TATA MEMORIAL CENTRE

HOMI BHABHA CANCER HOSPITAL & RESEARCH CENTRE, (PUNJAB)

A Unit of Department of Atomic Energy, Govt. of India

INSTITUTIONAL ETHICS COMMITTEE

Ref: IEC/HBCH/ 25/21

Date: 3rd Aug, 2021

To,

Dr Tapas K Dora,
Principal Investigator,
Department of Radiation Oncology,
Homi Bhabha Cancer Hospital & Research Centre,
Punjab-148001

Ref: Final Approval -1400006

Respected Sir,

Revised Project entitled, **"Non-Invasive application of Thermal Imaging to Co-relate Clinically Node Positive Head & Neck Cancer"** submitted on 29.07.2021 to Institutional Ethics Committee as per suggestions from 2nd IEC Board Meeting held on held **28.06.2021 at 10:00 a.m. in the Board Room, Main bldg., Surgical Block, 3rd Floor, Homi Bhabha Cancer Hospital & Research Centre, Sangrur, Punjab.**

The following documents were reviewed:

1. IEC form for re-review of research proposal.
2. Protocol Version 2.1 Dated 29.07.2021
3. Case Record Form Version 2.1 Dated 29.07.2021
4. Informed Consent Form English Version 2.1 Dated 29.072021
5. CV, MCI & GCP certificates of PI, Co-PI and CI

The following members of the Institutional Ethics Committee were present:

Sr. No.	Name	Position	Affiliation Status	Gender	Expertise
1.	Dr(Prof.) Raj Bahadur	Chairperson	Non Affiliated	Male	Surgeon(Orthopedic)
2.	Dr(Prof.) Shailendra Kumar Jain	Co-Chairperson	Non Affiliated	Male	Basic Scientist
3.	Dr Sankalp Sancheti	Member Seceratory	Affiliated	Male	BasicMedical Scientist(Pathology)
4.	Dr (Mrs) Sukhmeeen Sidhu	Member	Non Affiliated	Female	Social Scientist
5.	Mr Venugopal Jauhar	Member	Non Affiliated	Male	Legal Expert

mi Bhabha Cancer Hospital,
mpus Civil Hospital,
grur-148001 (Punjab)
one: 01672-223910, Ext. (4003)
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ਸਿਵਲ ਹਸਪਤਾਲ ਕੈਂਪਸ,
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ਕੈਂਸਰ ਇਲਾਜ ਯੋਗ ਹੈ, ਜੇਕਰ ਜਲਦੀ ਪਤਾ ਲੱਗੇ ।

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Sr. No.	Name	Position	Affiliation Status	Gender	Expertise
6.	Mr. Naresh K Garg	Member	Non Affiliated	Male	Lay person
7.	Dr(Prof.) Samir Malhotra	Member	Non Affiliated	Male	Basic Medical Scientist(Clinical Pharmacology)
8.	Dr(Prof.) Baljinder Singh	Member	Non Affiliated	Male	Basic Scientist (Nuclear Medicine)
9.	Dr(Prof.) Sunil K Arora	Member	Non Affiliated	Male	Basic Scientist(Immunology)
10.	Dr(Prof.) Rahatdeep S Brar	Member	Affiliated	Male	BasicScientist (Radiodiagnosis)
11.	Dr Debashish Chaudhary	Member	Affiliated	Male	Clinician(Surgical Oncologist)
12.	Dr Tapas K Dora	Member	Affiliated	Male	Clinician(RadiationOncologist)
13.	Dr Alok K Goel	Member	Affiliated	Male	Clinician(Medical Oncologist)

STATUS: [redacted] **the Principal Investigator should submit continuing review application/annual status report on or before 30th May every year till 30.05.2023. You may request for extension of validity in the submission of continuing review application/annual status report. In order to ensure that there is no lapse in the IEC approval period, it is mandatory to submit study status report prior to lapse of study validity.**

- **PI should intimate IEC on any extramural funding obtained as part of educational/unconditional support and/or other sources. Agreement/ MoU with the funding bodies should be submitted to the IEC, prior to starting accrual on the study.**
- **The source documentation should be done in the electronic medical record and case file.**
- **Project related expenditure should not be made from trust accounts/ Rajiv Gandhi etc.**
- **In case of sites of the study other than HBCH & RC, Punjab, then PI should submit the local IEC approval. PI will immediately intimate to IEC, if any adverse actions or decisions taken by the local IECs at other sites for this project.**

The study should be initiated only after -

- **Registration of the study with Clinical Trials Registry India (CTRI) (if applicable).**
- **Submission of Finalized Clinical Trial Agreement (if applicable)/ /Memorandum of Understanding Agreement/Material Transfer Agreement/Data Sharing Agreement**
- **Submission of DCGI approval to IEC (if applicable).**
- **Submission of HMSC approval to IEC (if applicable)**

Homi Bhabha Cancer Hospital,
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Following points must be noted:

1. **IEC has approved review of cases from 30.07.2021 to 29.07.2023.**
2. **IEC has approved the conduct of the study at Homi Bhabha Cancer Hospital & Research Centre, Sangrur, Punjab.**
3. Principal Investigator and study team should be GCP trained.
4. PI and other investigators should notify initiation of the study. Principal Investigator should intimate the IEC after accrual of first 10 participants in the study or after 6 months of initiation of study whichever is earlier.
5. PI and other investigators should co-operate fully with data and safety monitoring unit (DSMU), who will monitor the study from time to time.
6. The decision was arrived at through majority opinion amongst the voting members of IEC. Member(s)of the committee who is/are listed as investigator(s)on a research proposal opted out from all deliberations on the proposal and did not participate in decision making. Neither PI nor any of proposed study team members participated during the decision making of the IEC.
7. At time of PI's retirement/ intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD and/or convener of the PI's DMG and IEC. Status report including accounts details should be submitted to HOD and extramural sponsors.
8. The IEC functions in accordance with its SOP and is compliant with the New Drugs & Clinical Trial Rules, 2019, ICMR guidelines and Indian /ICH GCP.
9. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms as follows:
   a) The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc)
   b) Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted.
   c) If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Institutional Ethics Committee for approval.
   d) If the amendment demands a re- look at the toxicity or side effects to patients, the same should be document.
   e) If there are any amendments in the study design, there must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IEC, only then can they be implemented.
   f) Approval for amendment changes must be obtained prior to implementation of changes. Without including all the above points, the amendment is unlikely to be approved by the IEC.
10. Any Serious Adverse Events (SAEs) occurring on the study should be reported to IEC.
11. Any deviation/ violation /waiver in the protocol must be informed to the IEC.
12. Principal Investigator should conduct the study in accordance with the IEC approved protocol.
13. The PI should submit a report to the IEC at the time of study completion/ premature termination/ suspension/ discontinuation, as is applicable.
14. Principal Investigator should comply with regulations and guidelines as applicable.
15. PI should submit results and conclusions of the study to IEC before publication.

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[redacted]

Neither PI nor any of proposed study team members participated during the decision making of the IEC. IEC members with any conflict of interest opted out from all deliberations on the proposal and did not participate in decision making.

Thanking you,

[redacted]

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