PIS & Consent Form

PART 1

1. Information sheet

   You are requested to participate in the study titled "Assessment of Knowledge and Practices of Researchers towards Good Clinical Practice in a Tertiary Health-care Institute in Uttarakhand, India : A Cross-sectional Study". This study is being conducted by Harshita, 2nd year MBBS student (2019 batch), under the guidance of Dr. Prasan Kumar Panda, Associate Professor, Department of Medicine, for Short Term Studentship (STS) 2022 conducted by Indian Council of Medical Research (ICMR).

   The purpose of the study is to estimate the knowledge and practice gaps of Good Clinical Practice (GCP) among researchers in the tertiary care research institution.

   This is a questionnaire based study. The questionnaire used is based on the course of Good Clinical Practice by NIDA Clinical Trials Network. The questionnaire has 4 sections containing- consent, demographic details, questions for knowledge assessment and practice based questions.

2. Participant selection

   You are requested to partake in the research as you are/have been an investigator of Institutional Ethics Committee-approved research project(s).

3. Voluntary participation

   Participating in this study is voluntary. You may refuse to partake in the study/ exit the survey at any time without any penalty.

4. Benefits

   There are no direct benefits. However, engaging in this research will make you more aware of the GCP principles.

   Indirect benefits- This will help in improving knowledge about GCP, where a gap is observed. Accordingly, necessary actions may be suggested in future studies after finding the reason for such gaps.

5. Risks

   There are no foreseeable risks to the participants of the study.

6. Confidentiality

   The confidentiality of all participants will be maintained. Any data, which may identify the individual participants of the study will not be disclosed.

7. Contact

   In case of any queries, that you may have, please contact

Principle Investigator	Harshita	+9	harsh ı
Guide	Dr. Prasan Kumar Panda	+9	prasa esh.edu.in

PART 2

Certificate of Consent

I, the undersigned, am voluntarily willing to participate as a study subject in this research study. I have been informed regarding the procedures and techniques involved in the study in the language understood by me. I have no objection whatsoever to the results of the study being published for the advancement of medical knowledge as long as confidentiality is maintained. I have fully understood the aforesaid and willingly give my consent for the same.

Name and sign of researcher:
Date:

Statement by the Principle Investigator

I have read out the information provided in the information sheet to the participants precisely.
I confirm that all the queries of the participant were resolved. I confirm that the individual has not been coerced into giving consent and consent has been given freely and voluntarily.
A copy of this informed consent has been provided to the participant.

Name and sign of Principle Investigator:
Date: