



**MALABAR CANCER CENTRE - POST
GRADUATE INSTITUTE OF ONCOLOGY
SCIENCES AND RESEARCH**

(MCC-PGIOSR)

**FELLOWSHIP
IN
CLINICAL RESEARCH**



1.0 MALABAR CANCER CENTRE, THALASSERY

Malabar Cancer Centre - Post Graduate Institute of Oncology Sciences and Research, Thalassery (MCC-PGIOSR) is an autonomous institution under Health and Family Welfare Department, Government of Kerala, started with an aim to establish a comprehensive cancer centre, providing the much-required oncology care to the population of Northern region of Kerala and neighboring parts of Karnataka and Tamil Nadu states. The main objective of the centre is not only to provide comprehensive cancer care but also to develop as a Research and Training Centre of international standards. A society named Malabar Cancer Centre - Post Graduate Institute of Oncology Sciences and Research Society was registered under Societies Registration Act XXI of 1860 with the above aims and clinical work in MCC-PGIOSR started from March 2001 onwards. At present MCC-PGIOSR has more than 200 in-patient bed strength. The control and management of the Society are vested in the Governing Body consisting of 23 members with the Honorable Chief Minister of Kerala as the Chairman. The routine activities and functions of the Centre are supervised by the Executive Committee, with the Secretary, Department of Health and Family Welfare, Government of Kerala being the Chairperson of the Committee. The members in the Governing Body and Executive Committee are functioning by virtue of their official positions.

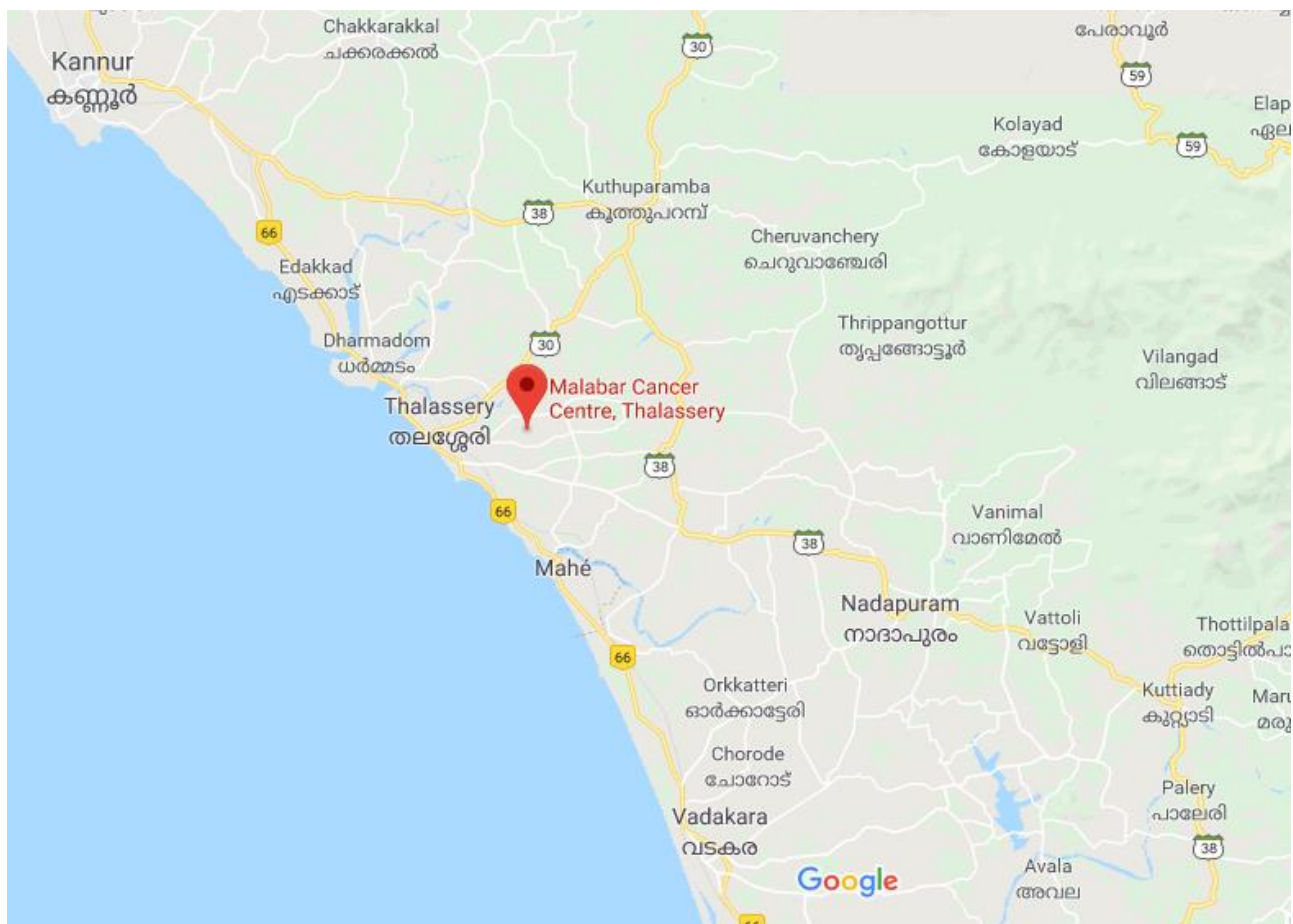
MCC-PGIOSR provides a full spectrum of oncological care as an autonomous not-for-profit institution funded by the State Government and other sources. Patients are categorized according to their economic status, and accordingly it is expected that 95-97% of patients will be provided free treatment through various financial assistance schemes of the Government. The main modalities of treatment offered by MCC-PGIOSR to patients, presently, include radiotherapy, chemotherapy, onco-surgery and palliative care. The Centre also carries out Community Oncology activities including cancer awareness and early detection programmes. The institute caters to patients from 7 districts of Northern Kerala in addition to the neighbouring states of Tamil Nadu, Karnataka and Mahe (a total population of over 1.5 crores).

Location: Kodyeri, Thalassery, Kannur District, Kerala.

Thalassery (formerly Tellicherry) is a commercial town on the Malabar Coast in Kannur district, in the state of Kerala, India, bordered by the districts of Mahe (Pondicherry), Kozhikode, Wayanad and Kodagu (Karnataka). The town of Thalassery is historically renowned for its 3 “C “ s of *Cake, Circus and Cricket*. Thalassery is at times referred to as the city of cricket, cakes and circus. It was a British bastion in the pre-independence era with marked contributions of colonial rule.

It is the second largest populated municipality of North Malabar.. The Europeans nicknamed the town "Paris" or in other words "The Paris of Malabar", as it was the sole French military base in Kerala in that era..Thalassery municipality has a population just under 100,000.and an area of 23.98 square kilometres. It is 22 km south of the district headquarters -Kannur city.

Thalassery municipality was formed on 1st November 1866 according to the Madras Act 10 of 1865 of the British Indian Empire, making it the second oldest municipality in the state. At that time the municipality was known as Thalassery Commission, and Thalassery was the capital of North Malabar. G. M. Ballard, the Malabar collector, was the first President of the municipal commission. Later a European barrister, A. F. Lamaral, became the first Chairman of Thalassery municipality. Thalassery grew into a prominent place during European rule, due to its strategic geographic location. Thalassery has played a significant historical, cultural, educational and commercial role in the history of India, especially during the colonial period.



2.0 INTRODUCTION

Global Cancer Burden

Cancer is an umbrella term covering over 40,000 unique disorders characterized by unlimited replicative potential, virtual mitotic immortality and propensity to invade non native tissues. Despite being one of the few curable non communicable diseases, cancer remains a major public health problem worldwide, accounting for over 8 million deaths worldwide. As per Globocan 2018 data, there were 18.1 million new cases of cancer. While cancer has been traditionally viewed as a disease of the affluent world, 65% of the cancer deaths occur in the less developed nations. Cancer is the 4th most common cause of death, accounting for almost 12.5% of all deaths occurring worldwide. Not only does cancer cause suffering in terms of mortality and morbidity, but it also has a significant socio-economic impact. As per the Global Economic Cost of Cancer Report (American Cancer Society), the total economic impact of premature death and disability from cancer worldwide was \$895 billion in 2008. This figure, which does not include direct costs of treating cancer, represents 1.5 percent of the world's GDP. Cancer causes the highest economic loss of all of the 15 leading causes of death worldwide. The economic toll from cancer is nearly 20 percent higher than heart disease, the second leading cause of economic loss (\$895 billion and \$753 billion, respectively).

Burden of Cancer in India

As per the estimates provided by Globocan 2018, worldwide the age standardized incidence of all cancers including non melanoma skin cancers, were 218 per 100,000 in males and 182.6 per 100,000 in females. In India it is around 90 per 100,000 population in males and females. In India the five most common cancers are cervical cancer, Breast Cancer, Head Neck Cancers, Lung and Colorectal cancers. This is also unlike the case in the USA where Prostate, Breast, Lung, Colorectal cancers and melanomas are the 5 most common cancers. It should be remembered that this data probably represents a gross under-representation of the true burden as the NCRP data that is the basis for this report has a single rural based cancer registry, where 70% of the Indian population is known to reside. As per Globocan 2018 there are 1.15 million new cancer cases annually. Perhaps more worrisome is the fact that the burden of cancer will nearly double in the next two decades with an estimated 1.7 million new cases and 1.2 billion cancer deaths occurring annually by the year 2035.

As India's population ages and the deaths attributable to infectious diseases are reduced, the burden of mortality due to non communicable diseases will experience an upsurge. Deaths caused by cancer are projected to increase from 730 000 in 2004 to 1.5 million in 2030, and those attributable to cardiovascular causes from 2.7 million in 2004 to 4.0 million in 2030 as per the Global Burden of disease study.

Challenges to Cancer Care in India

In a well publicized position paper in *Lancet Oncology*, Professor Mallath et al, have highlighted several challenges facing our nation in ensuring adequate and equitable cancer care. Despite the substantial socioeconomic progress made over the past 5 decades since Independence, our per capita purchasing power is only 5-10% of that of the Western nations. If we take the example of Trastuzumab, a monoclonal antibody that has proven to have significant benefits in a subgroup of breast cancer patients, the annual cost of treatment for an average Indian female works out to be \$20,000. This represents ~ 30% of the cost incurred for the same drug in the USA (\$70,000). As can be appreciated in terms of relative purchasing power, the same drug, although retailed for a lesser price, extracts a far more severe economic penalty on Indians. This economic burden is aggravated by the fact that use of such life saving drugs is associated with a net societal economic benefit in terms of quality adjusted life years (QALY) saved. As estimated by Lopes et al, the mean societal cost benefit due to herceptin in Singapore is \$4300. Given the central role that a woman plays in the family in India the socio-economic impact of lives lost, due to inability to afford this medication is likely to be higher. This is not only the case for new drugs but also for existing drugs and devices.

India is also experiencing a slower demographic transition in terms of disease burden. While the burden of chronic disease is increasing, a high burden remains for acute infectious diseases and accidents. As a result formulating an effective health policy remains a challenge. India thus requires a health care policy that combats malnutrition while emphasizing prevention of obesity at the same time. Till date the national cancer control program has focussed its efforts on enhancing and upgrading infrastructure at select cancer centres along with emphasizing education as the primary modality for prevention. We lack dedicated screening programmes for most cancers as till date the population prevalence for most cancers is below 5 per 100,000.

As highlighted in the report by Professor Mallath et al, India invests less than 1.5% of its GDP on central government-funded and state-funded health care, out of a total public plus private spend of little more than 4% of GDP. No other comparable nation spends as small a proportion of its national resources on public health care. The situation is further complicated by factors such as poor fiscal governance; sub-optimum (health sector-related) relationships between the federal and state governments; poor public health expertise (compounded by inadequate medical and other health professional education); substantial regional variations; and gross education, caste, and class-related inequalities in income and access to services.

Although Indian society places strong emphasis on familial bonds, there is an absence of a corresponding emphasis on ensuring adequate funding for service requirements in the community. As

a result majority of the treatment costs are borne out of pocket resulting in further exacerbation in the disparities in cancer care.

Perhaps the biggest problem faced by the policymakers in India today is the inadequate infrastructure available for training and education for professionals. While 60% of specialist facilities are located in regions to the south and the west of India, 50% of the population lives in the Central and Eastern parts of the country. The regional disparity in cancer care is even more apparent when we consider the imbalance in availability of therapy facilities. In addition to the disparity among regions, there is an imbalance in the availability of services in rural and urban areas. As a result of this disparity patients with cancer often have to travel long distances and stay in suboptimal conditions to access appropriate cancer care which they can afford.

Challenges to Cancer Research in India

Even more worrisome is the state of cancer research in India. India, which has about 17% of the world population, is involved in only about 1.5% of all clinical trials worldwide. The amount of ongoing research activities can be gauged from the number of clinical trials ongoing in the nation. In this respect a search of the Clinical Trial Registry of India reveals that there are only 331 registered trials in Cancer of which only 141 are actively recruiting participants. Of the 57 clinical trials being conducted in Kerala none are open to recruitment at present. In contrast, a search of the clinical trial registry database of the National Cancer Institute reveals 1518 active clinical trials dealing with various aspects of cancer research. As can be easily appreciated, the number of trials being conducted in India on Cancer at this point of time is less than 10% of what is being conducted in the USA. Perhaps more worrisome is the fact that there is a dearth of investigator initiated research with less than 3% of the registered trials being investigator initiated studies.

Another metric to gauge the research output is the number of publications in peer reviewed journals. In this regard also India is far behind that of the USA. In a bibliometric analysis of publications related to cancer research reported by Patra et al, only 648 publications were identified in Pubmed as originating from India in contrast to the 1,53,341 publications from India. Of the total number of publications, India contributed to only 0.4% of the available publications. The authors found that most of the publications were in low impact factor journals and there was a marked regional disparity with Kerala accounting for only 6.5% of the national research output.

We conducted a search of Pubmed using the same filters and found that 25,047 articles were identified from India. However during the same time period, the total number of publications from the USA was 3, 80,771. In the year 2012, 2122 articles were published from India as compared to 25,364 articles

from the USA. Thus over the period of the last decade while some increase in research activities has been observed the total research output of India remains less than 10% of that in the USA.

Hence from the above it can be easily concluded that Cancer research is at a nascent stage in India. Given the dearth of manpower and high patient load at most cancer centres it is not difficult to imagine the reasons behind the lack of research activities. Further impediments in conducting research activities in India include the phenomenon of “brain drain”, lack of appropriate training and infrastructure to conduct research, absence of incentives for conducting research and less funding available for research. Other problems that have been highlighted in a publication by Saini et al and Thatte et al include:

1. Shortage of trained staff well versed in GCP norms.
2. Lack of formal training in bioethics and research methodology
3. Heavy burden of clinical duties
4. Sub-optimal administrative support
5. Absence of oversight of functioning of ethics committees
6. Lack of mechanisms for ensuring quality of ethics review heightens societal concerns about safety of participants.

The current socioeconomic reality of the Indian health care system is that very few patients are able to get access to innovative drugs and treatments. The per capita total spending on health is \$132 for India versus \$3480 for the United Kingdom (currency assumed to be international dollars as per purchasing power parity). 70.8% of all healthcare expenditure in India is borne by private spending, compared to only 16.1% for the United Kingdom. As a result there is no incentive for international pharmaceutical companies to market the latest products in India. This, coupled with an adverse intellectual property environment, results in the large majority of the innovative drugs reaching the Indian market very late in their development. The need of the hour is to develop a robust mechanism to conduct clinical trials that have relevance to the cancer burden in India in the country itself. In this regard availability and continuous training of manpower assumes paramount importance.

3.0 FELLOWSHIP IN CLINICAL RESEARCH

THIS FELLOWSHIP PROGRAMME CONDUCTED BY MCC-PGIOSR IS INSTITUTIONAL FELLOWSHIP PROGRAMME. THESE PROGRAMS DO NOT HAVE THE RECOGNITION OF REGULATORY BODIES OR UNIVERSITIES.

Fellowship Programme in	Duration	Vacancy	Eligibility
Clinical Research	2 years	One	<ul style="list-style-type: none">• Post Graduates in Life Sciences or Biotechnology, MSc Statistics or Biostatistics, MPharm, Pharm D, MBBS, BHMS, BAMS, BDS, MPH• Candidates should not cross 45 years as on 1st January of current year.

Objective of the Programme

Fellowship in Clinical Research : Obtain a clear understanding of Good Clinical Practice and standard operating procedure for clinical research and clinical data. It provides individuals / Students / Professionals from Pharmacy, Medical, Nursing, Life Sciences, Research & Development, Clinical Research, Allied areas, and academic fields, a basic to advanced level understanding of various clinical trials. This two-year fellowship program will understand the evolving regulatory process standard and practice of ICH-GCP, conducting of clinical trials, and support the overall clinical trial process electronically by implementing Electronic Data Capture (EDC) system and Project Monitoring.

Academic eligibility

Post Graduates in Life Sciences or Biotechnology, MSc Statistics or Biostatistics, MPharm, Pharm D, Graduate in Allopathic Medicine, Homeopathy, Ayurveda, Dentistry, MPH

Duration of the programme

Total duration of the course is two years (one year course + one year mandate Internship)

Educational Objective

- Acquire an understanding of evolving regulatory processes standards and practices of ICH GCP in the conduct of different therapeutic trials and in the preparation of submissions to be made to regulatory authorities in India and overseas.
- Identify the roles and responsibilities of the different positions within the clinical research processes
- Learn to incorporate ethical practices
- To provide research experience in clinical and public health with advanced training in areas such as research design, research ethics, health informatics, clinical trials, and statistical analysis through mentored research training

- To provide knowledge and skills to prepare clinician trainees for careers in clinical research. The clinical research fellows will work and involving in the various clinical trials ongoing at site

Fellowship Curriculum

- History and Evolution of Clinical Trials
- Clinical Epidemiology
- Introduction to Clinical Trials
- Good Clinical Practices (GCP)
- Clinical trial design
- Ethical issues related to Clinical Research
- Clinical Data Management
- Clinical Research Quality control and Quality Assessment
- Epidemiological Studies
- Ethical aspects of Epidemiological research

Evaluation

Internal assessment of the candidates by faculty- 50 marks

This will be done on a continual basis with respect to the overall objectives of the course, based on the prescribed textbooks and study materials.

External examination -100 marks

This will be done based on the theory examination which consist of 100 marks

Dissertation and viva voce -100 marks

The candidate to be submitted a dissertation as part of the programme and viva voce is based on the dissertation and the overall curriculum

Internship

As part of the course, a one-year internship program is required. During this period the candidate will be provided a stipend. The certificate will be provided after completing the one-year course +mandate internship.

Completion

A pass mark is necessary for getting the certificate of fellowship. The certificate will be issued in an institutional function after successfully completing the 24 months of the programme, including the thesis work, required exams, and the mandated internship.

4.0 SUBMISSION OF APPLICATION

Online Application:

The applications should be submitted ONLINE through our website www.mcc.kerala.gov.in.

Application Fee:

Application fee is **Rs.1,500/-** (Rupees One Thousand Five hundred only). The application fee shall pay online through the payment gateway system provided in the online application

Selection process:

The selection will be based on an online screening test and/or personal interview.

5.0 FEES AND STIPENDS

Fees of **Rs.15,000/-** per annum with alumni fee of **Rs. 750/-** will be levied and **Rs.5,000/-** will be the refundable caution deposit (Total **20,750/-** in first year and **15,000/-** in second year). Stipend of **Rs.12,000/-** per month will be given for non sponsored candidates. For sponsored candidates and candidates from other countries the institution may decide on the fee structure as appropriate.

6.0 FACULTIES

SURGICAL ONCOLOGY	Dr.Satheesan Balasubramanian, M.S. M.Ch. (Surgical oncology) Director & Professor, HoD in Surgical oncology.
	Dr.Nizamuddin.M.P (MS, MCh.), Additional Professor and HoD, Dept.of Surgical Oncology
	Dr Adarsh D . MS (OBG), Assistant Professor in Gyn Oncology
	Dr Sandeep Vijay MS (ENT), Assistant Professor
	Dr Anoop.A MS (ENT), Assistant Professor
	Dr Ashitha MS (OBG), Assistant Professor
	Dr.Bony A Joseph, (MS, MCh.), Assistant Professor
	Dr. Prasanth P, DrNB, Assistant Professor
	Dr. Raveena R Nair, Assistant Professor
Dr. Shamna Muhammed, Assistant Professor	
CLINICAL HEMATOLOGY AND MEDICAL ONCOLOGY	Dr.Chandran K. Nair, M.D.,DNB(Int. Medicine), D.M. (Clinical Hematology), Fellowship in Bone Marrow/Peripheral blood Stem cell transplantation(Vancouver, Canada) Professor and HOD
	Dr.Praveen Shenoy (MD, DM), Associate Professor
	Dr.Jithin T K (MD, DM), Assistant Professor
	Dr.K G Gopakumar (MD, DM),Assistant Professor
	Dr. Nandini Devi, (MD, DM), Assistant Professor
	Dr. Abhilash Menon, (MD, DM), Assistant Professor
	Dr. Arun Krishnan M P, (MD, DM), Assistant Professor
	Dr. Shoaib Nawas P N, Assistant Professor
CLINICAL LABORATORY SERVICES AND TRANSLATIONAL RESEARCH	Dr.Sangeetha K Nayanar MD, DNB (Pathology) Professor and HOD
	Dr.Parthiban R, PhD Professor, Microbiology
	Dr.SitharaAravind MD (Pathology), Additional Professor
	Dr Mohandoss M MD (Transfusion Medicine), Additional Professor
	Dr Aswathy Krishnan M MD,DNB (Pathology), Associate Professor
	Dr Kandathil Philip Joseph MD,DNB (Pathology), PDCC Assistant Professor
Dr Anand Narayanan MD (Pathology), Assistant Professor	

	Dr.Vivek Nair, MD(Pathology), Fellowship in Oncopathology Assistant Professor
	Dr.Deepak Roshan PhD , Associate Professor, Cytogenetics
	Dr.Vipin Gopinath PhD, Associate Professor, Molecular Oncology
	Dr.Sindhu ER PhD, Assistant Professor, Biochemistry
	Dr Sarath KE MD, Assisntant Professor, Microbiology
RADIATION ONCOLOGY	Dr.Geetha M. MD (Radiotherapy),Professor and HOD Dr Vinin N V MD (Radiotherapy), Additional Professor Dr Joneetha Jones MD,DNB(Radiotherapy), Associate Professor Dr Greeshma K E DMRT,DNB (Radiotherapy), Associate Professor Dr Nabeel Yahiya MD (Radiotherapy), Assistant Professor Dr Arun.P.Narendran MD,DNB(Radiotherapy), Assistant Professor Dr Akhil.P.Suresh MD (Radiotherapy), Assistant Professor Dr. Megha Prem, MD (Radiotherapy), Assistant Professor
IMAGEOLOGY	Dr Nrithi P , MD (Radiodiagnosis) , Assistant Professor Dr. Suryakala, MD (Radiodiagnosis) , Assistant Professor Dr. Ashish Pavanan, MD (Radiodiagnosis) , Assistant Professor
PULMONOLOGY	Dr Anu Mariyam , MD (Pulmonology), Assistant Professor
PALLIATIVE MEDICINE	Dr Biji M S, Assistant Professor
COMMUNITY ONCOLOGY	Dr Neethu,MBBS,MPH, Lecturer Dr Phinse Philip, BDS,MPH,PhD,Lecturer
CANCER REGISTRY & EPIDEMIOLOGY	Dr SainaSunilkumar, MBBS,MPH,Lecturer Mr Ratheesan,MSc,MBA,Lecturer in Biostatistics Dr. Bindu, MSc,PhD, Lecturer in Biostatistics
CLINICAL RESEARCH & BIOSTATISTICS	Mrs Maya Padmanabhan,MSc,Mphil, Lecturer in Biostatistics Mr Riyas,MSc,Lecturer in Biostatistics
PSYCHO-ONCOLOGY	Mrs. Jisha Abraham,MSc,Mphil, Lecturer in Psycho-oncology

7.0 RULES AND REGULATIONS

- 1) The course is full time. Candidates are expected to perform all types of clinical, research and academic assignments as prescribed by the Academic Council of Malabar Cancer Centre - Post Graduate Institute of Oncology Sciences and Research.
- 2) It is a resident program of post-graduate training
- 3) Candidate is expected to wear identity card provided by MCC-PGIOSR
- 4) **Dress code:** Lady candidates are expected to put up the hair during working hours. She is permitted to wear any decent dress preferably, Sari and churidhar. Gentleman candidates should wear formal shoes. White apron is compulsory during working hours
- 5) **Attendance:** The candidate should mark the attendance in Biometric punching machine and also sign in the register kept in the department.
- 6) Completion of project work is compulsory for fellowship certification.
- 7) **Leaves:** Candidates will be eligible for 12 days leave during the programme. Not more than 5 days of leave will be granted together. Candidates who avail for more than 12 days of leave will have extension for those additional days of leave. Holiday leave/ holiday duty off will be given as per discretion of the Head of Department.
- 8) **Accommodation:** Accommodation is the responsibility of the candidate. For lady candidates, if available and formally requested in the Request form, shared room accommodation may be provided in the Nurses hostel. This is not guaranteed and it is not a right of the candidate. If accommodation is provided a nominal rent will be deducted from the stipend. A caution deposit of Rs. 1,000/- should be paid. This is refundable when the candidate vacates the hostel. Gentleman candidate is expected to find an accommodation themselves
- 9) Candidates should follow the rules and regulations of MCC-PGIOSR.

8.0 CONTACTS

For any clarifications and queries, please feel free to contact;

- Dr.Sangeetha K Nayanar, Professor & HOD, Department of Clinical Laboratory Services and Translational Research,
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- Mrs.Maya Padmanabhan, Division Incharge,, Division of Clinical Research & Biostatistics
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- Mrs.Jisha Abraham,Division Incharge, Division of Psycho Oncology
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Any technical queries regarding online applications please contact System Manager, Email: sm@mcc.kerala.gov.in with application Number (Phone: 0490-2399400, 2359881)



**MALABAR CANCER CENTRE - POST GRADUATE INSTITUTE OF
ONCOLOGY SCIENCES AND RESEARCH**

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