and action taken.
Medical History (please attach an additional sheet if this space is inadequate):

Relevant test / Laboratory findings

Laboratory test	Unit	Date	Value	Comments on laboratory finding

Action taken by the Investigator: Please tick appropriate box

	None		Concomitant drug discontinued
	Trial dosage changed		New drug therapy added
	Trial drug discontinued		Prolonged hospitalization
	Non-drug Therapy		

Outcome: Please tick appropriate box

	Completely recovered on (dd/mm/yy)		Condition deteriorated
	Recovered with sequel		Death, autopsy done (attach summary)
	Condition improving		Death, autopsy not done
	Condition still unchanged		

Casuality Assessment by investigator (is there any relationship with the test product?):

	Not related		Probable
	Unlikely		Most probably
	Possible		Insufficient data to assess

Could the SAE be related to the study procedure?:

	Not related		Probable

	Unlikely		Most probably
	Possible		Insufficient data to assess

What is the long-term prognosis for the patient and will the patient continue to receive treatment? Will the costs of treatment be covered by insurance or other arrangements? (Please describe in detail the arrangements that will be made)

Was the protocol followed in recruitment of the participant? Yes / No

Did the participant meet the exclusion / inclusion criteria of the protocol? Yes / No

Was informed consent obtained as outlined in the protocol? Yes / No …… If no please explain:

In your opinion, does this report require that the consent form for participants to be revised? Yes / No

If Yes, submit revised consent forms (one soft copy of each and one hard copy).

Name, address, telephone and e-mail address of the investigator

Name:_____ Profession (speciality): _____

Tel: _____ e-mail: _____

Signature of the Investigator reporting the event: _____

Reporting date (dd/mm/yy) PLEASE NOTE THAT THIS DATE MUST BE COMPLETED ON THE FORM _____

Date Received by the IEC Member Secretary: _____

Signature of the receiver: _____

6. Information Sheet and Informed Consent Checklists for PIs

The informed consent process should include an information sheet for the participant and an informed consent form. Although there is no template provided for each, the study PI should ensure that all of the information below is covered in the appropriate document/s. **Please complete and submit this checklist along with the proposal.**

Information Sheet Checklist	
Information	**Tick if covered**
Name of the study	
Nature and purpose of study, stating it as research	
Study treatments and the probability of random assignment	
Study procedures to be followed, including invasive procedures and investigations if any	
If any aspects of the study are experimental	
Expected effects of the intervention	
Expected duration of subject's participation	
Approximate number of subjects involved in the trial	
Subject's responsibilities	
Benefits to participant, community or medical profession as may be applicable	
Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk	
Availability of medical treatment for such injuries or risk management	
Alternative procedures if available, and their potential benefits/risks	
Expected participant expenses and compensation as part of the study	
Process of informing primary physician of participation if applicable	
That participation is completely voluntary	
Foreseeable circumstances/ reasons for termination of subject's participation	

No loss of benefits on withdrawal or refusal to participate	
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination	
Access to unidentifiable raw data and personal medical records for auditors, IEC, regulatory authority	
Steps taken for ensuring confidentiality, including if study is published	
What will happen after the study is over	
Benefit sharing in the event of commercialization	
Dissemination of new information in a timely manner	
If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines	
Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results	
Contact details of PI or local PI/Co-PI in multi-centric studies for asking more information related to the research or in case of injury	
Contact details of Chairman of the IEC for appeal against violation of rights	
Informed Consent Form Checklist	
Information	**Tick if covered**
Name of study, protocol version, date	
That the study has been explained	
That the participant has had a chance to ask questions	
That voluntary consent is being given	
Reference to confidentiality	
Right to compensation	
Consent for Storage of biological samples (if applicable)	
That the participant will receive a copy of the information sheet and informed consent form	
That the participant knows whom to contact if more information is required/wants to raise concerns	

Procedures for obtaining informed consent appropriate (written/verbal)	
Translations of all forms consistent	
Language is non-technical, practical, and understandable to participant	
A space for witness name / signature / date/ relationship to subject	
A space for investigator's name / signature / date	

7. Research Study Protocol Assessment Form for Reviewers

Samarth IEC Proposal ID No:	Date (D/M/Y):
Protocol Title:	
Protocol version no. & date:	
IEC Member name:	

		Yes	No	Comment
Need for the study (Check Background & Justification sections of protocol)				
1	Background and justification - sufficient?			
2	Literature review – adequate?			
3	Need for human participants justified?			
4	Does the study contribute to development of local capacity for Research / Treatment?			
Scientific value (Check Methods section of protocol)				
5	Methodology – clear and well-described?			
6	Objectives of the study – clear?			
7	Study Design - appropriate?			
8	Is the use of placebo justified?			
9	Inclusion Criteria – appropriate?			
10	Exclusion Criteria – appropriate?			
11	Laboratory methods – clear, well defined and feasible?			
12	Follow-up procedures well defined?			
13	Are study end points well defined?			
14	Are unbiased assessments used?			
15	Sample size adequate?			
16	Statistical methods proposed – appropriate?			
17	Is there a provision for interim analysis in interventional studies?			
Fair subject selection (Check Methods section of protocol)				
18	Inclusion Criteria – appropriate?			
19	Exclusion Criteria – appropriate?			
20	Is the recruitment of participants voluntary, non-			

	coercive?			
21	Is there an inducement for participation?			
22	Is participant deception avoided?			
Favourable risk-benefit ratio				
23	Risks and benefits assessment – acceptable?			
24	Are predictable risks minimized?			
25	Tests and procedures that are more than minimal risk cautiously used?			
26	Provision for medical/psychosocial support?			
27	Are participant discontinuation and withdrawal criteria appropriate?			
28	Provision for treatment of study-related injuries?			
29	Provision for compensation (where applicable)?			
30	Does the study benefit the individual?			
31	Does the study benefit the local community?			
Respect for human subjects				
32	Privacy and confidentiality ensured			
33	Are vulnerable populations involved?			
33.1	If yes, is it justifiable to conduct the study in that population?			
34	Are blood/ tissue samples sent abroad?			
34.1	If samples are sent, is it mentioned in the information and consent form?			
35	Is the fate of the samples once study is over mentioned?			
36	Is appropriate consent included for storage of biological samples?			

Others				
37	Are facilities and infrastructure of Participating Sites appropriate?			
38	Is community consultation addressed if required?			
39	Is disclosure or declaration of potential Conflicts of Interest addressed?			
40	Is the PI adequately qualified to do the study?			
41	Are qualification and experience of the Participating Investigators appropriate?			
Comments:				
Decision: *Approved /Minor modification(s)/Major modification(s)/Rejected*				
Signature of the reviewer:				
Date (DD/MM/YY):				

8. Informed Consent Review Form

INFORMED CONSENT REVIEW FORM	
Samarth IEC Proposal ID No.:	
Protocol Title:	
Participant Information Sheet Date and Version:	
Informed Consent Form Date and Version:	
Name of Reviewer and Date:	
Information Sheet Checklist	
Information	**Tick if covered**
Name of the study	
Nature and purpose of study, stating it as research	
Study treatments and the probability of random assignment	
Study procedures to be followed, including invasive procedures and investigations if any	
If any aspects of the study are experimental	
Expected effects of the intervention	
Expected duration of subject's participation	
Approximate number of subjects involved in the trial	
Subject's responsibilities	
Benefits to participant, community or medical profession as may be applicable	
Foreseeable risks and discomforts adequately described and whether project involves more than minimal risk	
Availability of medical treatment for such injuries or risk management	
Alternative procedures if available, and their potential benefits/risks	
Expected participant expenses and compensation as part of the study	
Process of informing primary physician of participation if applicable	
That participation is completely voluntary	
Foreseeable circumstances/ reasons for termination of subject's participation	
No loss of benefits on withdrawal or refusal to participate	
The consequences of a subject's decision to withdraw from the research	

and procedures for orderly termination	
Access to unidentifiable raw data and personal medical records for auditors, IEC, regulatory authority	
Steps taken for ensuring confidentiality, including if study is published	
What will happen after the study is over	
Benefit sharing in the event of commercialization	
Dissemination of new information in a timely manner	
If test for genetics and HIV is to be done, counseling for consent for testing must be given as per national guidelines	
Storage period of biological sample and related data with choice offered to participant regarding future use of sample, refusal for storage and receipt of its results	
Contact details of PI or local PI/Co-PI in multi-centric studies for asking more information related to the research or in case of injury	
Contact details of Chairman of the IEC for appeal against violation of rights	
Informed Consent Form Checklist	
Information	**Tick if covered**
Name of study, protocol version, date	
That the study has been explained	
That the participant has had a chance to ask questions	
That voluntary consent is being given	
Reference to confidentiality	
Right to compensation	
Consent for Storage of biological samples (if applicable)	
That the participant will receive a copy of the information sheet and informed consent form	
That the participant knows whom to contact if more information is required/wants to raise concerns	
Procedures for obtaining informed consent appropriate (written/verbal)	
Translations of all forms consistent	

Language is non-technical, practical, and understandable to participant	
A space for witness name / signature / date/ relationship to subject	
A space for investigator's name / signature / date	
Comments	
Decision: *Approved /Minor modifications/ Major modifications /Rejected*	
Signature of Reviewer:	
Date of Review (DD/MM/YY):	

9. IEC Member Confidentiality Agreement Form

From Date:

To

The Chairperson
Samarth Institutional Ethics Committee
No: 100, Warren Road, Mylapore
Chennai – 600 004, TN, India.

Dear Sir / Madam,

I do hereby agree not to use Samarth Institutional Ethics Committee related confidential and proprietary information for personal gain, nor disclose such information to third parties (other than in the course of performing my ethics committee related duties), nor copy or reproduce such information in any medium, except where I am required to do so by law, regulation, or court order. I understand that my obligation to abide by this 'confidentiality statement' shall continue indefinitely, even though my service with the Samarth IEC may end.

Thanking you.

Yours sincerely,

(Signature)

10. Declaration of Conflict of Interest Template

To Date:

The Chairperson
Samarth Institutional Ethics Committee
No: 100, Warren Road, Mylapore
Chennai – 600 004, TN, India.

I,_____ Member/Member-Secretary of the Samarth Institutional Ethics Committee declare conflict of interest for the following New/Ongoing protocols discussed in the meeting held on_____.

Agenda No.	**Proposal ID No.**	**Research Proposal Title**

Yours sincerely,

(Signature)