Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state

This document describes the procedures and processes that have been taken or will be taken to ensure ethical conduct of research in the above named project.

Ethical Protocol

The research protocol was submitted to the Health Research Ethics Committee of University of Nigeria Teaching Hospital and the Ethics Committee of Ebonyi State Ministry of Health.
Ethical approval has been secured from both Committees **(see Attached)**.

Consent procedure for quantitative survey

Informed consent/assent will be sought from all eligible participants. The household questionnaire will be administered to the head of household or an adult representative to obtain information on household demographic and socioeconomic characteristics, and a list of household members aged 13-18 years. The adolescent questionnaire will be administered to adolescents aged 13-18 years within selected households.

The enumerators/interviewers will take study participants through the consent process as applicable to the participants. They will inform participants of the purpose of the research, rights of participants and measures that will be taken by researchers to protect participants and their data.

Informed consent will be obtained from the head of household or an adult representative who will provide information for the household questionnaire **(Appendix 1)**.
Parental/guardian's informed consent will be sought for all eligible adolescents aged 13 to 17 years within a household **(Appendix 2)**. This will be followed by individual assent to participate from these adolescents **(Appendix 3)**. Adolescents that are 18 years of age and mature minors aged 15-17 years will be required to give consent for themselves **(Appendix 4)**. For this study, a mature minor is defined as an adolescent who is no longer under the care of a parent or guardian.
The head of household or adult representative will consent at the same time:

1. to being interviewed about the household;
2. for household members aged 13-17 years to be interviewed;

Documentation of informed consent will be through signature or thumb print, as appropriate.

The information sheet, consent form and assent form will be translated to Igbo language to aid comprehension. A duplicate signed/thumb printed copy of the informed consent and assent forms will be provided to adult participants or mature

minors as the case may be. All paper copies of the consent forms will be kept in a locked, fireproof cabinet for the duration of the research project.

Eligibility to give consent or assent: Household members who have cognitive disabilities that preclude them from consenting or giving assent will be excluded from participating. Cognitive and other disabilities will be assessed on a case-by-case basis. Participants aged 13-14 years who are no longer under the care of a parent/guardian will not be eligible to give consent for themselves.

Consent procedure for in-depth interviews and focus group discussions

Informed consent will be sought from all potential respondents. The interviewers will inform participants of the purpose of the research, rights of participants and measures that will be taken by researchers to protect participants and their data.

Informed consent will be obtained from each respondent for in-depth interviews.
Parental/guardian's informed consent will be sought for adolescents aged 13 to 17 years that will be selected for focus group discussion **(Appendix 2)**. Individual assent to participate will be obtained from these adolescents **(Appendix 3)**. Adolescents that are 18 years of age and mature minors aged 15-17 years will be required to give consent for themselves **(Appendix 4)**.
Documentation of informed consent will be through signature or thumb print, as appropriate.

The information sheet, consent form and assent form will be translated to Igbo language to aid comprehension. A duplicate signed/thumb printed copy of the informed consent and assent forms will be provided to adult participants or mature minors as the case may be. All paper copies of the consent forms will be kept in a locked, fire proof cabinet for the duration of the research project.

Confidentiality

All survey staff will be trained in ethical protection of survey participants. Strong emphasis during training will be made on the importance of keeping participants' data/information strictly confidential.
In order to ensure privacy for participants, surveys will be conducted in a private area of their house where they feel most comfortable to talk. Additional measures will be taken for adolescents' privacy by ensuring their parents or guardians are not in the same room or space during their interview. In-depth interviews and focus group discussions will be conducted in private spaces that suit the respondents.
All electronic databases will be encrypted and password protected to ensure confidentiality. Access to electronic data will be restricted to selected core-research team members. Self-identifying information will be encrypted at the point of data analysis.

Benefits

We will ensure that participants benefit directly or indirectly from the interventions that will be designed by targeting their communities with those interventions.

Payment

This is an IDRC-funded research. No payments will be made for participation as a respondent.

Risks

The risk to human subjects from participating in the interviews is minimal. Participants may be concerned about the confidentiality of the information they provide, or experience discomfort when responding to sensitive questions about sexual behaviour. Interviewers will remind participants that they can skip questions that cause discomfort and terminate the interview at any stage.

Incentives

No incentives will be offered to individuals who consent to participate.

Training of enumerators and interviewers in ethical conduct of research

All enumerators and interviewers will receive training on principles of ethical conduct of research. The training will be provided by the principal investigator who has a diploma in Bioethics. Ethical conduct of research with human participants will be included as a module during the training of enumerators and interviewers for data collection. The second edition of FHI360 Research Ethics Training Curriculum will be adapted and used for the training.

Participants who undergo the training will be tested before and after the training to ascertain their understanding, and only those who score 80% or more will be recruited for data collection. Participants who score less than 80% will be given an opportunity to study the training materials and retake the test.

Appendices

Appendix 1: **Information sheet and Household Consent Form**

Name of Research Study: Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state
Principal Investigator: Chinyere Mbachu

Introduction
I am a trained data collector from Health Policy Research Group University of Nigeria Enugu Campus and we are working with Ebonyi State government. We are conducting a survey about Adolescent Sexual and Reproductive Health, and your household has been selected purely by chance. Adolescent sexual and reproductive health refers to all matters relating to their safe sex life, capability to have children and freedom to decide when to do so.

We are asking you to let the members of your household aged 13-18 years take part in this survey. As the head of household you will consent to the household questionnaire. We want to be sure that you understand the purpose and your responsibilities in the research before you decide if you want to be in it. We would very much appreciate if you could take part in this survey.

This document contains information about the research and in order to be sure that you are informed about being in this research, we are asking you to read this document or have it read to you. You will also be asked to sign a household consent form or make your thumb print on it. We will give you a copy of the consent form.
This document might contain some words that are unfamiliar to you. Please ask us to explain anything you may not understand.

General Information about the Research
As part of this survey, we would like to ask some questions about your family such as how many people live here, their relationship to you and others in the family, their sex and age. We would also like to ask you questions about your household. This information is very important to help the State plan for programs to reduce unwanted teenage pregnancy and abortions in Ebonyi state.
The interview will take up to 30 minutes.

Possible Risks and Benefits
Participation in this study involves no more than minimal risk. We may ask you questions that make you feel uncomfortable. You are free to not answer any questions for any reason.
There are indirect benefits of participating in this research. We will ensure the interventions that will be designed from the findings of this survey will be implemented in your community.

If You Decide Not to Be in the Research
You are free to decide if you want you want your household members to be in this research or not and no one will penalize you for that.

Confidentiality
We will protect information about your household to the best of our ability. What we talk about will be kept private, even from other members of your family. Our records of your household information will not have personal identifying information and they will be kept in a secure location. The reports we write will not contain individual records.

Payment
Taking part in this study is free – meaning you do not have to pay for anything. Also, you will not be paid for your participation in this study.

Leaving the Research Study
You may end your participation at any time and may leave the research study at any time.

HEAD OF HOUSEHOLD AGREEMENT

The document describing the purpose, my rights, benefits and risks of participating in the research study titled **'Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state'** has been read and explained to me. I voluntarily agree to participate as a respondent.

_____ _____

Date Signature or thumb-print of participant

If participants cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the participant. All questions were answered and the participant has agreed to take part in the research.

_____ _____

Date Signature of Witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____ _____

Date Signature of Person Who Obtained Consent

If You Have Questions about the Study

If you have any questions about the research, please contact any of the following persons:

1. Dr Chinyere Mbachu, 0905201921
2. Prof Obinna Onwujekwe, 08037007771

Your rights as a Participant

This research has been reviewed and approved by Health Research Ethics Committee of University of Nigeria Teaching Hospital and the Ethics Committee of Ebonyi State Ministry of Health. If you have any questions about how your child/ward is being treated in the study or his/her rights as a participant you may contact:

1. Mazi Onyimba

Health Research Ethics Committee, University of Nigeria Teaching Hospital. 08034079903; 08091695149

OR

2. Dr Francis Onwe

Secretary, Research Ethics Review Committee, Ebonyi state Ministry of Health. 08068071246

Appendix 2: **Information sheet and Parental Consent Form for Adolescents (minors) aged 13-17 years**

Name of Research Study: Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state
Principal Investigator: Chinyere Mbachu

Introduction
I am a trained data collector from Health Policy Research Group University of Nigeria Enugu Campus and we are working with Ebonyi State government. We are asking you to let your child/ward take part in a survey about Adolescent Sexual and Reproductive Health. Adolescent sexual and reproductive health refers to all matters relating to their safe sex life, capability to have children and freedom to decide when to do so. We want to be sure that you understand the purpose and responsibilities of your child in the research before you decide if your child should be in it. Please know that your child/ward is also free to decide if he/she wants to participate, or not. We would very much appreciate if you agree for your child/ward to take part in this study.

This document contains information about the research and in order to be sure that you are informed about being in this research, we are asking you to read this document or have it read to you. You will also be asked to sign a parental/guardian consent form or make your thumb print on it. We will give you a copy of the consent form.

This document might contain some words that are unfamiliar to you. Please ask us to explain anything you may not understand.

General Information about the Research
In this survey, we are asking people about sexual behaviour, knowledge/use of contraceptives and ability to access sexual reproductive health services. This information is very important to help the State plan for programs to reduce unwanted teenage pregnancy and abortions in Ebonyi state.

We plan to be more involved with your community and engage with young people within the age range of 13 to 18 years over the coming months. The interview will take about 45-60 minutes.

Possible Risks and Benefits
Participation in this study involves no more than minimal risk. We may ask your child/ward questions that might make him/her feel uncomfortable. Your child/ward may decide not to answer some questions for any reason.

There are indirect benefits of participating in this research. We will ensure the interventions that will be designed from the findings of this survey will be

implemented in your community. Your child/ward may also benefit directly from these interventions.

If You Decide Not to Be in the Research
You are free to decide if you want you want your child/ward to be in this research or not and no one will be mad at you.

Confidentiality
We will protect information about your child/ward and his/her decision to take part in this research to the best of our ability. What we talk about will be kept private, even from other members of your family. Our records of your child/ward's information will not have his/her name or other personal identifying information and they will be kept in a secure location. The reports we write will not contain your child/ward's name or individual records.

Payment
Taking part in this study is free – meaning you do not have to pay for anything. Also, your child/ward will not be paid for his/her participation in this study.

Leaving the Research Study
Your child/ward may end his/her participation at any time and may leave the research study at any time.

PARENTAL/GUARDIAN AGREEMENT

The document describing the purpose, my child/ward's rights, benefits and risks of participating in the research study titled **'Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state'** has been read and explained to me. I voluntarily agree for my child/ward to participate as a respondent.

_____ _____

Date Signature or thumb-print of parent/guardian

If participants cannot read the form themselves, a witness must sign here:
I was present while the benefits, risks and procedures were read to the participant. All questions were answered and the participant has agreed for his/her child/ward to take part in the research.

_____ _____

Date Signature of Witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____ _____

Date Signature of Person Who Obtained Consent

If You Have Questions about the Study
If you have any questions about the research, please contact any of the following persons:

1. Dr Chinyere Mbachu, 0905201921
2. Prof Obinna Onwujekwe, 08037007771

Your rights as a Participant
This research has been reviewed and approved by Health Research Ethics Committee of University of Nigeria Teaching Hospital and the Ethics Committee of Ebonyi State Ministry of Health. If you have any questions about how your child/ward is being treated in the study or his/her rights as a participant you may contact:

1. Mazi Onyimba

Health Research Ethics Committee, University of Nigeria Teaching Hospital. 08034079903; 08091695149
OR

2. Dr Francis Onwe

Secretary, Research Ethics Review Committee, Ebonyi state Ministry of Health. 08068071246

Appendix 3: **Information sheet and Assent Form for Adolescents aged 13 -17 years of age**

Name of Research Study: Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state
Principal Investigator: Chinyere Mbachu

Introduction

I am a trained data collector from Health Policy Research Group University of Nigeria Enugu Campus and we are working with Ebonyi State government to conduct a study on Adolescent Sexual and Reproductive Health. This document contains information about the research and in order to be sure that you are informed about being in this research, we are asking you to read this document or have it read to you. You will also be asked to sign a consent form or make your thumb print on it. A parental consent form must be signed by your parent(s)/guardian(s) and returned to the research staff before you can take part in the research. Please understand that even if your parents agree that you can be in this research study you are free to decide yourself if you want to participate, or not. Your parents know you have this choice. We will give your parents a copy of the consent form.

This document might contain some words that are unfamiliar to you. Please ask us to explain anything you may not understand.

Reason for the Research

You are being asked to take part in a research study to collect information about reproductive health needs and sexual behaviours of adolescents aged 13-18 years in Ebonyi state. This information is very important to help the State plan for programs to address unmet needs for contraceptives among adolescents.

General Information about the Research

Adolescent sexual and reproductive health refers to all matters relating to their safe sex life, capability to have children and freedom to decide when to do so. In this survey, we are asking people about sexual behaviour, knowledge/use of contraceptives and ability to access sexual reproductive health services. We plan to be more involved with your community and engage with young people within the age range of 13 to 18 years over the coming months.

We hope you will take part in this study because your views are important. We have talked to your parents/guardians and they said it was okay to ask if you want to take part.

Your Part in the Research

If you agree to participate, we will ask you a few questions. Some of these questions will be about your sexual behaviour, knowledge/use of contraceptives and ability to access sexual reproductive health services. Your honest answers to these questions will help us better understand adolescents' reproductive health needs and sexual

behaviour. But please know if any of the questions upset you, or if you do not want to answer a question we can skip it and it is okay for you to do that. The information you give to us will help us to plan for health services. All the answers you give will be kept private and will not be shown to anyone outside of the research team. We will not share your answers with your family. The interview will take about 45-60 minutes.

Possible Risks and Benefits
Participation in this study involves no more than minimal risk. We may ask you questions that might make you feel uncomfortable. You are free not to answer any questions for any reason.

There are indirect benefits of participating in this research. We will ensure the interventions that will be designed from the findings of this survey will be implemented in your community. You may also benefit directly from these interventions.

If You Decide Not to Be in the Research
You are free to refuse to be in this research or not and no one will be mad at you.

Confidentiality
We will protect information about you and your decision to take part in this research to the best of our ability. What we talk about will be kept private, even from your family. Our records of your information will not have your name or other personal identifying information and they will be kept in a secure location. The reports we write will not contain your name or individual records.

Payment
Taking part in this study is free – meaning you do not have to pay for anything. Also, you will not be paid for your participation in this study.

Leaving the Research Study
You may leave the research study at any time.

Appendix 4: **Information sheet and Consent Form for Adolescents aged 18 years and mature minors aged 15-17 years**

Name of Research Study: Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state
Principal Investigator: Chinyere Mbachu

Introduction

I am a trained data collector from Health Policy Research Group University of Nigeria Enugu Campus and we are working with Ebonyi State government to conduct a study on Adolescent Sexual and Reproductive Health. This document contains information about the research and in order to be sure that you are informed about being in this research, we are asking you to read this document or have it read to you. You will also be asked to sign a consent form or make your thumb print on it. We will give you a copy of the consent form.

This document might contain some words that are unfamiliar to you. Please ask us to explain anything you may not understand.

Reason for the Research

You are being asked to take part in a research study to collect information about reproductive health needs and sexual behaviours of adolescents aged 13-18 years in Ebonyi state. This information is very important to help the State plan for programs to address unmet needs for contraceptives among adolescents.

General Information about the Research

Adolescent sexual and reproductive health refers to all matters relating to their safe sex life, capability to have children and freedom to decide when to do so. In this survey, we are asking people about sexual behaviour, knowledge/use of contraceptives and ability to access sexual reproductive health services. We plan to be more involved with your community and engage with young people within the age range of 13 to 18 years over the coming months.

Your Part in the Research

If you agree to participate, we will ask you a few questions. Some of these questions will be about your sexual behaviour, knowledge/use of contraceptives and ability to access sexual reproductive health services. Your honest answers to these questions will help us better understand adolescents' reproductive health needs and sexual behaviour. But please know if any of the questions upset you, or if you do not want to answer a question we can skip it and it is okay for you to do that. The information you give to us will help us to plan for health services. All the answers you give will be kept private and will not be shown to anyone outside of the research team. We will not share your answers with your family. The interview will take about 45-60 minutes.

Possible Risks and Benefits

Participation in this study involves no more than minimal risk. We may ask you questions that might make you feel uncomfortable. You are free not to answer any questions for any reason.

There are indirect benefits of participating in this research. We will ensure the interventions that will be designed from the findings of this survey will be implemented in your community. You may also benefit directly from these interventions.

If You Decide Not to Be in the Research

You are free to refuse to be in this research or not and no one will be mad at you.

Confidentiality

We will protect information about you and your decision to take part in this research to the best of our ability. What we talk about will be kept private, even from your family. Our records of your information will not have your name or other personal identifying information and they will be kept in a secure location. The reports we write will not contain your name or individual records.

Payment

Taking part in this study is free – meaning you do not have to pay for anything. Also, you will not be paid for your participation in this study.

Leaving the Research Study

You may leave the research study at any time.

VOLUNTEER AGREEMENT FOR ADOLESCENTS

The document describing the purpose, my rights, benefits and risks of participating in the research study titled **'Addressing unmet need for contraceptives among adolescents using a community-embedded research in Ebonyi state'** has been read and explained to me. I voluntarily agree to participate as a respondent.

_____ _____

Date Signature or Thumb print of Participant

If participants cannot read the form themselves, a witness must sign here:
I was present while the benefits, risks and procedures were read to the participant. All questions were answered and the participant has agreed to take part in the research.

_____ _____

Date Signature of Witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

_____ _____

Date Signature of Person Who Obtained Consent

If You Have Questions about the Study
If you have any questions about the research, please contact any of the following persons:

3. Dr Chinyere Mbachu, 0905201921
4. Prof Obinna Onwujekwe, 08037007771

Your rights as a Participant
This research has been reviewed and approved by Health Research Ethics Committee of University of Nigeria Teaching Hospital and the Ethics Committee of Ebonyi State Ministry of Health. If you have any questions about how your child/ward is being treated in the study or his/her rights as a participant you may contact:

3. Mazi Onyimba

Health Research Ethics Committee, University of Nigeria Teaching Hospital. 08034079903; 08091695149

OR

4. Dr Francis Onwe

Secretary, Research Ethics Review Committee, Ebonyi state Ministry of Health. 08068071246