MEMORANDUM OF UNDERSTANDING

Hospital Based Cancer Registries in India

National Cancer Registry Programme
ICMR-National Centre for Disease Informatics and Research, Bengaluru

The broad and overall objective of ICMR-National Centre for Disease Informatics and Research (ICMR-NCDIR), Bengaluru is to sustain and develop a national research data-base on cancer, diabetes, CVD, stroke, other NCDs and their risk factors through recent advances in electronic information technology with a national collaborative network, so as to undertake etiological, epidemiological, clinical and control research in these areas.

The National Cancer Registry Programme (NCRP) was initiated in 1981 by the ICMR, and is presently coordinated at ICMR-NCDIR, Bengaluru. It operates through a network of Population Based Cancer Registries(PBCRs) and Hospital Based Cancer Registries(HBCRs) across different parts of the country. The data collected enables to estimates cancer incidence, mortality, trends, burden, clinical management, outcome and survival. The information aids efforts towards cancer prevention and control in the country.

This Hospital Based Cancer Registry is being implemented by ICMR- NCDIR, Bengaluru at Shree Krishna Hospital Associated with Pramukhswami Medical College (Gujarat) with the following aim / objectives.

Profile and patterns of cancer in patients attending the hospital

1. Describe the clinical, treatment and outcome parameters
2. Contribute to the respective PBCRs in India under ICMR-NCDIR-NCRP

The basic methodology for the project "Hospital Based Cancer Registries in India" envisages capturing core patient information on demography, clinical details, treatment and outcome of all cancers reported/registered at all departments/units/sections who are involved in cancer diagnosis/ treatment/care in the hospital.

Agreement for co-operation in the performance of work on "Hospital Based Cancer Registries in India" through ICMR-NCDIR, Bengaluru between Dr. Prashant Mathur, Director, ICMR-National Centre for Disease Informatics and Research, Bengaluru, hereinafter called Principal Investigator (PI) and Dr. Priyanka Srivastava hereinafter called Principal Investigator of Participating Centre (C-PI).

The project is effective from 1st December 2022. The C-PI is responsible for the following:

1. Collection, collation and transmission of data of all malignant neoplasms reported/diagnosed/treated from the above centre from 1st January 2022 onwards.
2. Follow the terms and conditions (as specified in **Annexure I**) are necessary for uniformity and successful execution of the study.

The undersigned parties hereby agree and conclude the present agreement:

Signature:

Name, title & Institution:
Dr. Prashant Mathur
Principal Investigator & Director
ICMR-NCDIR, Bengaluru
Email ID: director-ncdir@icmr.gov.in
Date: 19/12/22

Signature: Priyanka Srivastava

Principal Investigator (C-PI)
Name: Dr. Priyanka Srivastava
Designation Consultant Medical Oncology
Telephone: 7574868577
Email: priyankass@charutarhealth.org
Date: 14/12/2022

Head of the institution

Name: Dr. Himanshu Pandya
Designation: Dean
Telephone: 02692-228452
Email: dean@charutarhealth.org

Full Postal address: Pramukhswami Medical College, Gokulnagar, Karamsad-388325, Anand, Gujarat.
Institutional website: www.bhaikakamsiv.edu.in
Date: 14/12/2022.

ANNEXURE-I

Terms and Conditions

Roles and Responsibilities:

A. Principal Investigator (PI), ICMR-NCDIR

1. Deploy standard protocol, tools and methods of National Cancer Registry Programme (NCRP) for collection of data at HBCRs. This includes provision of Core forms for abstraction of cases, procedure manuals and technical support to the participating center or study tools, as per needs of the study.
2. Access to the online software along with secure login credentials to the C-PI.
3. To organize periodic training, re-training of registry staff. This will employ physical onsite programs as well as online electronic methods
4. Monitor the quality of data being collected, transmitted to NCDIR, completeness and clarifications
5. The cancer data collected through this collaboration will be used to augment the NCRP database.
6. ICMR- NCDIR does not accept any responsibility for persons employed for the activity by the participating center or it's PI. ICMR-NCDIR will have no legal liability relating to staff so engaged in the implementation of this MoU.

B. Principal Investigator of the participating centre (C-PI)

1. C-PI will be nominated by the respective Head of Institution. All other Co-PIs will be identified by the C-PI as relevant (i.e., clinicians from surgical/radiation/medical oncology departments and a pathologist) to the implementation of the project with the approval of Head of the Institution.

2. C-PI will have overall responsibility for the execution of the project in the participating centre as per guidelines. This basically includes collection and collation of data of all malignant neoplasms reported/diagnosed/treated in the participating centre from the 1st January 2022, with specific attention to capture of complete and correct residential address, including patient identification details, exact anatomical site of cancer, stage and treatment. HBCR should cover the cases from various departments/units (surgery, radiation, medical oncology, pediatrics, general medicine/surgery, obstetrics and gynaecology, ophthalmology and other departments) from the entire institution whenever any case of cancer is diagnosed or managed to cover complete details. Data collection has to be done in the prescribed format (HBCR coreform) as per guidelines provided in the procedure manual. The same data should be entered into the online software provided by ICMR-NCDIR and transmitted preferably in real time to ICMR-NCDIR.

3. The C-PI will be the main corresponding / contact person for all matters and overall in-charge of the project Hospital Based Cancer Registry in India.

4. C-PI should have Co-Principal Investigators (Co-PI) from all the oncology and cancer related departments. If for any reason the C-PI leaves, an eligible clinician/Co-PI with the concurrence of the Head of the Institution should be nominated and a request for approval of ICMR-NCDIR should be sent well in advance along with detailed Biodata and letter of acceptance for the position and responsibility.

5. Based on local set-up the C-PI /Co-PIs could also identify junior staff members as Faculty-in-charge. This person(s) along with the senior most staff employed under the project would be responsible for the day to day working of the project. This day to day working includes ensuring:

i) Completion of core proforma for "Hospital Based Cancer Registry in India" and regular data transmission.

ii) Maintain the quality of data during abstraction and transmission.

iii) Ensure that the registry staff is acquainted with the methodology of data collection and abstraction through interim in-house reviews.

iv) Internal meetings with all the investigators and concerned staff should be conducted periodically.

v) Assist in order to provide any clarifications sought by ICMR-NCDIR;

6. Facilitate the Principal Investigator/representative(s) during their visits for monitoring, supervision and quality assurance of the data collected.

7. The C-PI and Co-PIs along with the concerned staff should strictly adhere to participate in the meetings along with suitable representative who will also participate in workshops / training programmes and present the progress of work.

8. The primary data of HBCR belongs both to your centre and to ICMR-NCDIR. Therefore, the C-PI should take approval from ICMR-NCDIR before providing/sharing the primary data with any third party / any agency. The ICMR-NCDIR policy on data processing and disclosure shall be followed as applicable from time to time.

9. The space and basic equipment, furniture and other assistance required for the smooth working of the project shall be provided by the host institution.

10. Hiring of manpower for the purpose of project as per the rules and regulations of the participating centre and should take the overall responsibility.

C. Core and Patient Information Form:

1. The project core forms will be printed and provided to the respective participating centre by ICMR-NCDIR.

2. A hard copy of the core form should be completed (and updated) for all malignant cases reported in the respective participating centre.

3. The filled hard copy of the core form shall be preserved for a minimum of 5 years from the date of termination of the project.

D. Data Transmission:

1. Transmission of data on each patient has to be done regularly through the website https://www.ncdirindia.org. The login credentials to access the online software will be provided by ICMR-NCDIR.

2. The centre has to place a request for replenishment of HBCR core forms at least one month in advance.

3. The core identifying and diagnostic information/ Treatment details has to be transmitted within two weeks of data collection.

4. Methods for coordination with other departments, verification of quality errors and data entry should be developed by each participating centre.

5. ICMR-NCDIR will monitor the completeness and quality of data transmitted periodically.

6. Poor quality of data will not be accepted for publication in the periodic reports of the NCRP.

7. Both parties should abide by the 'ICMR-NCDIR Policy on Data processing & Disclosure'

E. Report of Work Done:

1. The reports on the progress of work done on the project will be submitted by the participating centre to the ICMR-NCDIR, as and when called for as per format.

2. Timely submission of data to ICMR-NCDIR and the deadlines for submission of data have to be adhered.

F. Data use and Publication:

1. The HBCR can share information with another HBCR under NCRP only based on specific request from another HBCR under information to ICMR-NCDIR.

2. HBCR data shall be used by ICMR-NCDIR to strengthen the information in case diagnosis/treatment/follow up/outcome in any PBCR/HBCR under the NCRP.

3. ICMR-NCDIR shall finalize datasets of each HBCR on an annual basis.

4. The individual C-PI is responsible for publication of the collected / verified data from the participating centre, after the data is accepted by ICMR-NCDIR, with due acknowledgement of ICMR-NCDIR-NCRP

5. The analysis, report preparation and publication of the verified / collected pooled data is the responsibility of the ICMR-NCDIR-NCRP.

6. A list of papers published on the work carried out for this study under the auspices of the ICMR-NCDIR shall be submitted along with reprints of the papers periodically.

7. Data collected and finalized can be used for thesis/publication/sharing with government departments.

G. Ethical Clearance:

1. The participating centre shall obtain IEC approval for the project before commencement of data collection and submit the same to ICMR-NCDIR as per the ICMR 'National Ethical Guidelines for Biomedical and Health Research involving Human Participant-2017'. The necessary ethical clearance including patient consent will be the responsibility of the participating centre.

H. Data Confidentiality:

1. The participating centre will abide by the ICMR-NCDIR policy on data processing and disclosure to ensure a stable, reliable, ethical and legally compliant framework for data collection, use and dissemination by the NCDIR.

2. The C-PI should ensure that the staff of the participating centre maintain patient confidentiality and also maintain data confidentiality and data security. Measures to maintain data security and protection as per the ICMR-NCDIR policy will be followed by the centre.

I. Specific Conditions on Use of Software:

1. No part of this software may be copied or used without the written consent of ICMR-NCDIR. Copyright © 2014, ICMR, New Delhi, All Rights Reserved.

2. Software, database and login credentials should be used only by authorized persons at authorized locations. Change of C-PI or discontinuation of the services of any staff having knowledge of the login credentials must be intimated to ICMR-NCDIR so that the previous password is invalidated and fresh credentials will be issued to the participating centre. Undertaking on data confidentiality must be taken from staffs. Any violation of terms and conditions shall attract discontinuation of contract.

J. Termination of the project:

1. Either party can terminate the project, with valid reasons and adequate time.

This MoU is valid for two calendar years and needs to be renewed by both parties.