Annexure-I

Job Profile for the post of Scientist-II for CRU

S.No.	Post	Area of specialization	Job Profile
1.	Scientist-II	Biostatistics	The candidate will be required to : • Contribute to planning and designing community/ facility based epidemiological/ clinical research studies • Develop and implement statistical analysis plan to analyse complex data from various study designs • Calculate sample size for various community/ facility based epidemiological/ clinical research studies • Collaborate with investigators to develop Clinical Record Forms (CRFs) • Validate data collection tools for conduct of research studies • Supervise eCRF development and monitor data entered on a periodic basis to identify errors and generate queries to resolve the same • Establish a centralized system for data management to store data and ensure that all the team members are trained on appropriate data documentation pertaining to all data work • Be proficient in the use of at least one standard statistical package such as Stata, SPSS, SAS or R • Assist in coordinating communications arising from the office of the Dean/ Associate Dean (Research)/Ethics related to clinical research.
2.	Scientist-II	Clinical Trials	The candidate will be required to: • Assist the investigators in designing clinical trials • Coordinate smooth conduct of trials • Facilitate matters related to clinical trial agreement preparation, administration, finance, store, data management, verification, analysis and archival, preparation and implementation of SOPs, MoUs and manuals. • Provide advice about applicable regulations to the researchers and help them with relevant documentation • Liaising with regulators on behalf of Clinical Research Unit/ Principal investigator • Keeping up to date with regulatory legislations and guidelines applicable to different types of clinical research e.g. clinical trial rules, medical device rules, drug import licensing, and permissions from DGFT, HMSC, etc. • Conduct periodic training programs of faculty and coordinators in using tools related to clinical trials etc. • Facilitate SAE (serious adverse event) reporting as per current regulatory format and timelines • Report writing, Assist in coordinating communications arising from the office of the Dean/ Associate Dean (Research)/Ethics related to clinical trials.
3.	Scientist-II	Epidemiology	The candidate will be required to: • Plan and design community based epidemiological research studies • Facilitate grant applications • Facilitate application for ethics and other relevant clearances. • Facilitate preparation of SOPs related to conduct of specific research studies. • Design and test data collection tools for conduct of research studies. • Supervise, train and monitor research staff for smooth conduct of research studies. • Collaborate with data management team to test study databases, facilitate data entry and data cleaning. • Assist in designing reports and scientific manuscript. • Assist in coordinating communications arising from the office of the Dean/ Associate Dean (Research)/Ethics related to clinical research.