



Shri Vithalrao Joshi Charities Trust's  
**B. K. L. WALAWALKAR HOSPITAL,**  
**DIAGNOSTIC & RESEARCH CENTRE**

ISO 9001: 2015 Certified

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**Outward No:-BKLWH/IEC/07/2024**

**Date:- 07.02.2024**

To,  
**Dr. Neelam Shirsat,**  
**Principal Investigator,**  
**BKLWH**

**Subject: Final Approval of project # 256**

The Institutional Ethics Committee reviewed your revised application to conduct the research study entitled "**Circulating extracellular RNA as biomarker for ovarian cancer**", discussed during the **80<sup>th</sup> meeting held on 20.01.2024 at 9.00 am in the Meeting Room in OPD building at B. K. L. Walawalkar Hospital (BKLWH). Most members joined the meeting online.**

**The following members of the BKLWH-IEC joined the meeting:**

| Sr. No. | Name                 | Affiliation   | Gender | Expertise               |
|---------|----------------------|---|--------|-------------------------|
| 1       | Dr. Mahendra Gulati  | A201, Gold Coast Ivory Estate, Baner Road, Near Green Park Hotel Banner, Pune 8   | Male   | Chairman                |
| 2       | Dr. Arvind Yadav     | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Male   | Member Secretary        |
| 3       | Mr. Suresh S. Pakale | Advocate, Eliphistone Building, 1 <sup>st</sup> Floor, 10, Veer Nariman Road, Near Horniman Circle, Fort, Mumbai- 400001. | Male   | Legal Expert            |
| 4       | Mr. Mandar Phadke    | 17, Vrundavan Society, NaviPeth, Near Mhatre Bridge, Chintamani Bungalow, Pune- 30.                                       | Male   | Lay person              |
| 5       | Dr. Sunita Patil     | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Female | Clinical Pharmacologist |
| 6       | Miss. Dipali Parab   | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Female | Social Scientist        |
| 7       | Dr. Anand Joshi      | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Male   | Gastroenterology        |
| 8       | Dr. Rita Mulherkar   | B 813, Athashri, Pancard Club Road, Baner, Pune, 411045   | Female | Scientist               |
| 9       | Dr. Shivaleela       | BKL Walawalkar Rural Medical College & Hospital, Sawarde  | Female | Clinical Pharmacologist |
| 10      | Dr. Suneeti Gore     | 1128 Shivajinagar, S.No. 504, 8, Kamala Regency, Dynaneshwar Paduka Chowk, Fergusson College road, pune-411016            | Female | Social Scientist        |

**The following documents were reviewed:**

1. Project Submission Form
2. Study Protocol version 1.1 dated 12.10.2023

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3. Case Record form version 1.0 dated 26.03.2023
4. Patient informed consent form version 1.2 dated 12.10.2023 in English and marathi
5. Healthy Volunteer Informed consent form version 1.1 dated 12.10.2023 in English & Marathi
6. Memorandum of Understanding between BKL Walawalkar Hospital Diagnostic and Research Centre and Tata Memorial Centre submitted on 07.11.2023
7. IEC approval letter dated on 16.11.2023 Tata memorial Hospital

The IEC received query response letter dated 03.02.2024 along with the documents mentioned below which was reviewed by IEC.

1. Revised Submission Template
2. Summary list of changes
3. Project Submission Form
4. Study Protocol version 1.1 dated 02.02.2024 (Approved)
5. Healthy Volunteer Information Sheet & Informed Consent form version 1.1 dated 02.02.2024 in English and Marathi (Approved)
6. Patient Informed Consent form version 1.1 dated 02.02.2024 in English and Marathi (Approved)

**Decision: Approved. IEC approved the study till 07.02.2026 (2 years). The Investigators are requested to submit Continuing Review report on or before 07.02.2025.**

Following points must be noted:

- 1. IEC has approved analysis of 600 (300 cancer Patient +300 Healthy Volunteers) subjects on this study.**
- 2. IEC should be informed of the yearly progress of the study by the PI. Failure to submit the continuing review application/ annual status report may result in withdrawal of IEC approval.**
- 3. IEC has approved the conduct of the study at BKLWH & Tata.**
4. Principal Investigator and study team should be GCP trained.
5. PI and other investigators should notify initiation of the study.
6. The decision was arrived at through consensus/ unanimous or 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. IEC members with any conflict of interest opted out from all deliberations on the proposal and did not participate in decision making.
7. Any change, modification or deviation in protocol must be informed to IEC. Any protocol modification or amendment must receive IEC approval.
8. This Ethics Committee is organized and operates according to Good Clinical Practice and Schedule Y requirements.
9. Any deviation/ violation/ waiver in the protocol must be informed to the IEC.
10. Principal Investigator should conduct the study accordance to the IEC approval protocol.
11. The PI should submit a report to the IEC at the time of Study Completion or Premature Termination/ Suspension/ Discontinuation Report as is applicable.
12. Principal Investigator should comply with regulations and guidelines as applicable.

  
Dr. Arvind Yadav,  
Member Secretary,  
IEC