	<p style="text-align: center;"><b>Tata Medical Center</b> <b>Institutional Review Board</b></p>	<p>Supersedes Document Dated : 10/01/2022 SOP : TMC-IRB - SOP-13 Version No.: V12.1 Effective Date : <del>18/01/2024</del> 03-10-2025</p>
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**TMC/ IRB/ SOP-4: Undertaking by the investigator (As per Schedule III, Table 4 of NDCT Rules, 2019)**

**Annexure 2 (Page 1/3)**

**Protocol Name:** A study to assess the effectiveness of a structured educational intervention on knowledge and attitude regarding menstrual hygiene among adolescent girls in a selected school of Howrah, West Bengal. Hospital, Kolkata .

**Protocol No.:**

**1. Full name of the Principal Investigator –** Sriparna Giri

**Address-** Tata Medical center ,14 MAR, Kolkata 700106

**Title of the Principal Investigator –** Proffessor cum ANS

**2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted:** Education, training & experience that qualify the Investigator for the clinical trial – Tata medical Center,14MAR (EW)Kolkata -700106 .

**3. Name and address of the Ethics Committee –** The instituton review board ,Tata Medical Center that is responsible for approval and continuing review of the study .

**4. Names of the other members of the research team (Co- or sub-Investigators) who will be assisting the Investigator in the conduct of the investigation(s) –** Nasima Khatun.

**5. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator –** A study to assess the effectiveness of a structured educational intervention on knowledge and attitude regarding menstrual hygiene among adolescent girls in a selected school of Howrah, West Bengal. Hospital, Kolkata .


**6. Commitments:**

- (i) I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
- (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/ favourable opinion from the Ethics Committee of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
- (iii) I agree to personally conduct and/or supervise the clinical trial at my site.
- (iv) I agree to inform all Subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the GCP guidelines are met.
- (v) I agree to report to the Sponsor all adverse experiences that occur in the course of the study in accordance with the regulatory and GCP guidelines.

Page 1 of 5

*This Document is Electronically Signed*

<p><b>Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick</b></p> <p style="text-align: center;">IRB Secretariat</p>	<p><b>Reviewed by: Prof Siddhartha Roy</b></p> <p style="text-align: center;">TMC-IRB Chairperson</p>	<p><b>Approved by: Dr Pattatheyil Arun</b></p> <p style="text-align: center;">Head of the Institution</p>
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### Annexure 2 (Page 2/3)

- (vi) I have read and understood the information in the Investigator's brochure, including the potential risks and side effects of the drug.
- (vii) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
- (viii) I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
- (ix) I agree to promptly report to the IRB/EC all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
- (x) I agree to inform all serious adverse events to the Sponsor as well as the IRB/EC within 24hrs of their occurrence.
- (xi) I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.
- (xii) I have/do not have any conflicts of Interest (COI) in the study i.e. Financial/Personal or others.
- (xiii) I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical

Investigators participating in clinical trials


8. Signature of the Investigator with Date

Name of the Investigator: Sriparna Giri

Signature of the Investigator: 

Date: 4.4.26

<b>Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick</b>	<b>Reviewed by: Prof Siddhartha Roy</b>	<b>Approved by: Dr Pattatheyl Arun</b>
IRB Secretariat	TMC-IRB Chairperson	Head of the Institution

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### **Annexure 2 (Page 3/3)**

I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.

I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the Sponsor, Ethics Committee, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.

I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.

I agree to inform all unexpected serious adverse events to the Sponsor, Licensing Authority as well as the Ethics Committee and copy to the Head of the Institution within one day of their occurrence.


I will maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials

I agree to declare conflict of interest, if any during the discussion and decision taking in the EC Meetings.

**Name of the Principal Investigator: Sriparna Giri**

<b>Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick</b>	<b>Reviewed by: Prof Siddhartha Roy</b>	<b>Approved by: Dr Pattatheyl Arun</b>
IRB Secretariat	TMC-IRB Chairperson	Head of the Institution

 <p><b>TATA MEDICAL CENTER</b></p>	<p align="center"><b>Tata Medical Center Institutional Review Board</b></p>	<p>Supersedes Document Dated : 10/01/2022 SOP : TMC-IRB - SOP-13 Version No.: V1Z.1 Effective Date : 18/01/2024 03-10-2025</p>
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Signature of the Principal Investigator: *Shipanna Gur*

Date: 4.4.26

Prepared by : Dr Tanuj Chawla/ Dr Indranil Mallick	Reviewed by: Prof Siddhartha Roy	Approved by: Dr Pattatheyil Arun
IRB Secretariat	TMC-IRB Chairperson	Head of the Institution