DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

Ph.1 SOP A05a: Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

Version 1.2 dated 30th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

Title: Ph.1 SOP A05: Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

Version: 1.2 dated 30th of December 2024

Effective date: 1st of January 2025

Revision due date: 31st of December 2025

Prepared by: Dr Dhruve Soni

Signature with date: 30/DEC/2024

Reviewed by: Dr Bhaskar Krishnamurthy

Signature with date: 30/DEC/2024

Dr. Bhaskar Krishnamurthy
Assistant Professor,
Department of Clinical Pharmacology,
Seth GSMC and KEMH,Mumbai -400 012.

Authorized by: Dr Nithya Gogtay

Signature with date: 30/12/24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

Ph.1 SOP A05a: Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

Version 1.2 dated 30th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

Table of Contents

Ph.1 SOP A05a: Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

Version 1.2 dated 30th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to outline the process for preparing, reviewing, and finalizing the informed consent document (ICD) for a Phase I clinical trial with an investigational product in vernacular languages so as to ensure that the ICD is accurately translated and culturally appropriate for participants.

2. **Scope:** This SOP is applied to all personnel involved in the preparation, review, and finalization of the ICD for Phase I clinical trials with investigational products at our institute.

3. **Responsibilities:** The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI).

4. **Applicable rules, regulations and guidelines:**
   - Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR, 2017
   - International Council on Harmonization (ICH); Good Clinical Practice Draft Guidelines: (R3) dated 19th May 2023
   - Medical Devices Rules, 2017
   - New Drugs and Clinical Trials 2019

5. **References (to other SOPs)**
   - SOP Ph1 A05: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product

Ph.1 SOP A05a: Preparation, review, and finalization of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

Version 1.2 dated 30th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

6. Detailed Instructions:

S. No	Task	Persons responsible
1.	Prepare and finalize English ICD as per SOP Ph1 A05	PI / Co-I / Study co-ordinator
2.	Get approval from sponsor / funding agency to share finalized English ICD with the translator(s) for getting vernacular translations and back translations	PI
3.	Identify appropriate translator(s) and get quotation(s) for ICD vernacular translations and back translations from the translator(s)	PI / Co-I / Study co-ordinator
4.	Ensure feasible turnover time for the vernacular translations and back translations	PI / Co-I / Study co-ordinator
5.	Ensure getting of valid certificates from the translator(s) for vernacular translations and back translations	PI / Co-I / Study co-ordinator
6.	Finalize the translator(s) for vernacular translations and back translations	PI / Co-I / Study co-ordinator
7.	Draft and sign a MoU with the translator(s) for translations, back translations and confidentiality	PI
8.	Share finalized English ICD with the translator	Co-I / Study co-ordinator
9.	Get vernacular translations and back translations from the translator(s) along with the related certificates in stipulated time frame	Co-I / Study co-ordinator

10.	Review and verify the translations and back translations for accuracy, culture appropriateness and regulatory compliance	PI / Co-I
11.	Ensure that the back translations are not direct copy of the original English ICD	PI/Co-I
12.	Verify validity of the translations and back translations certificate	PI/Co-I
13.	If required, ask translator(s) to make necessary changes in the translations and back translations	PI / Co-I / Study co-ordinator
14.	Ensure necessary changes are done in the revised versions of translations and back translations along with updating of related certificates	PI / Co-I / Study co-ordinator
15.	Finalize and approve the vernacular translations and back translations and related certificates for IEC submission	PI
16.	Complete the translator payment formalities	PI / Co-I / Study co-ordinator
17.	Maintain and organize all the vernacular translations and back translations versions along with comments and revisions in the Trial Master File (TMF) along with the English ICDs	Study co-ordinator

7. Abbreviations:

Co-I	Co-Investigator
ICD	Informed Consent Document
ICMR	Indian Council of Medical Research
ICH	International Council on Harmonization
IEC	Institutional Ethics Committee
MoU	Memorandum of Understanding
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File