Approved Informed Consent Forms

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy (CHARM2)

NCT number: NCT03514914

Date of document creation: 4/4/2019

Date last approved by IRB: 3/31/2022

INFORMATION SHEET
(HUSBAND)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist – 'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. Who can take part in this research study?

Couples (husband and wife) with wives aged 18-29 years, residing in the village for the past 2 years and residing together in village for past 3 months and not adopted female/male sterilization will be part of the study.

5. How many participants will be included for this research study?

A total of 1200 couples will be part of the study.

6. What do you have to do if you agree to take part in the research study?

Couple will be part of the survey which will collect detailed information on age at marriage, length of marriage, frequency of sexual activity, and male versus female family size decision-making control, marital communication. Men and women will be asked to provide data on their fertility history, current breast feeding and family planning history, attitudes toward contraception, contraceptive knowledge, desire for and intent to use contraception, perceived access to contraception. The interview will be of 30-45 min duration and conducted in private setting.

7. How will the research study be done?

The study will be carried out in Junnar taluka of Pune district. A total of 1200 couples (600 experimental and 600 control) will be part of baseline survey and 9 & 18 month follow-up surveys. Intervention group will receive three sessions on gender equity and family planning.

8. What are the tests that will be performed on the participant/ biological sample?
Urine pregnancy test will be conducted at the baseline, 9 & 18 month follow up survey.

9. How long the biological samples will be stored and how will it be disposed?
Sample will be disposed of immediately after the pregnancy test.

10. How long will you be in the research study?
You will be part of the study for 24 months.

11. Under what conditions will your participation in the study be terminated?
Your participation in the study will be stopped at your request. A participant can be removed from the study by the PI, should the study become unsafe.

12. What are the possible risks and inconveniences that you may face by being in the research study?
You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices and giving urine sample for diagnosis of pregnancy. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. What happens if you are injured since you took part in this research study?
Not applicable

14. What are the possible benefits to you by being in the research study?
The study does not have direct benefit to you presently. However, referring to nearest Government health facility for further management and treatment will benefit participants diagnosed as pregnant. You will benefit in future in terms of improving knowledge, attitude, practice and health seeking behavior on reproductive health issues including ante-natal, post-natal care and contraception (contraceptive methods such as oral pills, Cu T and condom) through educational and counseling activities.

15. What are the other treatment options/alternatives to participation?
Your participation is voluntary, and the alternative is not to participate in the study.

16. What will happen if you change your mind about participation in this research study?
You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. How will your privacy and confidentiality be maintained?
The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researchers will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. Will you have to bear any Expenses or Costs by participating in the research study?

You will not have to bear any cost towards participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist - 'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office

Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012,
Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (non-scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute - National Institute for Research in Reproductive Health.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No:				

National Institute for Research in Reproductive Health
(Indian Council of Medical Research)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form

(HUSBAND)

I_____have read /have had read the participant information sheet version no. ……..dated……..…bearing page numbers ……. of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non-readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------

INFORMATION SHEET
(WIFE)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist – 'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. Who can take part in this research study?

Couples (husband and wife) with wives aged 18-29 years, residing in the village for the past 2 years and residing together in village for past 3 months and not adopted female/male sterilization will be part of the study.

5. How many participants will be included for this research study?

A total of 1200 couples will be part of the study.

6. What do you have to do if you agree to take part in the research study?

Couple will be part of the survey which will collect detailed information on age at marriage, length of marriage, frequency of sexual activity, and male versus female family size decision-making control, marital communication. Men and women will be asked to provide data on their fertility history, current breast feeding and family planning history, attitudes toward contraception, contraceptive knowledge, desire for and intent to use contraception, perceived access to contraception. The interview will be of 30-45 min duration and conducted in private setting.

7. How will the research study be done?

The study will be carried out in Junnar taluka of Pune district. A total of 1200 couples (600 experimental and 600 control) will be part of baseline survey and 9 & 18 month follow-up surveys. Intervention group will receive three sessions on gender equity and family planning.

8. What are the tests that will be performed on the participant/ biological sample?
Urine pregnancy test will be conducted at the baseline, 9 & 18 month follow up survey.

9. How long the biological samples will be stored and how will it be disposed?
Sample will be disposed of immediately after the pregnancy test.

10. How long will you be in the research study?
You will be part of the study for 24 months.

11. Under what conditions will your participation in the study be terminated?
Your participation in the study will be stopped at your request. A participant can be removed from the study by the PI, should the study become unsafe.

12. What are the possible risks and inconveniences that you may face by being in the research study?
You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices and giving urine sample for diagnosis of pregnancy. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. What happens if you are injured since you took part in this research study?
Not applicable

14. What are the possible benefits to you by being in the research study?
The study does not have direct benefit to you presently. However, referring to nearest Government health facility for further management and treatment will benefit participants diagnosed as pregnant. You will benefit in future in terms of improving knowledge, attitude, practice and health seeking behavior on reproductive health issues including ante-natal, post-natal care and contraception (contraceptive methods such as oral pills, Cu T and condom) through educational and counseling activities.

15. What are the other treatment options/alternatives to participation?
Your participation is voluntary, and the alternative is not to participate in the study.

16. What will happen if you change your mind about participation in this research study?
You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. How will your privacy and confidentiality be maintained?
The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researchers will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. Will you have to bear any Expenses or Costs by participating in the research study?

You will not have to bear any cost towards participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist - 'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office

Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012,
Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (non-scientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute - National Institute for Research in Reproductive Health.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No:				

National Institute for Research in Reproductive Health
(Indian Council of Medical Research)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form

(WIFE)

I_____have read /have had read the participant information sheet version no. ……..dated……..…bearing page numbers ……. of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non-readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------

Principal Investigator/Collaborator Name: Consent Administrator Name:

PARTICIPANT INFORMATION SHEET
In-Depth Interviews
(Husband)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist -'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres, this approach has not been very helpful for young couples because of the travel needed to get to these centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Rural Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. Who can take part in this research study?

The young husbands whose wives aged 18-29 years, currently married and regularly residing with their wife for the past 3 months, and reporting no sterilization for themselves or their wife will be eligible. Rural young wives aged 18-29, regularly residing with their husband for the past 3 months, and reporting no sterilization for either spouse. Private and public health practitioners serving rural villages in Junner taluka will be interviewed.

5. How many participants will be included for this research study?

30 Rural young husbands, 20 wives across and 12 private/public health practitioners across two villages.

6. What do you have to do if you agree to take part in the research study?

In depth interviews will be conducted to understand the perspectives of men, women and health care providers on family planning programmes available at the village, the difficulties in accessing them, the improvement that the project has been able to make. The strategies to improve the use of family planning methods too would be enquired.

7. How will the research study be done?

Participants will be requested by the staff in the study to participate in in-depth interviews. The interviews will be conducted in Marathi at a private location on the above mentioned issues.

8. What are the tests that will be performed on the participant/ biological sample?

No tests will be conducted.

9. How long the biological samples will be stored and how will it be disposed?

Not applicable

10. How long will you be in the research study?

For both men and women, the interview will be conducted on two separate days within the same week; the interviews will be 45-60 minutes per day. The interview would be around 60-90 minutes with village health providers from each of the following four disciplines (ayurveda, unani, homeopathy and allopathy).

11. Under what conditions will your participation in the study be terminated

Your participation in the study will be stopped at your request. . A participant can be removed from the study by the PI, should the study become unsafe.

12. What are the possible risks and inconveniences that you may face by being in the research study?

You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. What happens if you are injured since you took part in this research study?

Not applicable

14. What are the possible benefits to you by being in the research study?

You will not be paid any money for your participation in the study. You will not receive any direct benefit from this study, however, couples in your community may benefit in future in terms of improving knowledge, attitude, practices and health seeking behaviour on reproductive health issues through educational and counselling activities.

15. What are the other treatment options/alternatives to participation?

Your participation is voluntary, and the alternative is not to participate in the study.

16. What will happen if you change your mind about participation in this research study?

You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. How will your privacy and confidentiality be maintained?

The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researcher will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. Will you have to bear any Expenses or Costs by participating in the research study?

You will not have to bear any cost towards investigations or participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist - 'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

   If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office
Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012

Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (nonscientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute - National Institute for Research in Reproductive Health

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No: | | | | |

National Institute for Research in Reproductive Health
(Indian Council of Medical Research)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form: IN DEPTH INTERVIEW
(Husband)

I_____have read /have had read the participant information sheet version no. ……..dated…….bearing page numbers ……. of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non-readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------

Principal Investigator/Collaborator Name: Consent Administrator Name:

PARTICIPANT INFORMATION SHEET
In-Depth Interviews
(Wife)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist -'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres, this approach has not been very helpful for young couples because of the travel needed to get to these centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Rural Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. Who can take part in this research study?

The young husbands whose wives aged 18-29 years, currently married and regularly residing with their wife for the past 3 months, and reporting no sterilization for themselves or their wife will be eligible. Rural young wives aged 18-29, regularly residing with their husband for the past 3 months, and reporting no sterilization for either spouse. Private and public health practitioners serving rural villages in Junner taluka will be interviewed.

5. How many participants will be included for this research study?

30 Rural young husbands, 20 wives across and 12 private/public health practitioners across two villages.

6. What do you have to do if you agree to take part in the research study?

In depth interviews will be conducted to understand the perspectives of men, women and health care providers on family planning programmes available at the village, the difficulties in accessing them, the improvement that the project has been able to make. The strategies to improve the use of family planning methods too would be enquired.

7. How will the research study be done?

Participants will be requested by the staff in the study to participate in in-depth interviews. The interviews will be conducted in Marathi at a private location on the above mentioned issues.

8. What are the tests that will be performed on the participant/ biological sample?

No tests will be conducted.

9. How long the biological samples will be stored and how will it be disposed?

Not applicable

10. How long will you be in the research study?

For both men and women, the interview will be conducted on two separate days within the same week; the interviews will be 45-60 minutes per day. The interview would be around 60-90 minutes with village health providers from each of the following four disciplines (ayurveda, unani, homeopathy and allopathy).

11. Under what conditions will your participation in the study be terminated

Your participation in the study will be stopped at your request. . A participant can be removed from the study by the PI, should the study become unsafe.

12. What are the possible risks and inconveniences that you may face by being in the research study?

You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. What happens if you are injured since you took part in this research study?

Not applicable

14. What are the possible benefits to you by being in the research study?

You will not be paid any money for your participation in the study. You will not receive any direct benefit from this study, however, couples in your community may benefit in future in terms of improving knowledge, attitude, practices and health seeking behaviour on reproductive health issues through educational and counselling activities.

15. What are the other treatment options/alternatives to participation?

Your participation is voluntary, and the alternative is not to participate in the study.

16. What will happen if you change your mind about participation in this research study?

You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. How will your privacy and confidentiality be maintained?

The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researcher will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. Will you have to bear any Expenses or Costs by participating in the research study?

You will not have to bear any cost towards investigations or participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist - 'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

   If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office
Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012

Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people (nonscientific) who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute - National Institute for Research in Reproductive Health

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No: | | | | |

National Institute for Research in Reproductive Health
(Indian Council of Medical Research)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form: IN DEPTH INTERVIEW
(Wife)

I_____have read /have had read the participant information sheet version no. ……..dated…….bearing page numbers ……. of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non-readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------

Principal Investigator/Collaborator Name: Consent Administrator Name:

PARTICIPANT INFORMATION SHEET
(HEALTH CARE PROVIDERS)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist –'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study

is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres, this approach has not been very helpful for young couples because of the travel needed to get to these centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Rural Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. Who can take part in this research study?

The qualified village health care providers (VHPs) in the stream of allopath, ayurveda homeopathy, Unani etc, practicing in the project area and willing to take part in the in the research study.

5. How many participants will be included for this research study?

A total of 20 VHPs will be part of the study.

6. What do you have to do if you agree to take part in the research study?

The VHPs who wish to be a part of the study, will be asked to provide some information about background characteristics, their knowledge and practice about family planning and reproductive health issues through personal interview of in-depth interview. They will be trained in a three day training programme on reproductive health issues including family planning. They will be involved in conducting two sessions with husbands after the baseline survey. The provision of temporary methods such as condom and oral pills will be made available with them to provide it to the eligible couples as when required.

7. How will the research study be done?

The study will be carried out in Junner taluka of Pune district. A total of 1200 couples (600 experimental and 600 control) will be part of baseline survey and 9^{th} and 18^{th} month follow-up surveys.

8. What are the tests that will be performed on the participant/ biological sample?

Not applicable

9. How long the biological samples will be stored and how will it be disposed?

Not applicable

10. How long will you be in the research study?

You will be part of the study for 24 months.

11. Under what conditions will your Participation in the study be terminated

Your participation in the study will be stopped at your request. . A participant can be removed from the study by the PI, should the study become unsafe.

12. What are the possible risks and inconveniences that you may face by being in the research study?

You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. What happens if you are injured since you took part in this research study?

Not applicable

14. What are the possible benefits to you by being in the research study?

The study does not have direct benefit to you presently. You will benefit in future in terms of improving knowledge, attitude, practice and health seeking behavior on reproductive health issues including ante-natal, post-natal care and contraception (contraceptive methods such as oral pills, Cu T and condom) through educational and counseling activities.

15. What are the other treatment options/alternatives to participation?

Your participation is voluntary, and the alternative is not to participate in the study.

16. What will happen if you change your mind about participation in this research study?

You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. How will your privacy and confidentiality be maintained?

The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researcher will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. Will you have to bear any Expenses or Costs by participating in the research study?

You will not have to bear any cost towards investigations or participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist –'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office

Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012,
Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people(non scientific)who work towards safeguarding the rights of the study participants like you who take part in research studies undertaken at the institute - National Institute for Research in Reproductive Health.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No: | | | | |

National Institute for Research in Reproductive Health
(Indian Council of Medical Research)
J. M. Street, Parel, Mumbai 400 012.

Informed Consent Form – IN DEPTH INTERVIEW
(Health Care Provider)

I_____have read the participant information sheet version no. ……..dated……bearing page numbers …….... of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks/benefits and expected duration of the study, and other relevant details including my role as a service provider has been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me/by me during the research study will be kept confidential. The representatives of sponsor/government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------

PARTICIPANT INFORMATION SHEET

Focus group participants

(Mother-in-laws)

Project Title: Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy

Project sponsored by: *NIH Programme forPA-13-302 Research project Parent Grant*

Principal Investigator: Dr. Shahina Begum, Scientist - 'D'
National Institute for Research in Reproductive Health
Jehangir Merwanji Street, Parel, Mumbai - 400 012

Indian Collaborators: Dr. Niranjan Saggurti, Country Director
Population Council, New Delhi

US Collaborators: Dr. Anita Raj, Professor
University of California, San Diego, USA

Dr. Jay Silverman, Professor
University of California, San Diego, USA

Dr. Florin Vaida, Professor
University of California, San Diego, USA

Dr. Prashant Bharadwaj, Assistant Professor
University of California, San Diego, USA

Dr. Sarah Averbach, Assistant Professor
University of California, San Diego, USA

You are invited to be part of this research study. Research is different than routine care. Routine care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of this study is to gain knowledge that may help future patients.

This Participant Information Sheet gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take the time to review this information carefully. You are requested to ask for an explanation of any words you do not understand. After you have read the participant Information Sheet you are free to talk to the doctors/researchers about the study and ask them any questions you have. You will be given a copy of the participant information sheet to discuss with your friends, family, or other doctors about your participation in this study.

If you have decided to take part in the study, you will be asked to sign the informed consent form which is along with this participant information sheet. Before you sign the informed consent form, be sure you understand what the study is about, including the risks and possible benefits to you. You will be given a copy of the participant information sheet and signed informed consent form for your future reference.

Please remember that your participation in this study is entirely voluntary. You are free to withdraw from the study at any point of time without affecting your medical care and services. Also, by signing the Consent form you have not waived off any rights as a participant.

You may please note that being in a research study does not take the place of routine physical examination or visits to your own doctor and should not be relied on to diagnose or treat any other medical problems.

1. What is the research study about?

The study tries to identify ways to expand the use of available methods of contraception (oral pills, Cu T and condom), especially for young couples in the rural areas. Participants will be informed about the methods available for contraception. In case, a participant becomes pregnant she will be guided and referred to PHC.

2. What information is known about this type of research study?

Unplanned and too closely spaced pregnancies are major causes of death and illness among young mothers and infants in India. Also, there is large difference between urban and rural family planning. Rural young women are at a higher risk for unplanned pregnancies due to lack of family planning services at the village and also due to non-involvement of husband in family planning. Although the government has responded to this issue by providing family planning access and care through primary health centres, this approach has not been very helpful for young couples because of the travel needed to get to these centres.

3. Why is this research study being done?

The current study offers new approach of family planning within rural India by 1) enhancing access to contraceptive education and services for those who need the most (i.e., rural young couples); 2) improving access to family planning services (a goal of the National Rural Health Mission); and 3) focusing on husbands' role in family planning decisions and use.

4. **Who can take part in this research study?**
   Mothers of rural young men (n=40 across 2 villages) will be recruited through ANM, to ensure access to larger numbers of these mothers as focus groups require more participants.

5. **How many participants will be included for this research study?**
   40 women (mothers of rural young men) will be part of the study**.**

6. **What do you have to do if you agree to take part in the research study?**
   In the focus group, the role of daughters-in-law in the family, son preference and its role in family, the role of mothers-in laws in family planning decisions will be enquired. Also, mothers will asked about their knowledge and attitude towards contraceptive use and spacing births as well as various methods of contraception. No personal information will be asked, only peoples view in general about these issues in community will be asked.

7. **How will the research study be done?**
   Women will be invited to be part of group discussions. Each focus group will have around 8-12 participants who would be required to answer on issues related to family planning. The discussions will be conducted in Marathi by NIRRH female staff, and held in the Anganwadi centers of the study villages.

8. **What are the tests that will be performed on the participant/ biological sample?**
   No tests will be conducted.

9. **How long the biological samples will be stored and how will it be disposed?**
   Not applicable

10. **How long will you be in the research study?**
    Each focus group will be 90 minutes in length

11. **Under what conditions will your Participation in the study be terminated**
    Your participation in the study will be stopped at your request**.**

12. **What are the possible risks and inconveniences that you may face by being in the research study?**

You may feel discomfort while providing personal information on sensitive issues like sexual behavior and contraceptive practices. These discomforts will be managed by utilizing female staff adequately trained in counseling and data collection.

13. **What happens if you are injured since you took part in this research study?**
    Not applicable

14. **What are the possible benefits to you by being in the research study?**
    You will not be paid any money for your participation in the study. You will not receive any direct benefit from this study, however, couples in your community may benefit in future in terms of improving knowledge, attitude, practices and health seeking behaviour on reproductive health issues through educational and counselling activities.

15. **What are the other treatment options/alternatives to participation?**
    Your participation is voluntary, and the alternative is not to participate in the study.

16. **What will happen if you change your mind about participation in this research study?**
    You may withdraw from the research study for any reason, at any time, without penalty of any sort/loss of benefits to which you are otherwise entitled. If you withdraw from the research study at any time, any data that you have contributed will be destroyed at your request.

17. **How will your privacy and confidentiality be maintained?**
    The interview will be conducted in a private setting. The response will be kept confidential. Your name will not appear on the schedule. No identifying information will be reported with the data. Only researcher will have access to responses, which will be utilized to prepare report and for research purpose only. All the records will be kept confidential in a secured place. There will be no discrimination of any kind.

    To confirm that the study data collected about you is correct and related to you; selected people working for the sponsor, as well as representatives of government regulatory authorities and ethics committees will have access to your personal information at the study site. These persons are required to maintain the confidentiality of your information. By signing this document, you are authorizing such access.

18. **Will you have to bear any Expenses or Costs by participating in the research study?**

You will not have to bear any cost towards investigations or participation in this study.

19. Whom do you call if you have questions or problems?

a. Research related

Participant can contact following persons for clarification of any questions or problems.

1. Dr. Shahina Begum, Scientist - 'D'
   Department of Biostatistics
   National Institute for Research in Reproductive Health (ICMR)
   Jehangir Merwanji Street, Parel, Mumbai - 400 012
   Tel. No. 24192041
   Time to contact: Monday to Friday between 9.00 am to 5.00 pm
   Email: begums@nirrh.res.in

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office. (Please feel free to address the Ethics Committee through the Ethics Office and identify yourself by the 'participant identification number' as filled in your participant enrollment form – for sensitive study like HIV)

b. Regarding rights as a Participant

If you have questions or concerns about your rights as a research participant or a concern about the study, please feel free to address the Ethics Committee through the Ethics Office

Dr. Beena Joshi
Institutional Ethics Committee for Clinical Research
National Institute for Research in Reproductive Health (ICMR)
J. M. Street, Parel. Mumbai 400 012
Tel. No: Direct- 022-24192147, Board no.- 022-24192000
Time to contact: Monday to Friday between 9.00 am to 5.00 pm
Email : nirrh.cliethics@gmail.com

The Institutional Ethics Committee for Clinical Research comprises of a group of people like doctors, researchers, and community people(nonscientific)who work towards safeguarding the rights of the study participants like you who take part in

research studies undertaken at the institute - National Institute for Research in Reproductive Health

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

Sr. No: | | | | |

National Institute for Research in Reproductive Health
J. M. Street, Parel, Mumbai 400 012.

INFORMED CONSENT FORM
Focus Group Discussion (Mother-in-aw)

I_____have read /have had read the participant information sheet version no. ……..dated……bearing page numbers …… of the research study entitled 'Enhancing Male Participation in Interventions to Prevent Unintended Pregnancy'.

The information contained in the participant information sheet regarding the nature and purpose of the study, safety, and its potential risks / benefits and expected duration of the study, and other relevant details of the study including my role as a study participant have been explained to me in the language that I understand (Hindi/Marathi). I have had the opportunity to ask queries, which have been clarified to my satisfaction.

I understand that my participation is voluntary and that I have the right to withdraw from the study at any time without giving any reasons for the same. This will not affect my further medical care or any legal right.

I understand that the information collected about me during the research study will be kept confidential. The representatives of sponsor/, government regulatory authorities/ethics committees may wish to examine my medical records/study related information at the study site to verify the information collected. By signing this document, I give permission to these individuals for having access to my records.

I hereby give my consent willingly to participate in this research study. I am informed that I will be/ will not be given any compensation/ reimbursement for participation in the study.

For Limited or non-readers: (Illiterate participants) I have witnessed the consent procedure of the study participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness ----------

Witness Signature/Date----------

Signature/Thumb Impression/Date----------

Study Participant Name----------

Study Participant Signature/Date----------

Principal Investigator Signature/Collaborator----------

Consent Administrator Signature/Date ----------