Shaukat Khanum Memorial Cancer Hospital and Research Centre

PROCESS TO GET INSTITUTIONAL REVIEW BOARD (IRB) APPROVAL

PRO/A/CEN/CRO-001/v.1

Approved by: Chief Medical Officer(CMO), Chief Executive Officer (CEO) and Medical Director (MD)		Signature: _____
Original date: September 2018	Revision date: September 2018	Next Review Due on: September 2021

This document contains information on the process to get approval from Institutional Review Board (IRB) for research studies qualifying for full quorum review as well as for exemption.

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PART A

1.0 UNDERSTANDING WHEN IRB REVIEW IS NEEDED

Every research activity involving human subjects needs a prior approval from IRB, before it can be started at SKMCH&RC. Every investigator should determine

- whether an activity is research **AND** involves human subjects that must be reviewed by an IRB
- whether it needs a review by full quorum IRB **OR** the proposed activity is exempt from full quorum review

1.1 IS MY PROJECT HUMAN SUBJECT RESEARCH

This section provides guidance to investigators who may be uncertain if their study meets the definitions of human subject research. The guidance provided here is general and may not be specific enough for particular situations.

- **HUMAN SUBJECTS RESEARCH**
  The first question a researcher should consider with respect to IRB review is whether the research project fits the definition of human subject research. Following definitions will help in making this determination

- **DEFINING RESEARCH**
  Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

  Audits and service evaluations also employs systematic and rigorous methods but these differ from research in that audit seeks to measure existing practice against evidence based standards, and service evaluation addresses local service issues. It is noteworthy to understand audits done for quality assurance purposes are different from Clinical audits and outcome research.

- **DEFINING HUMAN SUBJECTS**

- A **human subject** is defined as **"a living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information."**

- The definition extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.

- **Living individual** – "The specimen(s)/data/information must be collected from live subjects". Specimens/information from subjects now deceased may not be human subjects.

- **"About whom"** – "a human subject research project requires the data received from the living individual to be **about** the person"

- **Intervention "**includes physical procedures, manipulations of the subject, or manipulations of the subject's environment for research purposes."

- **Interaction"** includes communication between the investigator and the subject. This includes face-to face, mail, and phone interaction as well as other modes of communication."

- **Identifiable private information** "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place," and "information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, medical record)."

- **"Identifiable" means the information contains one or more data elements that can be combined with other reasonably available information to identify an individual** (e.g. Medical Record Number).

  Studies based on data that are individually identifiable but are also publicly available may **not** constitute human subjects research. However, the term "publicly available" is intended to refer to record sets that are truly readily available to the broad public, such as cancer statistics data, or federal health or educational statistics
  An investigator should **not** assume information qualifies as "publicly available" merely because it has been posted on an electronic website and can be accessed without authorization.

1.2 WHAT TYPE OF IRB REVIEW IS NEEDED?

This section provides guidance to investigators to understand and determine what type of IRB review may be needed for their research project so that investigators can prepare IRB submission accordingly. IRB secretary or one of the designee of chairperson IRB will finally determine what type of review is needed for a certain activity after having a look at the research project.

Two common types of review are:

- **Exemption**

A subset of human subject research involving no more than minimal risk qualifies for Exemption/ grant of exempt status. It means that the proposed research activity is exempt from full quorum review by IRB and no further correspondence is required. A quick review by IRB chairperson and one of his designee is required and it is completed in 2-4 weeks of submission. This type of review is applicable when

- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, and
- if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects

(In this guidance document, only one category of exemption is focused which is most commonly requested and relevant in our setting)

Investigators should not make final determination that their research is exempt. IRB is authorized body to make final determination of exemption.
Detailed guidance is provided in section on exemption.

- **Full quorum review**

If your activity is research & involves living individuals about whom an investigator obtains

- data through intervention or interaction with the individual, or
- identifiable private information

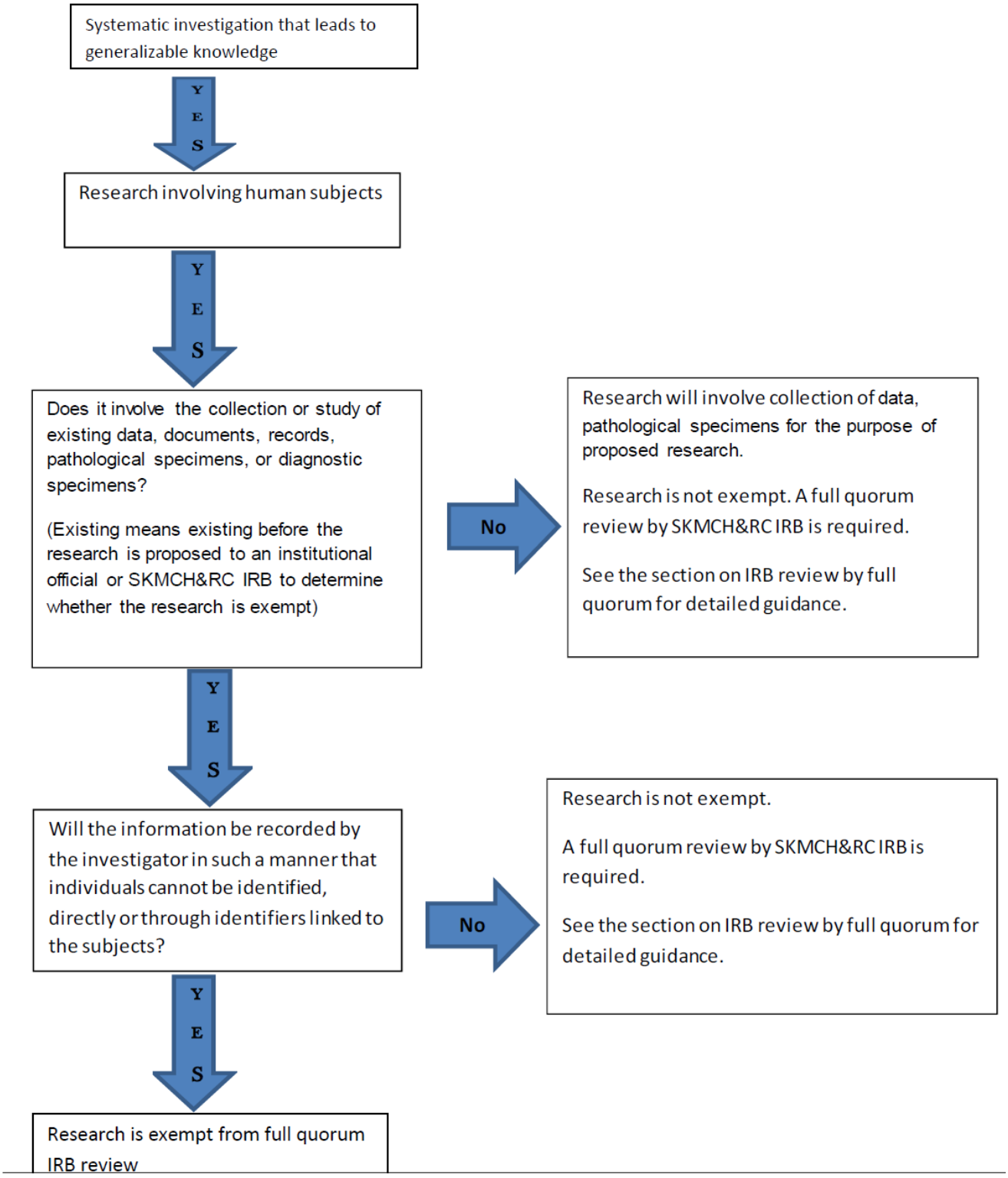
It would require full quorum review by IRB in a convened meeting with a quorum present. The studies should secure a prior Scientific Review Committee (SRC) approval.

1.3 DECISION CHART TO DETERMINE WHAT TYPE OF IRB REVIEW IS NEEDED

See chart below

DECISION CHART TO DETERMINE WHAT TYPE OF IRB REVIEW IS NEEDED

Simplified version with a focus on most common types of IRB review



2.0 HOW TO PREPARE FOR IRB

For making IRB submission, investigators should submit following documents.

1. IRB application
2. Research synopsis-hard copy & soft copy
3. Informed Consent Form-Hard copy & soft copy (English & Urdu version) for patients, if applicable
4. Informed Consent Form-Hard copy & soft copy (English & Urdu version) for healthy controls, if applicable
5. Questionnaire / Clinical data collection forms /interview guide as applicable -Hard copy & soft copy, if applicable
6. Itemized budget with indication of source of funding
7. A copy of the Investigator Brochure and any other available safety information
8. Information about payments and compensation available to subjects
9. The Investigator's current curriculum vitae
10. Conflict of interest declaration
11. Collaborator/Sponsor/Contract Research Organization undertaking (as applicable)
12. Material Transfer agreement/Collaboration Agreement/indemnity insurance documentation, where applicable
13. Waiver of informed consent (provide written justification for waiver request)

2.1 PREPARE YOUR STUDY DOCUMENTS

IRB application form and other templates are provided below to help you prepare your study documents

IRB application form

Template for writing synopsis

Template for developing informed consent

Conflict of interest declaration

IRB Application Form

Study ID:
(To be filled by CRO)

1. FULL TITLE OF RESEARCH PROPOSAL:

2. STUDY PERSONNEL:

Names of research team (affiliation and contact details)

3. Documents attached with this application

Sr No	Document	Attached with this application	If Not applicable, provide reasoning
1	IRB application Form	Yes/No	
2	Research synopsis-hard copy & soft copy	Yes/No	
3	Informed Consent Form-Hard copy & soft copy (English & Urdu version) for patients, if applicable	Yes/No	
4	Informed Consent Form-Hard copy & soft copy (English & Urdu version) for healthy controls, if applicable	Yes/No	
5	Questionnaire / Clinical data collection forms /interview guide		
6	Itemized budget with indication of source of funding	Yes/No	
7	A copy of the Investigator Brochure and any other available safety information	Yes/No	
8	Information about payments and compensation available to subjects	Yes/No	
9	The Investigator's current curriculum vitae	Yes/No	
10	Conflict of interest declaration	Yes/No	
11	Collaborator/Sponsor/Contract Research Organization undertaking (as applicable)	Yes /No	
12	Material Transfer agreement/Collaboration	Yes/No	

	Agreement/indemnity insurance documentation, where applicable		
13	Waiver of informed consent (provide written justification for waiver request)	Yes/No	

1. Have the research staff the relevant training? (E.g. protocol training of co-PIs, study nurses, GCP training etc.)

2. Are all relevant resources and protections for the research secured? (financial, staff, insurance indemnity)

3. Are there any other parties involved in the research? What potential interests of these parties might be in conflict?

4. What will happen when the research is either stopped or is complete?

5. How will the findings be disseminated? (e.g. publication plans etc.)

6. How do you plan to access, store and distribute any collected biological material? If applicable. Guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available at http://nbcpakistan.org.pk/guidelines.html

Template for Writing Synopsis

I. Study Title (Version and Date)
II. Investigator(s) *with institutional affiliations*
III. Introduction (*What is the research question? Why is it important?*)
IV. Objectives
V. Definitions
VI. Hypothesis
VII. Materials and Methods

A. **Study Design:***Describe in detail the design and methodology of the study. Identify and distinguish between those procedures that are standard of care and those that are experimental. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition.*

B. **Setting**

C. **Duration:***Include the frequency and duration of each activity and the total length of subject participation.*

D. **Sample Size and Sampling Techniques:***If applicable, include information on stratification or randomization plans, the maximum number of subjects you plan to recruit for this study. If this is a multi-site study, indicate the projected total subject accrual.*

E. **Inclusion and Exclusion Criteria**

F. **Study Procedures:** *Include details on medical procedures*

G. **Data analysis and statistical methods:***Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable.*

H. **For Interviews/Focus groups:***Attach copies of any scripts and/or questions that will be used to guide the interviews/groups. Indicate the member(s) of the study team who will conduct the interviews/focus groups and any necessary qualifications such as special training, supervision etc.*

I. **For Studies involving Surveys/Questionnaires:***List all of the measures/instruments that will be used for this study and attach copies. Indicate the member(s) of the study team who will use these measures/instruments and any necessary qualifications such as special training or licenses.*

J. **For studies involving use of existing data/specimen**

K. When using existing data/specimen and Applying for Exemption, Describe the follwoing

- *the source of data/specimen*
- *the process used to unlink the data or specimen/make it anonymized/ (the process by which identified data is recorded in a way that individuals cannot be identified)*
- *how is the above process effective*
- *the unlinking of the data/samples will not unnecessarily reduce the value of the research.*
- *Describe how the data/specimen will be labeled at the time of retrieval*

Viii. Human Research Subject Protection

A. RISK/BENEFIT ASSESSMENT:

Risks, Discomforts and Potential Harms:

Describe the risks associated with each research intervention (physical, psychological, social, and other factors) with estimated probability that a given harm may occur and the potential reversibility. Describe the safety precautions that will be taken to minimize risks/harms. When appropriate include a study monitoring plan for safety of participants and for the validity and integrity of data.

Potential Benefits and Alternatives:

Describe any potential for direct benefits to participants in the study. There may be no direct benefits. Also include information on the importance of the knowledge that may reasonably be expected to result. Also describe the alternatives available to patients in cases of non-participation in research.

B. INFORMED CONSENT:

Indicate the types of consent that will be involved in this study and attach copies of the informed consent/assent document that will be used for this study.

If waiver of Informed consent is considered justified, describe with reasoning.

C. DATA PRIVACY AND CONFIDENTIALITY

- How will the data for this study be collected and recorded? *Describe the provisions to protect the privacy of the individual*
- Where will the research data be stored? & how it will be secured.
- Who will have access to the study records or data? Specify their name, role and affiliation.

IX. Resource Requirement

Monetary, logistic and administrative or other

X. References

Guidance for Investigators:

1. IRB approval is needed, before start of data collection for any research activity. Take some time to find out: Is your project Human Subject Research? And what type of IRB review is needed? Comprehensive guidance is made available in research guidelines at following link: https://shaukatkhanum.org.pk/health-care-professionals-researchers/research/research-guidelines/. You may find following resources, helpful for making IRB application.

- Is my project Human Subject Research
- What type of IRB review is needed?
- Decision chart to determine what type of IRB review is needed
- How to prepare for IRB (for full quorum review as well as for exemption)
- Complete Application for IRB review
- Requirements for IRB submission (checklist)
- Prepare your study documents (Find Templates Below)
- Template for writing synopsis
- Template for developing informed consent
- Conflict of interest declaration
- Maintaining your IRB approval
- Continuing review
- Final Report (study completion)
- Amendment (changes in study protocol)
- Notifications (change of title, changes in study team)

2. Provide complete and accurate information. Contact clinical research office, if you need help in completion of any section of this application.

3. Research submissions received at clinical research office, by 5th of each month, will be reviewed in monthly SRC and IRB meetings (generally to be planned during last week of each month). Studies submitted after 5th each month, will be reviewed in meeting in the following month. Many minimal risk studies are reviewed through the exempt procedures. Review of complete submissions, which qualify for exemption, will be completed in 4 weeks. Submissions for IRB should reach IRB office by 5th of each month, and IRB will meet on last Friday, each month.

By submitting this form, the PI attests to the following:

Research team engaged in human subject research is responsible for compliance with SKMCH&RC research guidelines (https://shaukatkhanum.org.pk/health-care-professionals-researchers/research/research-guidelines/) and other applicable laws and regulations including that of National Bioethics Committee (NBC) Pakistan and Drug Regulatory authority of Pakistan, DRAP (www.nbcpakistan.org.pk). The Principal Investigator (and supervisor in case the Principal Investigator is a trainee) is responsible for assuring all study team members review and adhere to these guidelines for conduct of human subjects research.

Compliance requirements include approval from National Bioethics Committee (NBC), Pakistan, and regulatory body (Drug regulatory Authority, Pakistan (DRAP) or other relevant bodies, as applicable.

Principal Investigator is responsible for keeping study records (including copies of IRB approved proposal, information sheets and consent forms, signed consent forms, safety information, IRB correspondence and all other important documents). These study records will be reviewed at the time of continuing review or audits, and will be retained in clinical research office.

Name of Researcher:

Signatures of Researcher:

Date:

TEMPLATE FOR DEVELOPING INFORMED CONSENT

CONSENT TO PARTICIPATE IN RESEARCH

Title or paraphrased title of the study

You are asked to participate in a research study conducted by *names of PI (and faculty supervisor/facilitator if the PI is a student)*, from the *departmental affiliation* at Shaukat Khanum Memorial Cancer Hospital and Research Center SKMCH & RC *if multicenter studies then add* in collaboration with *indicate the name of the Institute.* The Institutional Review Board (IRB) of SKMCH & RC has reviewed this project. IRB is an independent hospital committee that safeguards the welfare and rights of human research participants. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

INFORMATION ON THE RESEARCH

1. **Why Are You Being Asked To Take Part In This Research?**

You are being asked to take part in this study because you *[e.g., have been diagnosed with high blood pressure, are a normal healthy volunteer, etc.]* _____.

2. **Why Is This Study Being Done?**

Briefly state what the study is designed to examine, assess or establish (purpose of research)

3. **How Many People Will Take Part In The Study?**

About ____ people will take part in this study.*[If multi-center studies add: at ____different hospitals and approximately _____ people will take part at SKMCH & RC.]*

4. **What Is Involved In The Study?**

*Describe the procedures chronologically using simple language, short sentences, and short paragraphs. If there are several **procedures** or if they are complex, the use of subheadings may help organize this section and increase readability.*
Define and explain scientific or discipline-specific terms.
Use language appropriate to the population.
*If applicable, specify the subject's assignment to study groups, **length of time for participation in each procedure** or study activity, the **total length of time for participation**, **frequency of procedures** and **location of the procedures** to be done.*
If subjects will be recorded? (audiotaped, videotaped, digitally), describe the procedures to be used.
If any study procedures are experimental, clearly identify which ones.

5. **How Long Will You Be In The Study?**

Describe the study duration (in weeks, days or months). Describe also (if applicable) if you intend to collect follow-up information and how long this will be done. For example, until six months after last study drug dose, etc.
When appropriate, state and specify the time frames of long term follow ups and its requirement. For example, "We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

POTENTIAL RISKS AND DISCOMFORTS

Describe any reasonable foreseeable risks or discomforts, including physical inconveniences and their likelihood, and explain how these will be managed. In addition to physiological risks/discomforts, describe any reasonably foreseeable psychological, social, legal, or financial risks or harms that might result from participating in the research.

If there are circumstances in which the researcher may terminate the study, describe them. (This refers to situations in which the study itself may be terminated. It is not the same thing as circumstances in which a specific subject may be withdrawn; this issue is to be discussed, if relevant.)

FOR STUDIES INVOLVING TISSUE SAMPLING

Include following statements:

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No".

No matter what you decide to do, it will not affect your care. If you have any questions, please talk to your doctor or nurse, call the given contact details.

1. My frozen tissue samples may be stored for use in future research.
   Yes No
2. Can you be contacted in future for any research related activity?
   Yes No
3. Do you want to know the results of this research?
   Yes No

*In case of studies involving **genetic testing** include statement that* "Any leftover sample may be retained by laboratory and can be used in future for subsequent research purposes" and *also clearly mention who will have access to you genetic test results.*

*Mention the **anticipated results** their **implications and clinical significance**.*

POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY

Describe benefits to subjects expected from the research. If the subject will not benefit directly from participation, clearly state this fact.

State the potential benefits, if any, to science or society expected from the research.

FOR BIOMEDICAL STUDIES ONLY – Include the following paragraph, if relevant

Based on experience with this (*drug, procedure, device, etc.)*, researchers believe it may be of benefit *to subjects with your conditionor, it may be as good as standard therapy but with fewer side effects*. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include: *describe the anticipated benefits to subjects resulting from their participation in the research.*

If there is no likelihood that participants will benefit directly from their participation in the research, state in clear terms. For example: "You should not expect your condition to improve as a result of participating in this research" *or* "This study is not being conducted to improve your condition or health. You have the right to refuse to participate in this study."

ALTERNATIVES TO PARTICIPATION (if applicable)

Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether to participate in the study. If applicable, explain why these procedures are being withheld. If there are no efficacious alternatives, state that an alternative is not to participate in the study.

CONFIDENTIALITY

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of *describe coding procedures and plans to safeguard data, including where data will be kept, who will have access to it, etc.*.

If information will be released to any other party for any reason, state the person or agency to which the information will be furnished, the nature of the information and the purpose of the disclosure.
If activities are to be audio- or videotaped or digitally recorded, describe who will have access, if the tapes/files will be used for educational purposes, and when they will be erased or destroyed.
In case of genetic testing study, clearly mention who will have access to the genetic testing result and how would it be communicated.

PAYMENT FOR PARTICIPATION

State whether the subject will or will not receive payment. If subject will receive compensation, describe type and amount, when compensation (e.g., money) is scheduled, and the proration schedule, if any, should the subject decide to withdraw or is withdrawn by the investigator.

PARTICIPATION AND WITHDRAWAL

You can choose whether or not to be in this study. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind or loss of benefits to which you are otherwise entitled. *Indicate if the participant has the option of not answering certain particular questions, if so then enter the statement saying* "You may also refuse to answer any questions you do not want to answer. There is no penalty if you withdraw from the study and you will not lose any benefits to which you are otherwise entitled".
We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.
Include the following paragraph in this section only if relevant
The investigator may withdraw you from this research if circumstances arise which warrant doing so. *Describe the anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.*

IDENTIFICATION OF INVESTIGATORS

If you have any questions or concerns about this research, please contact (*identify research personnel: Principal Investigator, Faculty Supervisor (if student is the P.I.), and Co-Investigator, if any. Include day phone numbers, addresses, and email addresses for all listed individuals. For some studies of greater than minimal risk, it may be necessary to include night/emergency phone numbers.*

RIGHTS OF RESEARCH SUBJECTS

The Institutional Review Board of SKMCH & RC has reviewed this project. If you have any concerns or questions about your rights in this study as a research subject, you should contact the Secretary, Institutional Review Board at +92-42-35905000 Ext 4280 or mail at crc3@skm.org.pk

I understand the procedures described above. My questions have been answered to my satisfaction, and I agree to participate in this study. I have been given a copy of this form.

_____
_____
Name of Subject Patient I.D

_____
_____
Signature of Subject Date

_____
Name of witness and / or interpreter

_____
_____
Signature of Witness and / or interpreter
Date

Name of the Person obtaining Consent Date

_____
Signature &Employee code of person obtaining consent

Note: Routing of copies of the consent form:
1) One copy to be given to patient/family;
2) One to be kept in investigator's file/Research record;
3) One to be placed in patient's Medical Record in case of interventional studies

CONFLICT OF INTEREST DECLARATION

Conduct of researchers at SKMCH&RC needs to be of high standards and calls for declaration of conflict of interest enabling further actions to either eliminate, reduce or manage such conflicts, as appropriate. It is in line with hospital policy on conflict of interest.

This policy applies to both researchers as well as reviewers of research.

Researchers:

All researchers must identify and declare any conflicting interests related to their research at the time of submitting it to for review. Conflicting interests exists when professional judgment/practice concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or professional rivalry). It may arise for researchers when they have relationship with sponsoring company (Paid or honorary position on advisory board or steering committee, sponsorship of symposium or meting, or a travel grant), which may influence their interpretation of efficacy of the product of the sponsor or reporting of serious adverse events.

Researchers are required to disclose such relevant information while submitting their studies via a COI form available at the research office. Medical Director will make final determination and advice on the matter under review.

Clinical research office will educate all reviewers and researchers to complete and submit signed conflict of interest forms in timely manner and ensure compliance to above.

Following are the examples for your information

Please specify if in last two years you have accepted any of the following from any organization/ person that may in way gain or lose financially from the results of your study

- A fee for speaking
- A fee for organizing education
- Reimbursement for attending a symposium/conference/meeting etc
- Sponsorship of your research or that of your trainees
- Paid or honorary position on advisory board or steering committee
- Employment

Note: Please disclose any sponsorship/funding that you have received to help conduct of your study.

The Medical Director will evaluate such conflicts and if necessary, determine

1. Whether the conflict is permissible in the context of proposed research
2. Whether the conflict warrants disclosure to potential participants as part of informed consent process or
3. Warrants further management to reduce or eliminate the interest.

Medical director will communicate when it determines that an interest must be disclosed and/or further managed.

CONFLICT OF INTEREST DECLARATION

It is mandatory that all researchers applying for IRB approval of their research complete this form and submit it to clinical research office. Please tick the appropriate box

I/ We have no conflicting interests to declare

I/we have competing interests to declare (please indicate conflicting interests in

Title of research study submitted:

_____

_____

_____

_____
Name

_____ _____
Signature Date

3.0 MAINTAINING YOUR IRB APPROVAL

After IRB approval, you would need to maintain approval conditions. For this purpose, you would need to continue to correspond with IRB in following cases

- Continuing review (see page 20 for details)
- Final Report at time of study completion (see page 20 for details)
- Amendment (changes in study protocol)

  If you wish to make any amendments in research study which is already IRB approved, kindly submit a letter addressing chairperson IRB, summarizing the proposed amendments. Also include in your letter, how it can affect study risk benefit ratio. Also submit a revised proposal incorporating the amendment. In case the risk benefit ratio is affected by amendment, IRB may seek further information or documents, as appropriate.

- Notifications (change of title, publications resulting from study originally approved from IRB etc)

  Notifications of change in title are sufficient, whereas the change in title remain the only change, with no other change in study methodology or data items to be collected. If other changes are also made, application for amendment of study should be submitted.

  Notification for change of study title should contain following information.

  Study ID:
  Study Title (original):
  Study Title (revised):
  Reason for revision:

  Similarly notifications should be submitted to IRB, in cases where multiple publications result from study originally approved from IRB. In such cases notifications should refer to the title of study originally approved from IRB.

Institutional Review Board
Continuing Review/ Final Report (Study completion)

Title of protocol:

Investigators (with their prime roles, institutional affiliations & contact details):

Note: Please attach a copy of CV of principal investigator.

Current Status of Research project:

Check all that apply: If checking **A or B** below, please complete the Progress Report (see page 2) and required additional pages. The IRB will notify you of the results of its review.

☐ A. Enrollment of subjects began on _____ (date) and will continue till _____
(Please submit a copy of current Consent form)

☐ B. Project is closed to enrollment and one of the following applies:

☐ Research is active only for data analysis

☐ Subjects have completed all research-related interventions and will undergo long-term follow-up only.

☐ Subjects are still undergoing research-related treatment.

☐ C. Funding **or** start of research is pending. Please keep this file active.

☐ D. Project was never begun. Please close this file.

☐ E Any other, please specify

_____

_____ _____

Principal Investigator's Signature

_____ _____

Co-investigator's Signature (if applicable)

_____ _____

1. Total number of subjects enrolled since this project began:_____

    - Approximately how many potential subjects have refused participation?_____
    - What was the target of enrollment?_____

2. Total number of subjects withdrawn since this project began_____

    - How many subjects have voluntarily withdrawn participation at their own request?
    - How many subjects have withdrawn participation at the request of the PI?

3. Please answer the following questions about consent taking?

Have all subjects signed a consent or assent form?	☐ Yes	☐ No
Have there been any problems obtaining informed consent or assent? Explain.	☐ Yes	☐ No
Are all signed forms on file and available for review?	☐ Yes	☐ No

4. Have activities involving human subjects during the past year followed procedures as described in the approved protocol?

    ☐ Yes ☐ No

    If no, please specify;

5. Were any Adverse events (AEs) or Serious Adverse Events (SAEs) experienced by any study participants?

    ☐ Yes ☐ No

    If any, please complete the table Adverse Events provided at page 5

For clinical, drug or device studies: If using an experimental drug or device what is its FDA status?

6. Were any grievances or complaints received about this study?

    ☐ Yes ☐ No

    If yes, please specify;

7. Please provide relevant multicentre report, if any available. (if applicable)

Summarize the preliminary results/current progress of this research.

List and explain any projected amendments to the research protocol since last review (for example, change in investigators, procedures, or size of population). **(Please attach copies of all amendments made).**

Attach a summary of recent literature that suggests anything new or important for continuing the project (e.g., new reactions, new treatments, changes in risk/benefit ratios, etc.).

Adverse Events & Serious Adverse events in Study participants

Type of Event	Study Related	Not Study Related	Possibly Study Related	Date Reported
e.g., (death, thrombocytopenia, anaphylaxis, etc.)				

Total Number of Each Type of Event in the Last Year (since Last Review)

Type of Event	Total Number	

Sources

- GCP guidelines
- National Bioethics Committee Pakistan, Ethical Research Committee-Guidelines
- Office for Human Research Protections (OHRP) US department of Human and health service
- NHS National Research Ethics Service

(Definitions and guidelines/processes are used verbatim)