Syllabus for PhD Entrance Test

Subject- Clinical Research

ICH GCP E6 R2:

a) Investigator Responsibilities: Investigators Qualifications and Agreement**,** Selection of Principal Investigator, Patient management, ICF Process, Communication of IRB/IEC, Drug administration, CRC Role and Responsibilities, assist in Audit and Inspection, Site close out process, Serious adverse event management by site, Principles of ICH GCP.

b) Sponsor Responsibilities: Overall quality process needs to be maintained by sponsors, CRF reviewing, submission of documents to Regulatory bodies and Ethics committee, Selection of CRO/SMO, Trial management, Data handling, SAE reporting management, Site selection, Audit process, Drugs Management, Monitoring process.

c) Ethics Committee responsibilities: Responsibilities of Ethics Committee, Composition of ethics committee, Functions and Operations of ethics committee, Procedures of submission and approval and Records keeping

d) Protocol and Investigator's Brochure: Protein Structure: General information, Trial Design, Trial objective and purpose, Selection and withdrawal of subjects, Treatment of subjects, Assessment of safety and efficacy, Publication policy. General consideration of IB, Contents of the Investigator's Brochure.

e) Essential Documents: Introduction, Before the Clinical Phase of the Trial Commences, During the Clinical Conduct of the Trial, After Completion or Termination of the Trial

ICMR Guidelines (Nov 2017):

a) **General Ethical Issues:** Benefit-risk assessment, Statement of General Principles (ICMR), General Ethical Issues, Responsible conduct of Research, Conflict of interest, Compensation for research related harm, Informed consent process, various ethical concerns while conducting clinical trials on Vulnerable population

b) **Ethical Review Procedure**: Terms of reference for ethics committees, Composition of an EC, Terms of reference for EC members, Criteria for selection of EC members, Roles and responsibilities of EC, Submission and review procedures, Full committee meeting, Review of multicentric research, Administration and management, Registration and accreditation of ECs.

c) **Informed consent process**: Essential information for prospective research participants, Documentation of informed consent process, Electronic consent, Specific issues in clinical trials, Waiver of consent, Re-consent or fresh consent, Procedures after the consent process, Special situations, Consent for studies using deception, Principles of research among vulnerable populations, Patients who are terminally ill.

d) **Clinical trials of drugs and other interventions:** Clinical drug/vaccine development, Ethical implications of study designs, Bioavailability/bioequivalence study, Device trials, Biologicals and

biosimilars, Clinical trials with stem cells, Surgical interventions, Community trials (public health interventions), Clinical trials on traditional systems of medicine, Investigator initiated clinical trials, Clinical trials in oncology.

e) **Human genetics testing and research**: General issues, Genetic counselling, Privacy and confidentiality, Informed consent, culturally sensitive issues, Storage of samples for future genetic research, Results of genetic testing, Publication aspects, Commercialization and COI, Role of the team in genetic testing and research, Quality standards of the laboratory, Misuse of genetic technology, Genetic diagnosis/testing and screening, Gene therapy, Use of newer technologies, Research on human embryos, Foetal autopsy

New Drug Clinical Trial (NDCT 2019):

a) Ethics Committee for Clinical Trial, Bioavailability & Bioequivalence Study: Constitution of ethics committee for clinical trial, Registration of ethics committee, validity and renewal process, functions and proceedings of EC, Maintenance of records, suspension or cancellation of registration of ethics committee, Registration of Ethics Committee related to biomedical and health research.

b) Requirements & Guidelines for Permission to Import or Manufacture of New Drug for Sale or to undertake clinical trial: Application for permission, Non-Clinical toxicity studies, Animal pharmacology studies, Fixed Dose Combinations, Stability testing of new drugs, List of documents that need to be submitted to conduct clinical trials, Import, Export and marketing

c) Data Generated by Applicant for conducting Clinical trials : Identification, authentication and source of plant used for extraction and fractionation, Conduct of clinical trial, Informed consent, Responsibilities of Sponsor, Investigator and Ethics Committee, information to be submitted by an applicant for grant of registration of ethics committee and format for according approval.

d) Protocol: Contents of the proposed protocol for conducting clinical trials, Checklist of informed consent documents for clinical trial, undertaking by the investigator (table 4), data elements for reporting serious adverse events occurring in a clinical trial or bioavailability or bioequivalence study.

e) Clinical Trial Report: structure, content and format for clinical trial report, Investigator Brochure (Table 7), Prescribing information (Table 8), Post Market Assessment

Global Regulations in clinical Research

a) US Food and Drug Administration (USFDA): 21CFR 11, 50, 52, 54, 316, 314

b) Medicines and Healthcare Products Regulatory Agency (MHRA): Overview of regulatory environment/ background, regulatory authorities, regulatory requirements, and procedures.

c) European Agency for Evaluation of medicinal Products (EMEA): National registration, the decentralized procedures, mutual recognition procedures

d) Regulations in Brazil, Japan and Auatralia: Overview of regulatory affairs in Brazil, Therapeutic goods administration (TGA), MHLW and PMDA in Japan