GUIDANCE DOCUMENT FOR RESEARCH PROPOSAL SUBMISSION FOR ETHICS COMMITTEE REVIEW BY RESIDENTS

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2023

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Note: Annexure III and Annexure VI are Guidance Documents

Submission Letter for Review of Research Proposal by Graduate Students

To,
The Member Secretary
NIMS Institutional Ethics Committee
Nizam's Institute of Medical Sciences
Hyderabad

Full Name of Principal Investigator		Date:
Designation		
Department		
Title of Project		
Type of Study (strike off the option that is not applicable) Refer to Annexure III, Page 1	Biomedical & Health Research / Academic Clinical Trial	
Name of Principal Investigator Signature Mobile number		
Head of Department Name Signature Date Department Seal		

NIMS Institutional Ethics Committee
Nizam's Institute of Medical Sciences, Hyderabad

Acknowledgement

Research Proposal Registration No:_____ Date:

Received _____copies of research proposal entitled

"……
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……."

From, Dr……
Designation……..
Department……

For IEC Review

*Name of IEC staff receiving application:…….
*Signature:……..
*Date:……

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*For Office Use only. Not to be filled by Applicant

Annexure-II

Application Form for Initial Review of Research Proposal

NIZAM'S INSTITUTE OF MEDICAL SCIENCES, HYDERABAD

General Instructions: **a) Tick one or more as applicable. Mark NA if not applicable**
b) Attach additional sheets if required
c) May select more than one option
d) Refer to 'Glossary- Application Form for Initial Review of Research Proposal' (Annexure-III) while filling

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested :

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

(h) Protocol number (If any): ..... Version number: .....

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission ..... ii) Co-Principal Investigator at time of submission: .....

(k) Duration of the study: .....

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: ……

(b) Self-funding ☐ Institutional funding ☐ Funding agency *(Specify)* ☐

……

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary (within 300 words) (Attach free pages if needed) :……

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(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/	☐	Case Control	☐
Prospective	☐	Public Health	☐	Cohort	☐
Qualitative	☐	Socio-behavioural	☐	Systematic Review	☐
Quantitative	☐	Biological samples	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

……

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site…… In India…… Globally ……

Control group…… Study group ……

Justification for the sample size chosen (100 words); In case of qualitative study, mention the criteria used for calculation

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(b) Is there an external laboratory/outsourcing involved for investigations? Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

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.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable persons/ Special groups ☐ Others *(Specify)* ☐

.....

i. Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/Friends visiting hospitals ☐ Telephone ☐

Others ☐ *(Specify)* .....

(b) i. Will there be vulnerable persons / special groups involved ? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable persons / special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐

Refugees/Migrants/Homeless ☐ Terminally ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐ .....

iii. Provide justification for inclusion/exclusion .....

.....

.....

iv. Are there any additional safeguards to protect research participants?.....

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.....

(c) Is there any reimbursement to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(d) Are there any incentives to the participants? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

(e)Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk :

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

ii. Describe the risk management strategy: .....

.....

.....

(b) What are the potential benefits from the study?

	Yes	No	If yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the society/community	☐	☐		☐	☐
For improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks .....

.....

.....

.....

(c) Are adverse events expected in the study[6] ? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

(a) Version number and date of Participant Information Sheet (PIS):.....

Version number and date of Informed Consent Form (ICF):.....

(b) Type of consent planned for :

Signed consent ☐ Verbal/Oral consent ☐ Waiver of consent ☐ Witnessed consent ☐

Consent from LAR ☐ (If so, specify from whom) For children<7 yrs ☐ parental/LAR consent Verbal assent form ☐ minor (7-12 yrs) along with parental consent Written assent form ☐ minor (13-18 yrs) along with parental cons

Audio-Video (AV) consent ☐ Other ☐

(specify) .....

(c) Who will obtain the informed consent?

PI/Co-PI ☐ Nurse/Counselor ☐ Research Staff ☐ Other ☐ *(Specify)* .....

Any tools to be used .....

(d) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done.....

If translation has not been done, please justify .....

.....

(e) Are you seeking waiver of consent? If yes, what are the reasons. Yes ☐ No ☐

.....

.....

(f) Provide details of consent requirements for previously stored samples if used in the study[7]

.....

.....

(g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Simple language	☐	Data/ Sample sharing	☐	Compensation for study related injury	☐
Risks and discomforts	☐	Need to recontact	☐	Statement that consent is voluntary	☐
Alternatives to participation	☐	Confidentiality	☐	Commercialization/ Benefit sharing	☐
Right to withdraw	☐	Storage of samples	☐	Statement that study involves research	☐
Benefits	☐	Return of research results	☐	Use of photographs/ Identifying data	☐
Purpose and procedure	☐	Payment for participation	☐	Sponsor contact information	☐
Others(Specify)	☐				

.....

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures ?

PI ☐ Institution ☐ Sponsor ☐ Other agencies ☐ *(specify)*

.....

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐

If yes, then who will provide the treatment? .....

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐

.....

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data *(specify)*:

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited /data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) ……

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(b) Who will be maintaining the data pertaining to the study? ……

(c) Where will the data be analyzed[9] and by whom? ……

(d) For how long will the data be stored? ……

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future?……

……

……

……

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐

……

……

(b) Will you inform participants about the results of the study? Yes ☐ No ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

……

……

(d) Is there any plan for post research benefit sharing with participants? If yes, *specify* Yes ☐ No ☐

……

……

(e) Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details Yes ☐ No ☐

……

(f) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide details. Yes ☐ No ☐

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SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure confidentiality of data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Guide/Co-Guide): ....
☐	I/We have read the Glossary- Application for Initial Review (Annexure-III) and Template of Participant Information sheet, Child Assent Form, Consent form for genomics research (Annexure VI) developed to aid the Principal Investigator

Name of PI: …….....……….....

Signature: .....……….....

Name of Guide: .....……….....

dd mm yy

Signature: .....……….....dd mm yy

Name(s) of Co-Guide(s) & Signature(s).

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12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Form A	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	BCBR & RMME course completion in last 3 years	☐	☐	☐		
4	Approval of PBAC committee	☐	☐	☐		
5	EC clearance of other centers, if applicable*	☐	☐	☐		
6	Approval of Institutional Scientific Review Committee	☐	☐	☐		
7	Agreement between collaborating partners	☐	☐	☐		
8	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
9	Copy of the research protocol (Annexure IV)[11]	☐	☐	☐		
10	Drug/Device Information (for academic clinical trials)	☐	☐	☐		
11	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated) or Request for Waiver of Informed Consent Process (Annexure V)	☐	☐	☐		
12	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
13	Study Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
14	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other permissions	Required	Not required	Received	Applied dd/mm/yy	EC Remarks
15	CTRI	☐	☐	☐		
16	Others (Specify)	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
17						
18						

**For Multicentric Research*
CTRI-Clinical Trial Registry-India

ICMR bioethics unit has developed the 'Application Form for Initial Review'.
The same has been adopted with minor permissible changes for Biomedical research and Academic Clinical Trial research proposals as "Application Form for Initial Review of Research Proposals".

ANNEXURE III

Glossary
Application Form for Initial Review of Research Proposal

This document provides the information related to the terms, based on which the Principal Investigator can select the appropriate options related to the questions.

As this document is developed as an aid to the principal investigator to fill the APPLICATION FORM FOR INITIAL REVIEW OF RESEARCH PROPOSAL, it presents the information related to the questions in the same order as in the application.

Glossary and definitions:

"Biomedical and Health Research" means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation.

"Academic Clinical Trial" means a clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licensing Authority or regulatory authority of any country for marketing or commercial purpose

SECTION A - BASIC INFORMATION

1 (a),(b),(c),(d),(e) – Self explanatory

1 (f) Type of review requested :

Exemption from review –
Proposals with less than minimal risk qualify for exemption from review, which include,
• research conducted on data available in the public domain for systematic reviews or meta-analysis;
• observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;
• quality control and quality assurance audits in the institution;
• comparison of instructional techniques, curricula, or classroom management methods;
• consumer acceptance studies related to taste and food quality; and
• public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

Expedited review- Proposals that pose no more than minimal risk qualify for expedited review which include
• research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
• research involving clinical documentation materials that are non-identifiable (data, documents, records);
• modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

• revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
• minor deviations from originally approved research causing no risk or minimal risk;
• progress/annual reports where there is no additional risk, for example activity limited to data analysis.
* review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
• for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
• research during emergencies and disasters

Full committee review – All research proposals that are not covered under exemption for review and expedited review shall qualify for full committee review,

1(g) Title of the study
It must precisely reflect the study design, the primary objective of study, study groups, intervention tested (if applicable) and the study population.
For instance,
" A prospective, randomised, double blind, parallel group study to compare the effectiveness and safety of drug XYZ with drug ABC in patients with SSS disease."
" A retrospective, observational study to study the risk factors that affect the survival of the patients with SSS disease"
" A prospective study to estimate diagnostic utility of biomarker CCC in diagnosing SSS disease"

1(h) Protocol Number, Version and Date:
These three entities, protocol number, version and date shall serve as unique identifiers of your study.
[(Assign a random protocol number: SSS/NNNNN (SSS- first three characters can indicate dept name; and NNNNN –can be EC No.)
Version: 1 (if submitted for first time to IEC for review)
Date: Roughly the date of identification of research question/ initiation of writing research protocol)]

1(i), 1(j), 1(k)- self explanatory
2(a), 2(b) – self explanatory

SECTION B - RESEARCH RELATED INFORMATION

3. Overview of Research

3(a) Lay Summary - Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it. (You can mention enclosed here and attach a separate sheet at the end, if required)

3(b) Type of study:

The following are the criteria for each type, based on which, the PI can choose which fits the best for the proposal, they can choose more than one option if it is relevant.

Basic Sciences: A study done in the domain of basic sciences (mostly bench side research)
Retrospective: A retrospective study is performed using information on events that have taken place in the past.
Prospective: In prospective studies, individuals are followed over time and data about them is collected as their characteristics or circumstances change.

Qualitative: Qualitative research involves collecting and analyzing non-numerical data (e.g., text, video, or audio) to understand concepts, opinions, or experiences. It can be used to gather in-depth insights into a problem or generate new ideas for research.
Quantitative research is a systematic investigation of phenomena by gathering quantifiable data and performing statistical analysis.
Mixed Method- When you combine quantitative and qualitative methods of research, the resulting approach becomes mixed methods of research.
Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.
Epidemiological/ Public Health - Community trials are studies involving whole communities and are conducted to evaluate preventive strategies like mass drug administration (MDA) trials, fortification of food, etc.
Social and behavioral research explores how and why people behave the way they do in certain situations and how this might impact human health.
Biological Samples: Research that is based on collected biological samples with or without patient contact.
Cross Sectional- A cross-sectional study looks at data at a single point in time.
Case-Control study: It compares two groups of people: those with the disease or condition under study (cases) and a very similar group of people who do not have the disease or condition (controls)
In a cohort study, the participants do not have the outcome of interest to begin with while having the exposure of interest; they are then followed over time to evaluate for the occurrence of the outcome of interest.
Systematic Review: Systematic reviews, typically involve a detailed and comprehensive plan and search strategy derived a priori, with the goal of reducing bias by identifying, appraising, and synthesizing all relevant studies on a particular topic.

4. METHODOLOGY

4(a) Sample size/ number of participants (as applicable)- PI needs justify the sample size proposed scientifically.

4(b) Is there an external laboratory/outsourcing involved for investigations?- If participant samples are sent outside for investigations, provide details of the laboratory, investigation proposed and attach relevant documentation.

4(c) How was the scientific quality of the study assessed? PI can select relevant response

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

5(a) Type of participants in the study:
Vulnerable: If research participants proposed to be enrolled in the study include any category mentioned under 5(b(ii)) then PI needs to select vulnerable population.
Rest of the types of participants are self-explanatory

5(b)(i) and 5b(ii) –self explanatory

5b(iii). Provide justification for inclusion/exclusion- PI needs to justify inclusion of vulnerable participants in the study as vulnerable participants should be included in research only when the research is directly answering the health needs or requirements of the group.

5b(iv). Are there any additional safeguards to protect research participants?-
PI must mention if any of the following safeguards are enabled in the proposal.

- Special care must be taken to ensure participant privacy and confidentiality- Breach of confidentiality may lead to enhancement of vulnerability.
- As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
- Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any
- Proper documentation of the consent process should be done.
- May require Audio-visual consent.
- Ensure that prospective participants are competent to give informed consent.
- Take consent of the LAR when a prospective participant lacks the capacity to consent.
- Respect dissent from the participant.
- Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc.
- Research should be conducted within the purview of existing relevant guidelines /regulations.

5(c) Is there any reimbursement to the participants? – Participants may be reimbursed for expenses incurred relating to their participation in research, such as travel related expenses if applicable, inconvenience incurred, time spent and other Incidental expenses
Any Payment in the form of CASH or KIND or both to research participants must be mentioned here.

5(d) Are there any incentives to the participants?
As Participants should not be made to pay for any expenses incurred beyond routine clinical care which are research related including investigations, patient work up, any interventions or associated treatment.
Payment and free services should not be undue inducement to participate, more so,
When the Legally acceptable representative (LAR) is giving consent on behalf of a participant- reimbursement to travel and other incidental expenses incurred due to participation of the child/ward in the research.
PI must mention any monetary/ non-monetary benefits are given to participants for participation in research.

5(e) Are there any participant recruitment fees/ incentives for the study provided to the PI / Institution? Self-explanatory

6. BENEFITS AND RISKS
Benefits to the individual, community or society refer to any sort of favorable outcome of the research, whether direct or indirect. The social and scientific value of research should justify the risk, which is the probability of causing discomfort or harm anticipated as physical, psychological, social, economic or legal.

6(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Self-explanatory
If yes, categorize the level of risk: PI must select into which one of the following categories the proposal fits based on the criteria given below

Less than minimal risk-Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population. Examples include research in adults involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.

Minor increase over minimal risk or Low risk- Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

More than minimal risk or High risk- Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

6a(ii). Describe the risk management strategy-
PI must mention if any of these have been enabled in study
Withdrawal criteria with rescue medication or procedures.
Minimization of risk/discomfort by close supervision and early identification of suspected complications/adverse events
Adequate provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable

6(b) What are the potential benefits from the study?
Please describe how the benefits justify the risks-
The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research.
Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level.
It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole.

6(c) Are adverse events expected in the study?
Are reporting procedures and management strategies described in the study?
If Yes, Specify
PI must specify which among of the following is described in the protocol

- All adverse events should be classified according to their seriousness and causal relationship with the study drug.
- During and following a subject's participation in trial, the investigator should ensure that adequate medical care is provided to the participant for any adverse events.
- Investigator shall report all serious adverse events to the ethics committee that accorded approval to the study protocol, within twenty-four hours of their occurrence.
- In case, the investigator fails to report any serious adverse event within the stipulated period, he shall have to furnish the reason for the delay.

- The report of the serious adverse event, after due analysis, shall be forwarded by the investigator to the Chairperson of the ethics committee and the Head of the institution where the academic clinical trial has been conducted within fourteen days of the occurrence of the serious adverse event.
- The investigator shall provide information to the trial subject's right to claim compensation in case of academic clinical trial related injury or death.

7. INFORMED CONSENT

7(a) Version number and Date of Participant Information Sheet (PIS)
Version number and date of Informed Consent Form(ICF)
These can be the same as of the protocol.

7(b) Type of consent planned for :

Signed Consent: Consent from a literate, adult research participants to participate in the study on a written informed consent form. ***(Refer Annexure-VI for template of Participant Information sheet)***

Verbal/oral consent- When a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely.

Waiver of consent- PI may request for a waiver of informed consent process and the EC may grant consent waiver in the following situations:
• research cannot practically be carried out without the waiver and the waiver is scientifically justified;
• retrospective studies, where the participants are de-identified or cannot be contacted;
• research on anonymized biological samples/data;
• certain public health studies/surveillance programmes/ programme evaluation studies;
• research on data available in the public domain; or
• research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

Consent from LAR- Where a subject is not able to give informed consent (e.g. an unconscious person or a minor or those suffering from severe mental illness or disability), the same may be obtained from a legally acceptable representative (a legally acceptable representative is a person who is able to give consent for or authorise and intervention in the patient as provided by the law of India). If the trial subject his or her legally acceptable representative is unable to read or write an impartial witness should be present during the entire informed consent process who must append his or her signature to the consent form.

For children<7 yrs parental/LAR consent- There is no need to document assent for children below 7 years of age. Only parental consent is sufficient.

Verbal assent from minor (7-12 yrs) along with parental consent- verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.

Written assent from minor (13-18 yrs) along with parental consent- ***(Refer Annexure-VI for template of child assent form)***
For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.

Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained.

Audio-Video (AV) consent- An audio-video recording of the informed consent process in case of **vulnerable subjects** in clinical research studies including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record: Provided that in case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

7(c), 7(d), 7(e)- Self explanatory

7(f) Provide details of consent requirements for previously stored samples if used in the study-
PI must specify if the research requires re-use of collected identifiable biological material to generate the data or utilize the pre-existing identifiable dataset, where consent may be impossible or impracticable to obtain for such research
The following must be considered when stored samples are to be used, PI must mention if any of the following are enabled in protocol

1. whether provisions for ensuring anonymity of the samples for secondary use are stated
2. whether the previous research study consent form mentions retention and various possible future uses of tissues in the form of a tiered consent; and
3. Whether provisions have been made for allowance of waiver of consent if the donor is not traceable or the sample/data is anonymized or it is impractical to conduct the research

7(g) self-explanatory

8. PAYMENT/COMPENSATION

8(a) Who will bear the costs related to participation and procedures?
Participants should not be made to pay for any expenses incurred beyond routine clinical care and which are research related including investigations, patient work up, any interventions or associated treatment. This is applicable to all participants, including those in comparator/control groups. PI/sponsor should bear all the costs related to participation and procedures.
PI must mention research related costs involved in the study and who will bear these costs.

8(b) Is there a provision for free treatment of research related injuries?
Medical management should be free if the harm is related to the research. For student conducting clinical trials as part of their academic thesis, the guide and the academic institution should take up the responsibilities of the sponsor.

8(c) Is there a provision for compensation of research related SAE?
Research participants who suffer direct physical, psychological, social, legal or economic harm as a result of their participation are entitled, after due assessment, to financial or other assistance to compensate them equitably for any temporary or permanent impairment or disability. In case of death, participant's dependents are entitled to financial compensation. The research proposal should have an in-built provision for mitigating research related harm.
Compensation should be given to any participant when the injury is related to the research. This is applicable to participants in any of the arms of research, such as intervention, control and standard of care.While deliberating on the quantum of compensation to be awarded to participants who have suffered research-related injury, the EC should consider aspects including the type of research (interventional, observational, etc.), extent of injury (temporary/permanent, short/long term), loss of wages, etc.

In investigator initiated research/student research, the investigator/institution where the research is conducted becomes the sponsor.

8(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify.
All research participants who suffer harm, whether related or not, should be offered appropriate medical care, psycho-social support, referrals, clinical facilities, etc. Medical management should be free if the harm is related to the research.

9. STORAGE AND CONFIDENTIALITY

9(a) Identifying Information: Study Involves samples/data (specify):

Anonymous or unidentified-No identifiers are present from the start or if collected, are not maintained. Such samples are received by bio-banks without any identifiers and supplied to researchers.
Anonymized: This involves systematic de-identification, reversible or irreversible: link of samples/data to personal identity is reversibly or irreversibly cut.
Coded or reversibly anonymized: There is an indirect link of sample/data to the participant's identity with restricted access. This link could be re-linked if required; therefore, it may also be termed reversible anonymization.
Irreversibly anonymized: Link to the participant's identity is removed and cannot be re-linked.
Identifiable - A direct link of sample/data to the participant's identity exists.

9(b), 9(c) self-explanatory

9(d) For how long will the data be stored? All records must be archived for a period of at least 3 years after the completion/termination of the study. All samples of test and reference drug products should be retained by the organisation carrying out study for a period of five years after the conduct of the study or one year after the expiry of the drug, whichever is later.
9(e) Do you propose to use stored samples/data in future studies? If yes, explain how you might use stored material/data in the future?
PI must mention if any of the biological materials are kept for future research.

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

10(a) Will the results of the study be reported and disseminated?
Research that is completed, irrespective of results, must be published, since it would be unethical to expose another set of participant/patients/volunteers to the same risks to obtain the same results. Researchers should provide results of study in the public database of the Clinical Trial Registry-India (CTRI)

10(b) Will you inform participants about the results of the study?
The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant. Sometimes more than the benefit to the individual participant, the community may be given benefit in an indirect way. Efforts should be made to communicate the findings of the research study to the individuals/communities wherever relevant.

10(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished?

- The research team should make plans wherever applicable for post-research access and sharing of academic or intervention benefits with the participants, including those in the control group.
- Post-research access arrangements or other care must be described in the study protocol so that the EC may consider such arrangements during its review.

- If an investigational drug is to be given to a participant post-trial, appropriate regulatory approvals should be in place.
- The EC should consider the need for an a priori agreement between the researchers and sponsors regarding all the points mentioned above
- In studies with restricted scope, such as student projects, post study benefit to the participants may not be feasible, but conscious efforts should be made by the institution to take steps to continue to support and give better care to the participants

10(d) Is there any plan for post research benefit sharing with participants?

The benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant. Sometimes more than the benefit to the individual participant, the community may be given benefit in an indirect way. Biological materials and/or data have potential commercial value but the participants' contribution and they do very often not know their share in this benefit. The informed consent document should emphasize this aspect with necessary clauses for clarity about benefit sharing.

1. The document should describe whether donors, their families, or communities would receive any financial or non-financial benefits by having access to the products, tests, or discoveries resulting from the research.
2. The benefits accrued, if any, should be returned to the communities from where the donors were drawn in community-based studies.
3. To the maximum extent possible, benefits should be indirect or in kind.

10(e). Is there any commercial value or a plan to patent/IPR issues? If yes, please provide details

The participating centers should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR as appropriate. There must be free flow of knowledge and capacity at bilateral/multilateral levels. When a folklore medicine/ethno-medicine is ready for commercialization after it has been scientifically found effective, benefit sharing should be ensured and the legitimate rights/share of the tribe or community from which the knowledge was gathered should be taken care of appropriately while applying for the IPRs and patents for the product.

10(f) self explanatory

Annexure-IV

RESEARCH PROTOCOL

Note:

1. This form is for use by students registered for any course at NIMS submitting research proposals for NIEC review
2. Kindly draft the research protocol in accordance to the guidance provided under each sub-heading of the template. Do not delete any sub-heading instead the student cam mention ‘not-applicable’ if the sub-heading is not relevant to the research proposal (Annexure-VII)

General Instructions:

Font: Times New Roman, 12 for text, for subheadings, 14, and for subtitles 14 bold
Page numbering: footer, right hand corner
All the subheadings must be incorporated in the research protocol

RESEARCH PROTOCOL

1. Title of the study:

(Study Title must reflect study design, primary objective, study population, intervention tested(as applicable). Abbreviations should not be used in title)

2. Protocol Number, Version and Date:

(These three entities serve as unique identifiers of the study. Protocol number can be assigned by the PI in the form of PPP/SSS/NNN)

[(SSS- first three characters can indicate dept name as per IP/OP records; PPP- second three characters can relate to study title and NNN –last 3 digits of EC No); Version: 1; Date: Roughly the date of identification of research question/ initiation of writing research protocol)]

3. Details of Principal Investigator:

a. Name:
b. Designation:
c. Department:

4. Introduction / Background of research study:

(The Introduction section should explain the scientific background relevant to address the rationale for the study by describing why the study is planned and what research question does it address. This will usually include a) what is currently unknown (Knowledge gaps)? b) Inconclusive or contested results from previous studies on the same or similar topic.)

5. Review of Literature

(Review of Literature builds up on the introduction and provides meaningful discussion about current (preferably last 10 years) knowledge in the area/field and existing knowledge gaps.)

6. Hypothesis:

(State the null hypothesis and alternative hypothesis for the study)

7. Aim of the study

(Specify what needs to be achieved at the end of the study)

8. Study Objectives:

Mention primary and secondary objectives
(Objectives must reflect how research aim will be achieved)

9. Participant recruitment plan:

(Mention when the study shall start and how will the patients be recruited for the study, whether they shall be recruited from outpatient dept/ inpatients/ general population.Mention any recruitment strategies that are planned to be used for recruitment, if applicable)

10. Study site:

(Mention the departments that will be involved in the study)

11. Study Design:

(Mention if it is prospective/retrospective;
If retrospective- case report/Cross-sectional/ case – control/cohort
If prospective- experimental/ observational
If experimental- Randomised/Non-randomised; Blinded /open-label; parallel-group/cross-over/any other design)

12. Study Duration:

(Mention that study shall start after obtaining IEC approval and will be conducted for what duration (approximately)).

13. Study Population:

(Mention Inclusion Criteria, Exclusion Criteria for enrolment of participants into study)

14. Study Intervention details:

(Mention complete details of intervention. Intervention could be drug/device/diagnostic test/biomarker/questionnaire/teaching method etc.,)

15. Study Procedures:

(Mention whether consent will be taken?
Mention the screening procedures to enroll the patient into study?
How will the randomization be done, if it is applicable? How will be blinding be ensured, if it is applicable?
How many study visits are there in the study?
Mention the procedures done during each of the study visits? Mention the primary and secondary endpoints/outcome measures?
What data shall be collected and for measuring what outcome?)

16. Statistical Analysis:

(Mention how the patient characteristics shall be presented Mention the statistical tests that will be used to analyze primary and secondary endpoints. Which statistical software shall be used?

17. **References**

(in Vancouver style)

Name, Signature and Date of Principal Investigator:
Name, Signature & Date of Guide/Co-guide(s)/Co-Investigator(s)

ANNEXURE V

Please refer to ANNEXURE VI for guidance in drafting Participant Information Sheet

INFORMED CONSENT
(TEMPLATE)

Instructions: Replace each element with information related to your study as per Annexure VI. Refer to Annexure VI for Guidance

1.Check list for study Participant Information Sheet in Biomedical Health & Research Studies.

1.1 Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research.

2. Expected duration of the Subject's participation.

3. Description of the procedures to be followed, including all invasive procedures.

4. Description of any reasonably foreseeable risks or discomforts to the Subject.

5. Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

6. Disclosure of specific appropriate alternative procedure or therapies available to the Subject.

7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.

8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).

9. Statement describing the financial compensation and medical management as under:
In the event of an injury occurring to the academic clinical trial subject, such subject shall be provided free medical management as long as required.

10. An explanation about whom to contact for study related queries, rights of Subjects and in the event of injury.

11. The anticipated prorated payment, if any, to the Subject for participating in the study.

12. Subject's responsibilities on participation in the study.

13. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.

14. Any other pertinent information.

1.2 **Additional elements, which may be required**

a. Statement of foreseeable circumstances under which the Subject's participation may be terminated by the investigator without the Subject's consent.

b. Additional costs to the Subject that may result from participation in the study.

c. The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

d. Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.

f. Appropriate number of Subjects enrolled in the study.

2. Format of informed consent form for Subjects participating in a research study.

Informed Consent form to participate in a research study

Study Title:

Study Number:

Subject's Initials: Subject's Name:

Date of Birth/ Age:

Address of the subject:

Qualification:

Occupation: Student/ Self-employed / Service / Housewife / Others (Please tick as appropriate)

Name and address of the nominee(s) and the relation to the subject: ----------

(for the purpose of compensation in case of trial related death)

	Please initial box (subject)
(i) I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions.	[ ]
(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected.	[ ]
(iii) I understood that the Sponsor of the clinical trial, others working on the Sponsor's Behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

(v) I agree to take part in the above study [ ]

Signature (or thumb impression) of the Subject/Legally Acceptable Representative:_____

Date:_____/_____/_____

Signatory's Name:_____

Signature of the investigator:_____Date:_____/_____/_____

Study Investigator's Name:_____

Signature of the Witness:_____Date:_____/_____/_____

Name of the Witness:_____

(Copy of the Patient Information Sheet and duly filled informed Consent Form shall be handed over to the subject or his / her attendant)

Annexure-VI

Guidance Document for

(i) Participant Information Sheet of Written Informed Consent Form

(ii) Child Assent Form

(iii) Consent Form for Genomics Research

Reference:
(i) Appendix - NIMS-IEC/AP-03
(ii) Appendix - NIMS-IEC-014, Form-1
(iii) Appendix - NIMS-IEC/AP-09
Standard Operating Procedures, IEC, NIMS
Prepared and Revised By: Dr P Usharani, Member Secretary, ESGS; Member,NIEC; Head, Dept of CP&T
Authorised By: Dr K Manohar, Director, NIMS
September 2015

Template for Patient Information Sheet

Introduction

Introduce yourself and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Simplified terms for a disease, need to be used, preferably local words so that they understand better. Avoid using terms like pathogenesis, indicators, determinants, equitable etc.

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

Participant selection

Describe how and why subjects are selected for the study.. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

Voluntary Participation

It must be clearly stated that their participation is voluntary. Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate.

Information on the Trial Drug [Name of Drug] – If it is a clinical drug trial -

1) The Phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

Procedures to be followed (Methodology in detail)

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.Participants should know what to expect and what is expected of them. Use active, rather than conditional, language.

If the protocol is for a clinical trial:- describe the process of randomization and/or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

3) Role and use of rescue medication if any..

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used for this research. Amount and Number of samples which will be taken needs to be mentioned. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study.

Duration

Statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant needs to be mentioned.

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

Reimbursements

A statement on the reimbursements for expenses incurred as a result of participation in the research is to be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context. Additionally, if any compensation is paid for loss of wages, inconvenience etc same needs to be mentioned.

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

Alternatives to Participating

It is important to explain and describe the standard treatment available for studies involving use of new drug, device or procedure.

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how. This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB or your rights, contact **[name, address, telephone number.]**)

You can ask me any more questions about any part of the research study, if you wish to any time during the study process. Contact details of the **investigator** needs to be given.

Compensation and/or treatment(s) available to the Subject in the event of a trial-related injury

Statement on medical care in case of study related injury and compensation to be paid in case of death or serious adverse events as per regulatory requirements needs to be mentioned.

Subject's responsibilities on participation in the trial

Mention needs to be made regarding subjects responsibilities on participation like Following the directions of the researcher; Arriving for all scheduled appointments etc.

Template of Child Assent Form-

[Title of Study]

Assent Form

My name is [researcher name]. I am trying to learn about [insert topic of study in simple language] because [explain research purpose in age-appropriate language]. If you would like, you can be in my study.

If you decide you want to be in my study, you will [explain all tasks and procedures clearly and simply].

[Explain the risks and benefits in clear, simple child-friendly language. The benefits must outweigh the risks]

Other people will not know if you are in my study. I will put things I learn about you together with things I learn about other [children, teens], so no one can tell what things came from you. When I tell other people about my research, I will not use your name, so no one can tell who I am talking about.

Your parents or guardian have to say it's OK for you to be in the study. After they decide, you get to choose if you want to do it too. If you don't want to be in the study, no one will be mad at you. If you want to be in the study now and change your mind later, that's OK. You can stop at any time.

My telephone number is [researcher's telephone number]. You can call me if you have questions about the study or if you decide you don't want to be in the study any more.

I will give you a copy of this form in case you want to ask questions later.

AGREEMENT

I have decided to be in the study even though I know that I don't have to do it. [Name of researcher] has answered all my questions.

Name of the participant_____ _____

Signature of Study Participant Date

Name of the parent / Legal guardian_____ _____

Signature parent / Legal guardian Date

Name of the PI _____ _____

Signature of PI Date

Informed Consent Elements For Genomics Research

1. Purpose of Research Project
2. Description of Research Procedures
3. Financial compensation, Costs and Commercialization (if applicable)
4. Potential Benefits of Participating in the Project
5. Potential Risks of Participating in the Project
6. Confidentiality
7. Returning Results to Research Participants
8. Withdrawal
9. Alternatives to Participating in the Project
10. Voluntary Participation
11. Contact Information

1.Purpose of Research Project

Why is this research study being done?

We are requesting your participation in a study involving blood and tissue samples as well as medical information that were previously collected from you as part of [Insert Name of Project]. Your blood and tissue samples contain genes, which are made up of DNA and which serve as the "instruction book" for the cells that make up our bodies. Your samples and medical information will help us study how genes interact with other factors to influence the development of diseases such as cancer, cardiovascular disease, diabetes and glaucoma.

2.Description of the Research Procedures

The process for the collection of samples (blood or other tissue) and health information.

- How samples and health information will be coded and stored.
- Whether there will be access to a research participant's medical records and, if so, the process for accessing them (*e.g.*, one-time vs. ongoing collection of information from medical records).
- The duration of storage.
- Whether and how samples and health information will be shared with qualified investigators for appropriate research use both during the study period and after the study ends.
- A general description of the types of researchers who will have access to samples and data (*e.g.*, academic, industry, government)
- Whether and how future contact (*i.e.* re-contact) is planned.

Future Contact: This section should clearly outline the investigator's intentions for future contact with the research participant, if any, and how the investigator or other study staff will contact the research participant at a later date.

3. Financial Compensation, Costs and Commercialization

It is important to communicate to the potential research participant whether there will be any 1) financial compensation for taking part in the research project, 2) costs for taking part in the research project, and 3) compensation for a research-related injury.

Any proposed compensation should **not** be included in the "Benefits" section of the consent form.

4.Potential Benefits of Participating in the Project

Potential benefits to the research participant and to others should be described in the consent form. It is important to include potential benefits for society, but investigators should be careful to distinguish between potential benefits to the individual research participant versus society.

5.Potential Risks of Participating in the Project

Research participants need to be informed of the risks in any research project, including genomics research projects where large amounts of genomic- and health-related data may be generated, stored, and broadly shared with other qualified investigators for appropriate use..

Physical Risks

- If a blood sample is not taken from you, there are no physical risks associated with this project.
- If a blood sample is taken from you, there are very few physical risks. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes.

Psychological or Social Risks Associated with Loss of Privacy

- Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measures that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.

- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a blood relative) carry a genetic disease.
- There also may be other privacy risks that we have not foreseen.

6.Confidentiality

It is important to address participants' concerns about protection of their identities against undesired intrusions (privacy) and about limiting the access to study information that might identify them (confidentiality).

7.Withdrawal

Participants have the right to withdraw from the study at any time and the implications and consequences of withdrawal should be discussed in this section of the form and as part of the overall consent process.

For certain genomic studies, complete withdrawal of samples and information may not be possible once samples have been distributed to laboratories and information has been posted for broad data sharing. In such circumstances, a full explanation of the inability to withdraw all samples/information should be provided.

8.Alternatives to Participating in the Project

For genomics studies this generally means that the individual may choose not to participate in the project. (*The alternative option is not to participate).*

9.Voluntary Participation

This section should convey that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

10.Contact Information

This section should list whom the research participant should contact for 1) answers to pertinent questions about the research and research participants' rights and 2) in the event of a research-related injury.

Name, Signature Date
Study Participant

Name, Signature, Date
Impartial witness / Legally accepted representative

Name, Signature, Date
Principal Investigator