



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB – SOP-13
Version No.: V13.1 Effective
Date:
18.01.2024 03-10-25

Format of informed consent form for Subjects participating in a clinical trial

Protocol Title: '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.'

Study Number:

Subject's Initials:

Study Number:

Subject's Name:

Date of Birth / Age:

Nominee:

Informed Consent form to participate in a clinical trial Date:

Name of Legal Relation:

Relationship with Subject:

Signature:

Date:

Name of the Impartial Witness:

**Name of the person/Signature of the person administering consent Name
of Principal Investigator : Sriparna Giri**

Contact Details of Principal Investigator

- Email ID: sriparna.giri@tmckolkata.com
- Contact Number: +9051297990 / +918017947844
- Address: J-14,604. SP Shukhobristi. Newtown, Kolkata-700160

Institutional Review Board (IRB) - Tata Medical Center

- Phone Number: +91336605 7579/ 7629/ 8146
- Email-ID: irb@tmckolkata.com
- Address: 14 MAR, Kolkata-700160



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V13.1 Effective
Date:
~~18.01.2024~~ 03-10-2025

Child assent statement for Adolescent Girls [13 to 18] years (wherever applicable)

I have had the above research project explained to me in language that I can understand and I agree to participate.

Protocol Title:

Study Number:

Subject's Initials: Study

Number:

Subject's Name:

Date of Birth / Age: Date:

Signature of child:

Date:

Name of person obtaining Signature of person:

Date:

Name of Legal Relation:

Relationship with Subject:

Signature:

Date:

Name of the Impartial Witness:

Name of the person/Signature of the person administering consent Name
of Principal Investigator Sriparna Giri

Contact Details of Principal Investigator

- Email ID:
- Contact Number:
- Address

Institutional Review Board (IRB) - Tata Medical Center

- Phone Number • Email-ID:
- Address

Assent form for children: TMC studies

An Informed Assent Form doesn't replace a consent form signed by parents or guardians. The assent is in addition to the consent and signals the child's willing cooperation in the study.



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V12.1 Effective
Date:
18.01.2024 03-10-2025

For children between 13 and 19 years of age, oral assent must be obtained in the presence of parent/LAR. For children between 13 and 19 years of age, written assent must be obtained. If a child becomes 13 years old during the course of the study, then written assent must be obtained in addition to parent/LAR consent. If the child becomes an adult then proper written consent should be obtained.

PART 1. The type and amount of information given should be simplified as per the adolescent girl's cognitive and developmental level. The information should be simple, age-appropriate and in a language which is easy to understand for school girls. The basic information that needs to be provided includes:

1. What the study is about and how it might help?

A. "We want to learn about menstrual hygiene (period care) & see if this education helps girls like you improve their knowledge and attitude".

"This study will help you understand how to take care of yourself during periods and stay healthy."

2. What will happen and when?

A. "You will attend a short teaching session at your school. We will explain about menstrual hygiene using simple language, charts, or videos."

"You may also be asked to answer some questions before and after the teaching session."

3. What discomfort might there be and what will be done to minimize it?

A. "You may feel shy or uncomfortable while talking about periods, but we will make sure the environment is friendly and comfortable."

"You can skip any question you don't want to answer." What discomfort there might be and what will be done to minimize it? "

4. Who will answer, if I have any questions during the study?

A. If you have any questions, you can ask Researcher any time."

5. Whether an option to say "no" exists?

A. "You can say 'No' if you do not want to take part in the study."

"No one will be angry with you. Even if you say 'Yes' first, you can change your mind later."



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - 500-13
Version No.: V¹³12.1 Effective
Date:
~~18.01.2024~~ 03-10-2025

Information on the Educational Intervention :

What is this study and what should you know ?

- ❖ This study is a research project designed to evaluate how a structured educational intervention affects the knowledge and attitude of adolescent girls regarding menstrual hygiene.
- ❖ The study involves a "Pre-test" and "Post-test" design. This means we will compare your level of understanding before the teaching session with your level of understanding after the session to see how much you have learned.
- ❖ The intervention consists of a structured teaching program specifically developed for adolescent girls in Howrah. It uses visual aids and planned lessons to explain the biological process of menstruation and the best practices for hygiene and self-care.
- ❖ The known experience with this type of educational intervention is positive; it is a standard health promotion tool used to empower young women with accurate health information and to reduce social stigma.
- ❖ There are no physical risks or "side effects" associated with this study. The intervention is purely educational and does not involve any medication, invasive procedures, or physical examinations.

PART 2: Certificate of Assent: This section can be written in the first person. It should include a few brief statements about the research and be followed by a statement similar to the one identified as 'suggested wording' below. If the child is illiterate but gives oral assent, a witness must sign instead. A researcher or the person going over the informed assent with the child must sign all assents.

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.

I agree to take part in the research.

OR

I do not wish to take part in the research and I have not signed the assent below.

(Initialed By child/minor) _____ Only

if child assents:

Print name of child _____

Signature of child: _____

Date (DD/MM/YYYY): _____



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V¹³1.1 Effective
Date:
~~18-01-2024~~ 03-10-2025

Consent of Parent/LAR

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.
2. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.
3. Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.
4. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological wellbeing and school attendance, in addition to all components described in the participant information sheet.
5. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.
6. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.
7. Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

If illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____

Thumb print of participant _____



TATA MEDICAL CENTER

Tata Medical Center
Institutional Review Board

Supersedes Document Dated:

10/01/2022

SOP: TMC-IRB - SOP-13

Version No.: V12.1 Effective

Date:

~~18-01-2024~~ 03-10-2025

Signature of witness _____

Date (DD/MM/YYYY) _____



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the child understands that the following will be done:

- 1.
- 2.
- 3.

I confirm that the child was given an opportunity to ask questions about the study and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this assent form has been provided to the participant.

Name of Researcher/person taking the assent Nasima Khatun

Ph no :- 6295795987

Signature of Researcher /person taking the assent _____ Date

(DD/MM/YYYY) _____

Copy provided to the participant _____ (signed by researcher team member) Parent/Guardian
has signed an informed consent: ☐ Yes ☐ No



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V12.1 Effective
Date: 13.1
~~18-01-2024~~ 03-10-2025

Name of Principal Investigator: Sriparna Giri

Name of Co-Investigators: Nasima Khatun

Name of the Department: Nursing

Contact Details of Principal Investigator

- Email ID: sriparna.giri@tmckolkata.com
- Contact Number: +91 9051297990
- Address: Tata Medical Center, 14 MAR, Kolkata-700160

Institutional Review Board (IRB) - Tata Medical Center

- Phone Number : +91336605 7579/ 7629/ 8146
- Email-ID: irb@tmckolkata.com
- Address: Tata Medical Center, 14 MAR, Kolkata-700160



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB – ১০৮-১৩
Version No.: V13.1 Effective
Date:
18-01-2024 ০৩-১০-২০২৫

● অংশগ্রহণকারীদের জন্য অবগত সম্মতি পত্র

প্রোটোকল শিরোনাম:

হাওড়া জেলার একটি নির্বাচিত বিদ্যালয়ে কিশোরীদের মধ্যে ঋতুচক্র স্বাস্থ্যবিধি সম্পর্কে জ্ঞান ও মনোভাবের উপর একটি কাঠামোবদ্ধ শিক্ষামূলক হস্তক্ষেপের কার্যকারিতা মূল্যায়ন।

প্রধান গবেষক: শ্রীপর্ণা গিরি

ইমেইল: sriparna.giri@tmckolkata.com

যোগাযোগ নম্বর: +91 9051297990

সহ-গবেষকের নাম – নাসিমা খাতুন

ফোন নম্বর – ৬২৯৫৭৯৫৯৮৭

ইমেল আইডি – nasimakhatunkhatun93@gmail.com

- ❖ আমি বুঝতে পারছি যে আমাকে একটি গবেষণায় অংশগ্রহণ করতে বলা হয়েছে। এই গবেষণার উদ্দেশ্য হলো ঋতুচক্র স্বাস্থ্যবিধি সম্পর্কে কিশোরীদের জ্ঞান ও মনোভাব উন্নত করা।
- ❖ এই গবেষণায় অংশগ্রহণের সময় আমাকে একটি শিক্ষামূলক সেশনে অংশ নিতে হবে এবং কিছু প্রশ্নের উত্তর দিতে হতে পারে (সেশনের আগে ও পরে)।
- ❖ এই গবেষণায় কোনো শারীরিক ঝুঁকি নেই। তবে ঋতুচক্র নিয়ে আলোচনা করতে গিয়ে কিছুটা অস্বস্তি হতে পারে। আমি চাইলে যেকোনো প্রশ্ন এড়িয়ে যেতে পারি।
- ❖ আমার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছাসেবী এবং আমি যেকোনো সময় গবেষণা থেকে সরে যেতে পারি।
- ❖ আমার সমস্ত তথ্য গোপন রাখা হবে।
- ❖ আমি এই গবেষণায় অংশগ্রহণ করতে সম্মত।

স্বাক্ষর (অংশগ্রহণকারী):

তারিখ:

Version I Date 22/04/2025



TATA MEDICAL CENTER

Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V12.1 Effective
Date:
18-01-2024 03-10-2025

কিশোরীদের সম্মতি (১৩-১৮ বছর)

আমি সহজ ভাষায় গবেষণাটি বুঝেছি এবং এতে অংশগ্রহণ করতে সম্মত।

স্বাক্ষর: _____ তারিখ: _____

গবেষণার সহজ ব্যাখ্যা (শিশুদের জন্য)

এই গবেষণাটি কী সম্পর্কে?

- ✓ আমরা জানতে চাই খতুচক্র সম্পর্কে শিক্ষা কিভাবে তোমার জ্ঞান বাড়াতে সাহায্য করে।

কি করতে হবে?

- ✓ তোমাকে একটি ক্লাসে অংশ নিতে হবে এবং কিছু প্রশ্নের উত্তর দিতে হবে।

অস্বস্তি হতে পারে কি?

- ✓ কিছু প্রশ্নে লজ্জা লাগতে পারে, কিন্তু তুমি চাইলে উত্তর না-ও দিতে পারো।

প্রশ্ন থাকলে?

- ✓ তুমি যেকোনো সময় গবেষককে জিজ্ঞাসা করতে পারো।

না বলার অধিকার আছে?

- ✓ হ্যাঁ, তুমি চাইলে অংশগ্রহণ না-ও করতে পারো।

অভিভাবকের সম্মতি

আমি আমার সন্তানের গবেষণায় অংশগ্রহণের জন্য সম্মতি প্রদান করছি।

অভিভাবকের স্বাক্ষর: _____ তারিখ: _____

- সাক্ষীর ঘোষণা



Tata Medical Center
Institutional Review Board

Supersedes Document Dated:
10/01/2022
SOP: TMC-IRB - SOP-13
Version No.: V12.1 Effective
Date:
18.01.2024 03-10-2025

আমি নিশ্চিত করছি যে তথ্য সঠিকভাবে পড়ে শোনানো হয়েছে এবং সম্মতি স্বেচ্ছায় দেওয়া হয়েছে।

সাক্ষীর স্বাক্ষর: _____ তারিখ: _____

• গবেষকের ঘোষণা

আমি নিশ্চিত করছি যে অংশগ্রহণকারীকে গবেষণাটি স্পষ্টভাবে বোঝানো হয়েছে।

গবেষকের স্বাক্ষর: _____ তারিখ: _____

বিভাগ ক: জনসংখ্যাতাত্ত্বিক তথ্য (Demographic Variables)

নির্দেশনা: অনুগ্রহ করে সঠিক উত্তরের পাশে টিক (✓) চিহ্ন দিন।

১. বয়স: -

ক .১৩-১৫ বছর []

খ .১৬-১৭ বছর []

গ .১৮-১৯ বছর []

২. শ্রেণী:-

ক .সপ্তম []

খ .অষ্টম []

গ .নবম []

ঘ .দশম []

৩. প্রথম ঋতুস্রাবের বয়স:-

ক .১২ বছরের নিচে []

খ .১২-১৪ বছর []

গ . ১৪ বছরের উপরে []

৪. তথ্যের উৎস:-

ক .মা []

খ .বন্ধু-বান্ধব []

গ . শিক্ষক-শিক্ষিকা []

ঘ .মিডিয়া (টিভি/ইন্টারনেট) []

বিভাগ খ: জ্ঞান সংক্রান্ত প্রশ্নাবলী (Knowledge Questionnaire)

১. একটি স্বাভাবিক ঋতুচক্রের সময়কাল কত দিন?

ক) ১৫ দিন []

খ) ২৮-৩০ দিন []

গ) ৪৫ দিন []

২. ঋতুস্রাবের সময় স্বাস্থ্যকর শোষণক হিসেবে কোনটি ব্যবহার করা উচিত?

ক) পুরানো না কাচা কাপড় []

খ) স্যানিটারি প্যাড []

গ) খবরের কাগজ []

৩. সংক্রমণ রোধ করতে কতক্ষণ অন্তর স্যানিটারি প্যাড পরিবর্তন করা উচিত?

ক) দিনে একবার

খ) প্রতি ৪-৬ ঘণ্টা অন্তর []

গ) দুদিন অন্তর একবার []

৪. অপরিচ্ছন্ন ঋতুচর্চার ফলে প্রধানত কী হতে পারে?

ক) হজমের সমস্যা []

খ) প্রজননতন্ত্র ও মূত্রনালীর সংক্রমণ []

গ) চোখের সমস্যা []

বিভাগ গ: মনোভঙ্গি পরিমাপক স্কেল (Attitude Scale)

বিকল্পসমূহ: সম্পূর্ণ একমত (SA), একমত (A), নিরপেক্ষ (N), দ্বিমত (D), সম্পূর্ণ দ্বিমত (SD)

বিবৃতি	সম্পূর্ণ একমত (SA)	একমত (A)	নিরপেক্ষ (N)	দ্বিমত (D)	সম্পূর্ণ দ্বিমত (SD)
১. ঋতুস্রাব একটি স্বাভাবিক শারীরিক প্রক্রিয়া।					
২. ঋতুস্রাবের সময় মেয়েদের ধর্মীয় অনুষ্ঠানে যোগ দিতে দেওয়া উচিত।					
৩. ঋতুস্রাবের রক্ত "অশুচি" বা "নোংরা"।					
৪. ঋতুস্রাব নিয়ে খোলাখুলি আলোচনা করা লজ্জাজনক।					

Section A: Demographic Variables

Instructions: Please tick (✓) the most appropriate option.

1.Age: -

- 13–15 years []
- 16–17 years []
- 18–19 years []

2.Class:-

- Class VII []
- Class VIII []
- Class IX []
- Class X []

3.Age at Menarche: -

- Under 12 years []
- 12–14 years []
- Above 14 years []

4.Source of Information:

- Mother []
- Friends/Peers []
- Teachers []
- Media (TV/Internet) []

Section B: Structured Knowledge Questionnaire

1.What is the normal duration of a menstrual cycle?

- A) 15 days []
- B) 28–30 days []
- C) 45 days []

2. Which of the following is a hygienic absorbent during periods?

- A) Old unwashed cloth []

B) Sanitary pads []

C) Newspaper []

3. How often should a sanitary pad be changed to prevent infection?

A) Once a day []

B) Every 4–6 hours []

C) Once every two days []

4. Poor menstrual hygiene can primarily cause:

A) Digestive issues []

B) Reproductive and urinary tract infections []

C) Eye infections []

Section C: Attitude Scale (Likert Scale)

Response options: Strongly Agree (SA), Agree (A), Neutral (N), Disagree (D), Strongly Disagree (SD).

Parameter	Strongly Agree (SA)	Agree (A)	Neutral (N)	Disagree (D)	Strongly Disagree (SD)
1. Menstruation is a natural physiological process					
2. Menstruating girls should be allowed to attend religious events.					
3. Menstrual blood is "impure" or "dirty."					
4. Discussing menstruation openly is shameful.					