**Application Form (Full Board and Expedited Review)**

**SECTION A: Protocol and Contact Information**

**Protocol Title** : Data Analysis for a Digital Literacy Intervention to Improve Menstrual Hygiene Awareness in Bangladesh **Protocol Number:**

**PI Name and Degrees**: Dr. Swapneel Mehta, Ph.D. **Preferred Pronoun:** he/him

**PI Email Address**: swapneel@bu.edu **PI Phone Number: +1 551 328 7074**

**BU Mailing Address:**  N/A **PI Department: Questrom Business School**

**Additional Contact/Faculty Advisor:**  Prof. Marshall van Alstyne

**Contact Information:**  mva@bu.edu

**SECTION B: Funding**

☐ The research is unfunded

 The research is funded. Complete the table(s) below for each funding source:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Funding Source** | **Award Status** | **Grant / Award #** | **Period of Support** | **BU Award Status** | **Awardee Institution\*** | **Grant Title if different from Protocol title** |
| Goethe Institute | Confirmed | N/A | N/A | N/A | One Fact Foundation | Team AI4Good |
| enter text | Choose an item. | enter text | enter text | Choose an item. | enter text | enter text |
| enter text | Choose an item. | enter text | enter text | Choose an item. | enter text | enter text |

**☐** The research is funded by more than 3 sources**.** If yes, provide the above information for each funding source via email to [IRB@bu.edu](mailto:IRB@bu.edu).

**\*NOTES:**

* Provide a copy of the grant application, funding proposal, contract/agreement, scope of work, or sub-award agreement supporting the research. If an award is pending, once the funding has been awarded, submit an amendment to the IRB to add the funding source.
* If this research study is for your dissertation, provide a copy of your prospectus (if available).

**SECTION C: Conflict of Interest**

|  |  |
| --- | --- |
| Yes  **(REQUIRED)** | I confirm that **ALL** those responsible for the design, conduct, or reporting of the proposed research, including at minimum, all Senior/key personnel in the grant application, have completed financial conflict of interest disclosures and training as required by the [BU FCOI Office](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/) and as provided under [*the Boston University Investigator Conflicts of Interest Policy for Research*](https://www.bu.edu/researchsupport/forms-policies/investigator-financial-conflicts-of-interest-policy-for-research/)*.* |
| No ☐Yes | Have any Investigators or Study staff on the protocol disclosed a Financial Conflict of Interest related to the research? If yes, provide the name of the individual(s): enter text  *If yes, the IRB office will contact the FCOI office for more information.* |

**SECTION D: Type of Review**

For Guidance regarding Type of Review please refer to the [CRC IRB website](http://www.bu.edu/researchsupport/compliance/human-subjects/submitting-an-irb-protocol/)

1.  **FULL BOARD**

Please refer to the [CRC IRB website](http://www.bu.edu/researchsupport/compliance/human-subjects/dates-and-timing-of-the-irb-committee/) for Full Board submission deadlines and meeting dates.

1. ☐ **EXPEDITED**

To qualify for expedited review, the study must be no more than minimal risk (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) **AND** must fall into one of the categories below. Check all that apply:

☐ **1**. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **2**. Collection of blood samples by finger stick, heel-stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

☐ **3**. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisﬁguring manner, (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction, (c) permanent teeth if routine patient care indicates a need for extraction, (d) excreta and external secretions (including sweat), (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue, (f) placenta removed at delivery, (g) mniotic ﬂuid obtained at the time of rupture of the membrane prior to or during labor, (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques, (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, (j) sputum collected after saline mist nebulization.

☐ **4**. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and eﬀectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of signiﬁcant amounts of energy into the subject or an invasion of the subject’s privacy, (b) weighing or testing sensory acuity, (c) magnetic resonance imaging, (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood ﬂow, and echocardiography, (e) moderate exercise, muscular strength testing, body composition assessment, and ﬂexibility testing where appropriate given the age, weight, and health of the individual.

☐ **5.** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ **6.** Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ **7**. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Note: The IRB will make the final determination on the Type of Review**

**SECTION E: Study Staff and Training**

Instructions:

* List ALL current members of the research team in the table below.
* Add more rows as necessary.
* Student Research: The Faculty Advisor must be listed as a co-investigator in this section and must complete the Human Subjects training requirements. Faculty Advisors are responsible for reviewing the IRB application, agreeing to serve as the Co-PI for this study with the student and are responsible for the ethical conduct of this student’s human subjects research. Faculty Advisors must sign this Application prior to it being submitted to the IRB.

1. **CRC Investigators and Study Staff:**BUMC and other non-CRC personnel should be listed below in the Non-BU Investigator/study staff section

|  |  |  |
| --- | --- | --- |
| **Name, Degree & School** | **Study Role**  **(e.g. co-i, research coordinator, RA, etc.)** | **Human Subjects Training** |
| Swapneel Mehta, Ph.D., Boston University | PI | CITI: 21 Sept 2023  ☐ Other\*: enter name and date  ☐ GCP\*\*: enter date and provide copy |
| Marshall van Alstyne, Ph.D., Boston University | co-PI | CITI: 13 June 2023  ☐ Other\*: enter name and date  ☐ GCP\*\*: enter date and provide copy |
|  |  |  |

\*If CITI was not completed, a copy of the training record must be submitted.

\*\*For NIH-funded clinical trials, Good Clinical Practice (GCP) training is required.

For more information on training requirements, please refer to the CRC [Human Subjects Training Policy](https://www.bu.edu/researchsupport/compliance/human-subjects/human-subjects-training/).

1. **Non-CRC Investigators and Study Staff**   **N/A**

Instructions:

* BUMC and BMC staff are considered non-BU staff and should be listed in this section.
* Add more rows as necessary.
* All the columns in the box below must be completed.
* You must complete the box that follows with a description of the activities for each staff member.
* If IRB approval will be obtained from a non-BU site, only list the lead investigator from that site.

|  |  |  |
| --- | --- | --- |
| **Name, Degree, Institution** | **Study Role**  **(e.g. co-i, research coordinator, RA, etc.)** | **Staff Information** |
|  |  | ☐This staff will interact with subjects  ☐This staff will have access to subject identifiers  ☐The research is related to the staff role at their home institution. |
|  |  | ☐This staff will interact with subjects  ☐This staff will have access to subject identifiers  ☐The research is related to the staff role at their home institution. |

**2a. Include a summary of research activities to be conducted by each non-BU staff person listed above.**

Advisory role for research design and data analysis for drawing causal inferences.

**2b.** **If IRB approval will not be conducted at the home institution of the non-BU study staff, provide the rationale** (e.g. external institution not engaged in research, reliance agreement with BU, etc.):

enter text

**SECTION F: Location of the Research**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **YES** | **NO** | |  | | |
| ☐ |  | | Will this research take place at Boston University?  Provide the location (e.g. building and room number): | | |
|  | ☐ | | Will this research take place outside of Boston University?  If yes, please complete the below table: | | |
| **Institution Name and Address (if known)** | | | | **Site Activities**  **(e.g. recruitment, consent, data analysis, study interventions, etc.)** | **Describe Site IRB/Ethics Approval/Permission** |
|  | | | |  |  |
|  | | | |  |  |
| **YES\*** | **NO** |  | | | |
|  | ☐ | Is the off-site location requesting the CRC IRB review the protocol in place of local IRB review? If **YES**, complete the [Single IRB Review Form.](http://www.bu.edu/researchsupport/forms-policies/single-irb-request/) | | | |
|  | ☐ | Will this research be conducted outside of the United States?  If **YES**, complete the [International Research Form](http://www.bu.edu/researchsupport/forms-policies/appendices-a-international/). | | | |
|  | ☐ | Is the CRC PI the lead investigator **OR** is BU the lead site for this research?  If yes, complete the below information. | | | |
| Provide the following information in the box below:   * The plan for collection and management of data from all the sites * The plan for evaluating and reporting: * Unanticipated problems * Serious and/or continuing non-compliance * Suspensions and terminations of research * Interim results * Protocol modifications * The name of the Principal Investigator from each site * If IRB approval will be obtained at the site, confirmation that you have a copy (or will obtain a copy) of the IRB approval letters and the IRB-approved protocols from each site * If IRB approval will be obtained at the site, confirmation that the site IRB has a FederalWide assurance (FWA) | | | | | |
| **Data will be collected by the nonprofit conducting the study, called WaterAid, and remotely provided to BU researchers through an encrypted, role-based accessible environment. The project’s primary goal is to evaluate conversational datasets for evidence of the success of the intervention. BU researchers will only access this data and backend infrastructure of this chatbot to conduct data analysis collected through the chatbot and feedback forms. This may be supplemented by data collected by WaterAid Bangladesh regarding the regional uptake of menstrual health and hygiene products WaterAid is delivering on-ground support and launching this research study. They have volunteers who run the program in person and will be in regular communication with us to share the experimental details. We will analyze the data they collect for a scientifically rigorous evaluation of the utility and impact of chatbots on local awareness efforts for menstrual hygiene.** | | | | | |

**SECTION G: Study Summary**

|  |
| --- |
| **Summarize the study in lay language (do not copy from the grant/scope of work/proposal, etc.). This summary should include the research design, purpose, objectives, research question, hypothesis, and any relevant background information.**  Do not include a list of citations in this section. Please limit this section to no more than 300 words. |
| **WaterAid Bangladesh runs the experiment and BU helps with data analysis. Up to 100 young schoolgirls and women in Bangladeshi schools will be offered access to a chatbot that delivers accurate information over WhatsApp based on retrieval augmented generation i.e. answering questions over a fixed set of documents that includes materials which WaterAid Bangladesh uses to run physical camps and delivers through information packets. They digitize this physical intervention through a chatbot and we help evaluate its utility to improve awareness of menstrual hygiene management practices in their target community.** |

**SECTION H: Research Methods and Activities**

Check all that apply:

|  |  |
| --- | --- |
| ☐ | Collection of audio, video, digital, or image recordings |
| ☐ | Biological samples → [Complete Biological Samples Form](http://www.bu.edu/researchsupport/forms-policies/appendices-d-samples/)  Examples: blood, hair, cheek swab, urine, tears, saliva, etc. |
| ☐ | Collection of data that may be sensitive and if disclosed could put subjects at risk for legal or social harms. (e.g. Illegal behaviors, HIV status, psychiatric illness, information related to sexual behaviors, etc. |
|  | Coordinating Center/Lead Site |
| ☐ | Deception |
| ☐ | Devices → [Complete Devices Form](http://www.bu.edu/researchsupport/forms-policies/appendices-c-device/) |
| ☐ | Drugs → [Complete Drugs Form](http://www.bu.edu/researchsupport/forms-policies/appendices-b-drugs/) |
| ☐ | Ethnographic: The study of people in their own environment through the use of methods such as participant observation and face-to-face interviewing |
| ☐ | Focus Groups |
| ☐ | Genetics Testing → [Complete Genetics Form](http://www.bu.edu/researchsupport/forms-policies/appendices-e-genetics/) |
| ☐ | MRI → [Complete MRI Form](http://www.bu.edu/researchsupport/forms-policies/appendices-f-mri/) |
| ☐ | Placebo |
| ☐ | Pregnancy Testing |
| ☐ | Randomization |
| ☐ | Surveys, interviews, questionnaires |
|  | Secondary Data Analysis |
| ☐ | Other (please describe): |

**SECTION I: Participant Population**

|  |  |
| --- | --- |
| **Provide the Number of Participants to be Enrolled. If you have sub-groups or more than one arm, please separate out these enrollment numbers.** **Note:** Please account for participants who may drop out or be withdrawn from the study. Anyone who signs a consent form is considered to be enrolled in the research regardless of whether they complete any study procedures. | |
|  | |
| **Check all categories that apply to your participant population:** | |
|  | Adults |
|  | Children (< 18 years of age) |
| ☐ | Adults with Limited Decision-Making Capacity |
|  | Non-English Speaking |
| ☐ | Prisoners |
| ☐ | BU Employees |
| ☐ | BU Students |
| ☐ | Wards of the state |
| ☐ | Other (please describe): |
| **If a population other than ‘Adults’ has been checked, describe the additional safeguards that have or will be put in place to protect those individuals, and provide the rationale for including this population in the research study.** | |
| **A significant proportion of young and adolescent girls in Bangladesh lack access to accurate menstrual hygiene management information which results in negative health and psychological outcomes at the onset of menarche. The intervention aims to improve literacy among young girls who do not have access to this kind of information but would benefit from it, through a digital chatbot within a familiar messaging application.** | |
| **Eligibility Criteria** | |
| Inclusion Criteria: Females under the age of 10 | |
| Exclusion Criteria (criteria which would disqualify an individual from participating in the study not simply the opposite of the inclusion criteria): Females above the age of 35 | |

**SECTION J: Recruitment**

|  |
| --- |
| **Provide a summary of the recruitment process, including who will recruit, when and where recruitment will occur, and how subjects will be identified.**  **Submit all recruitment materials (e.g. advertisements, brochures, flyers, letters/e-mails, scripts, etc.) as separate documents in either Word or PDF format.** |
| Recruitment |

**SECTION K: Consent and Assent**

Please refer to the [consent](https://www.bu.edu/researchsupport/files/2021/10/CRC_Informed-Consent-Template_REV-9.2021.docx) and [assent](http://www.bu.edu/researchsupport/files/2016/08/Assent-Form-Template-March-20132.docx) form templates on the [IRB website](https://www.bu.edu/rehttps:/www.bu.edu/researchsupport/compliance/human-subjects/searchsupport/compliance/human-subjects/) when creating your materials. The templates include the required elements of consent/assent and will help to ensure that your materials meet federal regulations, IRB policies and best practices.

|  |
| --- |
| **Provide a summary of the consent process, including who will consent participants, when and where consent will occur. The summary should include, as appropriate, any waiting period between informing the prospective participant about the research and obtaining consent, such that the prospective participant or the legally authorized representative has sufficient opportunity to consider whether to participate, and steps taken to minimize coercion or undue influence.**  **Submit copies of all consent forms and scripts; materials should be submitted as separate documents in Word format.** |
|  |

**Indicate the consent and/or assent process and document(s) to be used in this study.**

Check all that apply:

|  |  |
| --- | --- |
| **Consent: Adults (>18 years old); One of the following MUST apply N/A ☐** | |
|  | Consent Form/Information Sheet |
| ☐ | Verbal Consent (Script)  **Note:** If written consent will not be obtained, complete the ‘Waiver of Written Documentation Consent’ box (Box 1) located further down in this section |
| ☐ | Consent will not be obtained  **Note**: If consent will not be obtained, complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section |
| **Assent of Children (< 18 years old): One of the following MUST apply N/A ☐** | |
|  | Assent Form or Parental Consent Form/Information Sheet (for older children who may sign with their parents using an age-appropriate form) |
| ☐ | Verbal Assent (Script) |
| ☐ | Assent will not be obtained;one of the following conditions must exist:  ☐ 1. The capability of some or all of the children is so limited that they cannot reasonably be consulted;  ☐ 2.The children are too young to provide assent;  ☐ 3.The intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research;  ☐ 4. The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at [45 CFR 46.116(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html)\*. Complete the ‘Waiver or Alteration of Consent’ box (Box 2) located further down in this section. |
| **Parental Permission: One of the following MUST apply N/A ☐** | |
|  | Parental Consent Form |
| ☐ | Parental Verbal Consent (Script)  If written consent will not be obtained, complete the ‘Waiver of Written Documentation of Consent’, Box 1, located further down in this section. |
| ☐ | Parental permission will not be obtained; one of the following conditions must exist:  ☐ 1. The research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children).  ☐ 2. The research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at [45 CFR 46.116(d](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html))\*. *Note:* Complete the ‘Waiver or Alteration of Consent’, Box 2, located further down in this section. |
| **Consent of Legally Authorized Representatives N/A** | |
| Describe the consent and/or assent process for enrolling legally authorized representatives and the assent process of those they represent (e.g. adults with limited decisional capacity to consent to research): | |
| Assent will be obtained from:  All Subjects  ☐ Some participants, specify:  ☐ No participants. If no participants will assent, provide a rationale: | |
| List who will serve as LAR: | |

|  |
| --- |
| **Consent of Non-English Speaking Subjects N/A** ☐ |
| Describe the process for obtaining consent from non-English speaking subjects (a copy of the translated consent along with the [Attestation Form for Translation of Consent](https://www.bu.edu/researchsupport/compliance/human-subjects/#supplemental-forms) must be submitted). |
| List who will serve as the interpreter and their qualifications: **WaterAid Bangladesh Staff** |

|  |  |  |
| --- | --- | --- |
| **Box 1 - Waiver of Written Documentation of Consent N/A**  **Criteria 1 or 2 must be met to qualify.** | | |
|  | **Yes** | **No** |
| ☐ **Criteria 1** | | |
| The research is **NOT** FDA Regulated | ☐ | ☐ |
| The only record linking the subject and the research would be the consent document | ☐ | ☐ |
| The principal risk would be potential harm resulting from a breach of confidentiality | ☐ | ☐ |
| Each subject will be asked whether the subject wants documentation linking the subject to the research and the subject’s wishes will govern | ☐ | ☐ |
| A written statement/information sheet will be provided to subjects. **If NO**, provide rationale for not providing this information: | ☐ | ☐ |
| ☐ **Criteria 2** | | |
| The research is **NOT** FDA Regulated | ☐ | ☐ |
| The research presents no more than minimal risk of harm to subjects | ☐ | ☐ |
| The research involves no procedures for which written consent is normally required outside of the research context | ☐ | ☐ |
| A written statement/information sheet will be provided to subjects. If **NO**, provide rationale for not providing this information: | ☐ | ☐ |
| ☐ **Criteria 3** | | |
| The research is **NOT** FDA Regulated | ☐ | ☐ |
| The research presents no more than minimal risk of harm to subjects | ☐ | ☐ |
| The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm | ☐ | ☐ |
| There is an appropriate mechanism for documenting that informed consent was obtained | ☐ | ☐ |
| A written statement/information sheet will be provided to subjects.  If **NO**, provide rationale for not providing this information: | ☐ | ☐ |

|  |  |  |
| --- | --- | --- |
| **Box 2 – Waiver of Alteration of Consent N/A** | | |
| **The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent provided the IRB finds and documents ALL of the criteria listed below:** | | |
|  | **Yes** | **No** |
| The research is **NOT** FDA Regulated | ☐ | ☐ |
| The research involves no more than minimal risk to the subjects; |  |  |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects; | ☐ | ☐ |
| The research could not practicably be carried out without the waiver or alteration; | ☐ | ☐ |
| If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; | ☐ | ☐ |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information: | ☐ | ☐ |
| **Provide the justification/rationale for why this study meets the above criteria for waiving or altering consent (REQUIRED):** | | |

|  |  |  |
| --- | --- | --- |
| **FDA Regulated Research N/A** | | |
| **The IRB may waive or alter informed consent requirements for certain minimal risk clinical investigations when the IRB finds and documents ALL of the criteria listed below.** | | |
| |  |  |  | | --- | --- | --- | |  | **Yes** | **No** | | | |
| The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects; | ☐ | ☐ |
| The waiver or alteration will not adversely affect the rights and welfare of the subjects; | ☐ | ☐ |
| The clinical investigation could not practicably be carried out without the waiver or alteration | ☐ | ☐ |
| Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **If NO**, provide rationale for not providing this information: | ☐ | ☐ |
| **Additional Comments:** | | |

**SECTION L: Study Procedures**

|  |
| --- |
| **In the box below provide a detailed description of the study procedures to be performed (preferably in sequential order). Be sure to specify which procedures are for research purposes and which procedures are part of standard of care, if applicable. Be sure to include the following information:**   * **Methods of data collection** * **Details regarding research activities/procedures/interventions** * **Number, frequency, duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)** * **Time required from each subject** * **Use of equipment (eye-tracker, treadmill, sensors, etc.). Provide a brief description of equipment that will be used in the study.\***     \*Note: The IRB may request more information about the equipment (including equipment manuals) and/or request that you submit [Appendix C: Device Form](https://www.bu.edu/researchsupport/compliance/human-subjects/#supplemental-forms).  Submit copies of all surveys, interview questions, assessments, screening scripts, etc. that will be used during the conduct of this study; materials should be submitted as separate documents in either Word or PDF format. |
| 1. **We are supporting WaterAid Bangladesh who has staff to conduct in-person activities and take on in-person logistics.** 2. **In-person workshop hosted at two school sites in Dhaka, Bangladesh, and Shyamnagar, Bangladesh.** 3. **Students that provide consent to be study subjects are introduced to the WhatsApp chatbot and a pre-treatment survey is conducted through a questionnaire.**    1. **Where applicable, we request the completion of parental consent forms.** 4. **Students chat with the Sakhi chatbot on WhatsApp on their own time, whenever convenient.** 5. **Over the next 6 weeks we monitor conversations with Sakhi and track what students are sharing with the chatbot.**    1. **For each conversation they are asked to rate their satisfaction with the system.** 6. **In conclusion, we ask subject to fill out a post-experimental survey and questionnaire to measure the effects of the chatbot.** |

**SECTION M: Risks**

|  |
| --- |
| **Describe any expected risks to subjects. Consider physical, psychological, social, political, legal, economic, or other risks that are related to the study.** |
| 1. **Psychological risks: Subjects can start sharing sensitive information with the chatbot.** 2. **Medical risks: Subjects can be exposed to information beyond the domain of expertise of the chatbot.** 3. **User volume: Too many users can overwhelm the chatbot and data may be lost.** |
| **Describe the plan to minimize risks. Include in the description the availability of any medical or psychological resources.** |
| 1. **Place rate limits on usage per day** 2. **Onboard users through a unique, personal passcode provided to them to utilise the application** 3. **Limit the scope of the chatbot to only answer menstrual hygiene management questions and state explicitly if it cannot find any facts in its database about a question to mitigate hallucinations.** 4. **Reliability testing of the chatbot and monitoring of incoming queries by human-in-the-loop systems.** |

**SECTION N: Benefits**

|  |
| --- |
| **Describe the potential benefits to subjects related to the study. State if there are no direct benefits. NOTE:** Compensation and/or course credit are not considered benefits. |
| **Improvement in menstrual hygiene management practices, improvement in public health outcomes at individual and community levels. Increased awareness to health issues and reduced social stigma against menstruation.** |
| **Describe the potential benefits to society and/or others related to the study.** |
| **This project will analyse data collected by a nonprofit organization in Bangladesh. It will evaluate the efficiency of digital interventions in multilingual contexts for a small number of people (100) in low-resource regions resulting in significant practical benefit and driving societal change towards AI-amplified literacy interventions.**  **Over the duration of the proposed project implementation, we expect to produce software code, educational materials, technical reports and protocols, scientific peer-reviewed publications, and ancillary media and documentation, which will be published online through our project website (**[**https://simppl.org/**](https://simppl.org/)**) or GitHub. Specifically:**   * **Patient outcomes, location, and medical information with privacy protections and anonymization;** * **Interoperable platform, concluding with a user portal;** * **Educational materials and open-source ecosystem growth and community-building assessment evaluations;** * **Quality Control / Quality Assurance data relying on the appropriate AI/ML protocol for security and privacy.** |

**SECTION O: Costs and Payments**

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Are there any costs to subjects as a result of participating in this study?  **If YES**, provide a description of the costs: | ☐ |  |
| Will subjects be compensated for participating in the study? Compensation may include cash, checks, gift cards, lotteries, course credit, etc. Payments should be prorated to compensate subjects for time and procedures completed  **If YES**, provide a description of the compensation: | ☐ |  |
| Will identifiable information be sent to Accounts Payable, Post Award Financial Operations, etc. for payment purposes? **If YES**, this information must be disclosed in the consent form. | ☐ |  |

**SECTION P: Confidentiality of Data**

For guidance on securing computers, please review the [InfoSec Safe Computing webpage](https://www.bumc.bu.edu/it/infosec/safe-computing/).

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Yes** | **No** |
| Are you using BU-managed computers? | | ☐ | ☐ |
| Are you using any non-BU managed computers (e.g. personal computer)?  If yes, confirm that the non-BU managed computer(s) have the following: | |  | ☐ |
| * A current and supported Operating System | |  | ☐ |
| * Malware Protection (e.g. Microsoft Defender, BU Crowdstrike – no cost) | |  | ☐ |
| * Encryption enabled (i.e. turned on) | |  | ☐ |
| * Automatic screen lock to password/code at 15 minutes or less | |  | ☐ |
|  | **Describe how data will be stored (e.g. paper, electronic database, etc.)** | | |
|  |  | | |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
|  | ☐ | Will you collect identifiable information? (e.g. names, social security numbers, addresses, email addresses, telephone numbers, photo/video/voice etc.). **If YES**, complete the box below. |
| **Describe the coding system that will be used to protect the information including who will have access to the code.** Coding systems are used to: 1) protect the confidentiality of the research data and 2) allow the investigator to link subjects to their responses. Each subject is assigned a unique study ID at the beginning of the study. A separate document (key) should be maintained that links the names of the subjects to the study ID numbers. | | |
| **The raw data will be received by PI Swapneel Mehta, who will conduct the aggregate statistical analysis that is shared with other members of the team and the WaterAid staff in a privacy-preserving manner. Raw data will only be accessed by the PI and NLP systems will be set up in such a way as to remove all named entities and personally identifiable information at the source.** | | |
| **YES** | **NO** |  |
|  | ☐ | Will you share data with others outside of the study? **If YES**, complete the box below. |
| **Describe how data will be transferred and how confidentiality will be maintained (e.g. identifying information will not be sent outside, etc.):** | | |
| **Before it is shared, all user data is anonymized and maintained in password-protected servers that require multi-factor authentication to access. Personally identifiable information will be removed at the source and replaced with a randomized unique identifier to prevent reverse engineering of patient information should the data be otherwise accessed. Data transfers will remain internal to the secured cloud environment.** | | |

|  |
| --- |
| **Describe how you will maintain the confidentiality of the data (e.g. locked cabinet, password-protected files, encryption, etc.). Note:** Confidentiality refers to the researcher’s agreement with the participant about how the subject’s identifiable private information will be handled, managed, and disseminated. |
| **Offline archival storage will include geo-distributed cloud-based and hard drive backups. We will devote at least 1TB to archive data produced by our research. Plans to transfer digitized information to new storage media or devices will be developed and deployed as technological standards or practices change.** |

Under the [BU Data Classification Policy](http://www.bu.edu/policies/data-classification-policy/), human subject data that is both health-related\* and personally identifiable (e.g., email address, phone number, picture or video recording of face) is classified as Restricted Use, while personally identifiable human subject data that is not health-related is classified as Confidential. Additionally, when direct identifiers are removed from personally identifiable human subject health data (i.e., identifiers are limited to dates, city, and Zip Code) the data is classified as Confidential. \*Health-related information is very broad, including stress or anxiety related to school, but does not typically include social engagement, decision making, number of texts sent per day, or educational practices, strategies, or effectiveness.

|  |
| --- |
| **Please identify where you will store Restricted Use data: for example, in BU REDCap; on a BU Restricted Use network drive; on a BU managed computer or server; on paper in a locked cabinet/office, or other services cleared for Restricted Use data by** [BU Information Security](https://www.bu.edu/tech/support/information-security/). |
| **Restricted use data will be stored in an air-gapped device that is not connected to the public internet for data analysis.** |
| **Please identify where you will store Confidential data: for example, using a non-BU, third-party app but with anonymous accounts setup by research project; BU network drive; IS&T/Research Computing, Shared Computing Cluster 4 (SCC4); BU managed computer; or other services cleared for Confidential data by** [BU Information Security](https://www.bu.edu/tech/support/information-security/). |
| **This data will be stored on an encrypted hard drive on a password-protected cloud server in accordance with standard security practices for confidential datasets. We also adhere to robust data encryption protocols to safeguard the confidentiality of both fact-checking data and user interactions. Our team is committed to compliance with relevant data protection regulations, ensuring that user privacy is maintained throughout the conversational process and usage of the chatbot in general.** |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| ☐ |  | **Will subjects setup accounts (e.g., personal email address) for a non-BU, third-party app that is not listed on the** [BU Information Securit**y**](https://www.bu.edu/tech/support/information-security/) **website?**  Note: BU Information Security needs to complete a security review before the research protocol is approved. Send an email to [buinfosec@bu.edu](mailto:buinfosec@bu.edu) with the name of the vendor/app and an email address of someone at the vendor/app who can answer security questions. |
| **If YES**, please list the name(s) of the non-BU, third party apps: | | |

**SECTION Q: Certificate of Confidentiality**

|  |
| --- |
| In 2017 the NIH updated its policy for issuing [**Certificates of Confidentiality**.](https://grants.nih.gov/policy/humansubjects/coc.htm#:~:text=Certificates%20of%20Confidentiality%20(Certificate%20or,a%20few%20other%20specific%20situations.)Under the policy, all **eligible** research studies funded by the NIH are automatically issued a certificate of confidentiality. Investigators whose research is not funded or supported by the NIH may request and obtain from the NIH a Certificate of Confidentiality. Investigators who request and receive Certificates must follow the NIH and PHS policies governing such certifications. |

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** |  |
| ☐ |  | Is your research funded by the NIH and eligible for a Certificate of Confidentiality? |
| ☐ |  | If your research is not funded by the NIH, will you be applying for a Certificate of Confidentiality? |

**SECTION R: Privacy**

|  |
| --- |
| **Describe how you will protect the privacy of subjects (e.g. where will consent procedures take place, if interviews or other interventions, where will these procedures take place)** |
| The experiment is conducted by WaterAid in Bangladesh on-site before we receive access to the data.  **(1) Privacy and Anonymity: Users will have the default option to interact with the chatbot anonymously, without revealing personally identifiable information unless they voluntarily share information to receive physical resources from WaterAid. (2) User Safety: We will implement features to mitigate harmful content and interactions. This will include filters to limit or censor abusive language and hateful speech.** |

**SECTION S: Monitoring Study Data**

|  |  |
| --- | --- |
| **Indicate how data will be monitored.**  The Data and Safety Monitoring Plan should be tailored to the nature, size, and complexity of the research protocol, the expected risks of the research, and the type of subject population being studied. | |
|  | Principal Investigator |
|  | Monitor/Monitoring Group |
| ☐ | Data and Safety Monitoring Board (DSMB)  The DSMB Charter must be submitted with this Application. For more information regarding a DSMB, please refer to the [NIH website](https://www.nidcr.nih.gov/research/human-subjects-research/interventional-studies/data-and-safety-monitoring-board-guidelines). |

|  |
| --- |
| **Describe the plan for monitoring study data. This should include a description of how data will be collected and analyzed as the project progresses to assure the appropriateness of the research, its design, and subject protections.** |
| 1. **Informed Consent: There will be no data shared with third parties. Since our chatbot may collect personal data like name and location through surveys for adults, in order to cater to WaterAid product offerings to the most under-resourced areas. We will ensure that users are provided with informed consent prompts in their local languages to opt into data sharing. We will clearly explain what data is being collected, how it will be used by WaterAid and BU, and designated data anonymization mechanisms to eliminate any risks associated with data leakage.** 2. **Fairness and Transparency: We will regularly audit and adjust the chatbot's responses to ensure fairness and inclusivity using an appropriate combination of guardrails through prompt tuning, soft-prompting, and instruction tuning.** |

**SECTION T: Health Insurance Portability and Accountability Act/HIPAA**

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
| ☐ |  | Is this research being conducted in a covered entity?  The following BU CRC Departments are considered covered entities:   * Sargent College Rehabilitation Services   + Physical Therapy Center at the Ryan Center for Sports Medicine and Rehabilitation   + Sargent Choice Nutrition Center * The Danielsen Institute * Boston University Health Plan   \*If YES, contact the IRB office for assistance. |

**SECTION U: Family Educational Rights and Privacy Act (FERPA)**

FERPA is the federal law that protects the privacy of student education records. Research funded by the Department of Education or research conducted in educational institutions that receive funds from the Department of Education (for research or other purposes) must comply with FERPA.

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
| ☐ |  | Does this study involve collection of information from student school/university records? \*If YES, refer to the following websites for guidance on FERPA:   * <http://www.bu.edu/reg/general-information/ferpa/> * <http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>   **If FERPA applies, you must complete the box below:** |
| In accordance with FERPA, written consent must be obtained to access student records. The consent must: specify the records that may be disclosed, state the purpose of the disclosure and  identify the person or class of parties to whom the disclosure can be made. | | |
| ☐YES  **(REQUIRED)** | | I confirm that I will comply with the FERPA policy that is in place at the educational institution where I am conducting my research. This includes, if applicable, the requirements for written agreement when requesting a waiver of consent for personally identifiable information. **If an agreement is required, this agreement must be submitted to the IRB.** |

**SECTION V: Protection of Pupil Rights Amendment (PPRA):**

PPRA is a federal law that affords certain rights to parents of minor students regarding surveys that ask questions of a personal nature. Research funded by the Department of Education or research conducted in educational institutions that receive funds (for research or other purposes) from the Department of Education must comply with the PPRA.

|  |  |  |
| --- | --- | --- |
| **YES\*** | **NO** |  |
| ☐ |  | Does PPRA apply to this study? If YES, refer to the following website for guidance: <https://studentprivacy.ed.gov/resources/protection-pupil-rights-amendment-ppra-general-guidance>  **If PPRA applies, you must complete the box below:** |
| In accordance with PPRA, written parental consent must be obtained prior to subject’s participation in the study. | | |
| ☐YES  **(REQUIRED)** | | I confirm that I will comply with the PPRA policy that is in place at the educational institution where I am conducting my research. |

**Section W: Clinical Trial Registration**

The Food Drug and Administration Amendments Act (known as FDAAA 801) requires that “applicable clinical trials” be registered and have results reported on clinicaltrials.gov. In addition, the International Committee of Medical Journal Editors (ICJME) and the National Institutes of Health (NIH) also have requirements for registration. Please see box below to determine if your study requires registration in accordance with either FDAAA 801, ICJME, or NIH.

|  |  |  |
| --- | --- | --- |
| **YES** | **NO** | **FDAAA 801 Requirements** |
| ☐ |  | Does your study meet the definition of an applicable clinical trial (ACT) and require registration **AND** results submission in accordance with FDAAA 801?  ACTs include:   * Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation * Trials of devices [(see note)](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#footnote3): 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) [pediatric post-market surveillance](https://clinicaltrials.gov/ct2/manage-recs/fdaaa#PedPostmarket) required by FDA   **Note:** If your study meets the [requirement](https://clinicaltrials.gov/ct2/manage-recs/fdaaa) for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval**.** NCT #: |
| **YES** | **NO** | **ICMJE Requirements** |
| ☐ |  | Does your study meet the definition of a clinical trial and require registration in accordance with [ICMJE](http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/)?  **Note:** If your study meets the requirement for registration, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.  NCT #: |
| **YES** | **NO** | **NIH Requirements** |
| ☐ |  | Does your study meet the definition of an applicable clinical trial and require registration **AND** results submission in accordance with NIH?  For more information on this policy please refer to:   * [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22379.pdf) * [Checklist](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf) for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial   **Note:** If your study meets the requirement for registration and reporting, you must submit the National Clinical Trial (NCT) Identifier # to the IRB prior to IRB approval.NCT #: |

**Certification / Signatures**

* By submitting this protocol I attest to the fact that all research activities to be implemented related to human subjects have been completely and accurately described herein.
* I agree to conduct the describe research in an ethical manner.
* I agree to comply with all institutional policies and procedures related to human subjects research and will not begin any human subjects research activities until I have obtained full approval from the IRB.
* I agree to conduct the research as described in this protocol and not to make any changes (except to eliminate immediate harm to subjects) without first obtaining approval for the changes from the IRB.
* I agree to immediately report any unanticipated problems involving risks to subjects or others, any subject complaints, and any incidents of non-compliance with the requirements of this protocol as soon as I become aware of them.
* I agree to comply with any relevant HIPAA and FERPA regulations if applicable.
* I verify that allthose responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, have completed the financial conflict of interest disclosures and completed training as required by University [Policy](https://www.bu.edu/researchsupport/compliance/conflicts-of-interest/).

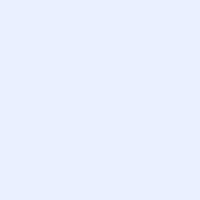
Principal Investigator Signature: Swapneel Mehta Date: December 21, 2023

**FACULTY Research:**

**The Department Chair signature is required:** This application must be signed by the Department Chair for all faculty researchers. If the PI is the Department Chair, then signature by the appropriate Dean is required. Department Chair signature is not required for student research.

By signing this form you are indicating that you have reviewed the application, the faculty/staff person listed as PI on this protocol is a member of your department, that they are qualified to serve as the PI for this study, that they have the adequate resources, and the research utilizes acceptable practice for the discipline**.**

Department Chair Printed Name: enter text

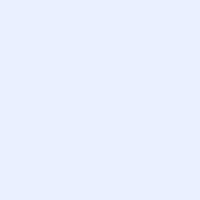
Department Chair Signature:  Date:

**STUDENT Research**

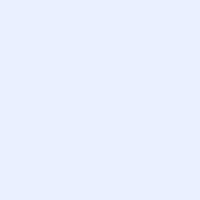
**Student research:** Student research must be signed by the faculty advisor AND the designated School IRB pre-reviewer (if applicable) PRIOR TO submission to the IRB. Students should check with their School to determine if School IRB pre-review is required. Students must submit a copy of their dissertation with the IRB Application

By signing this form, you are indicating that you have reviewed the application, that you agree to serve as the Co-PI for this study with the student and that you will be responsible for the ethical conduct of this student’s human subjects research.

Faculty Advisor Printed Name: Marshall Van Alstyne

Faculty Advisor Signature:  Date: 26 Dec 2023

School Review Name, if applicable: enter text

School Reviewer Signature:  Date:

**Submission:** Electronic signatures are acceptable, as are emails confirming the certification information. This form can be completed, signed, scanned and submitted to the IRB at [irb@bu.edu](mailto:irb@bu.edu). Faxed documents and handwritten materials are not accepted. Be sure to include all relevant attachments.