Consent Form
CATCH STUDY
Community Access to Cervical Health

Title: Comparison of multiple methods of screening for cervical cancer in Medchal Mandal

Purpose of the study:

Cervical cancer is the most common cancer of women in India. In this research project, we will compare three methods of screening for cervical cancer and for conditions that lead to cervical cancer (Pap smear, HPV testing, and visual inspection using acetic acid [VIA]). This is a joint project of the MediCiti Hospital, Medchal, and the Johns Hopkins University in Baltimore, USA. You have been invited to participate because you are a woman 25 years old or older, and are a resident of Medchal Mandal.

Of the above methods, Pap smear is the standard procedure used to screen for cervical cancer and pre-cancer used all over Of the above methods, Pap smear is the standard procedure used to screen for cervical cancer and pre-cancer used all over the world. Infection with HPV is strongly linked with cervical cancer. The HPV assay and VIA are new methods which show promise as cervical cancer screening methods.
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Procedures:

We plan to ask all women 25 years old or older, with prior sexual experience, who live in Medchal Mandal, and who have an intact uterus (no hysterectomy), to participate in our study. If you agree to be in the study:

(a) a trained female interviewer will ask you a few questions about your reproductive, smoking, and Pap smear screening history; this will take about five minutes;
(b) You will be requested to collect a vaginal swab sample for a test for human papillomavirus (HPV). A female physician will explain the collection procedures to you and direct you to a private room where you can collect the samples. This procedure will take about one to two minutes.
(c) You will be given a pelvic examination by a female physician who will first obtain one sample of your cervical cells (Pap smear) for microscopic examination, and a second sample of your cervical cells for a laboratory test for HPV. The doctor will then apply vinegar (3% acetic acid) to your cervix and examine it for abnormalities (VIA). The pelvic examination and the sample collection procedures will take about 15 – 20 minutes.

(d) We will collect a small amount of blood (approximately 4 teaspoons) that will be used for tests which may help us to better understand the causes of cancer.

(e) Each day we will draw lots to randomly select some women to have their cervix viewed under magnification (colposcopy). If abnormal areas are found, a small piece of tissue will be taken to determine if treatment is needed. All women who consent to participate will be eligible to be selected by the lottery for the colposcopy test.

We will inform you of the results of the Pap smear, HPV and VIA tests in about 6 weeks. Women who are found to have an abnormal result by any of these tests will be given additional tests to identify cancer and other abnormalities that can be treated to prevent development of cervical cancer. Treatment will be provided free of cost to women who need them. If all tests are normal, you have a very small risk of cervical cancer and we will give you an appointment for a future clinic visit in about 5 years. If any of the assays are abnormal, we will ask you to return for the additional test of colposcopy. At the time of the colposcopy exam, we will take three samples of your cervical cells for additional tests for HPV and other changes in your cells. In the colposcopy procedure, the cervix is examined after magnification. If any abnormality is seen, a small piece of the abnormal tissue (a biopsy) will be removed for microscopic examination. If treatment is required it will be offered free of cost to you. If you have a colposcopy exam and were found to have no abnormalities, we will ask you to return for Pap smear, HPV testing, and VIA each year for 4 years.

Risks/Discomforts:

The pelvic examination may cause you some minor discomfort and minor bleeding may result. There may be some minor discomfort or soreness from the blood drawing and rarely a bruise may develop. The acetic acid used to look at your cervix may cause some minor burning. If you are found to have some abnormality at your cervix, the procedures to collect a sample of tissue (biopsy) and the treatment of your lesion may cause cramping (in rare cases this can be severe) and bleeding.

Benefits:

The project will be beneficial to all participants. If all of your tests are normal, you can be confident that you have almost no risk of cervical cancer in the next few years. If you have any abnormal screening result, follow-up with colposcopy, and if necessary, biopsy, will ensure prompt treatment and/or appropriate follow-up to all who need it.

Alternatives to participation:

If you decline to participate, or wish to withdraw from the study at any time, your care at MediCiti Hospital will not be affected in any way. You should ask the principal

investigator listed below any questions that you may have about this research study. You may ask them questions in the future if you do not understand something that is being done. The doctors will share with you any new findings that may develop while you are participating in this study.

Confidentiality:

All of the records we take of your participation will be kept in a locked room. Access to these records will be restricted only to authorized study personnel. The data will be reported as a group, without personal identifying information. Every effort will be made to protect the confidentiality of the information provided insofar as it is legally possible.

Enrollment Consent Options

Participants may elect not to have all of the tests, and there will be no possible bad consequences if you do not agree to participate in all the testing.

I agree to participate in the following parts of the study *(check all that apply)*:

☐ Screening exams, including pelvic exam with Pap smear, VIA, and HPV DNA testing (required to be eligible for study enrollment)

☐ Self collected vaginal swab (optional)

☐ Blood sample (optional)

Who to contact if you have any questions:
If you have any questions or concerns about your participation in this study, please call Dr. Meenakshi Jain, the prinicipal investigator of the study at 256231 or 256238, MOBILE 98482-77076. You may also speak with a member of the Mediciti Review Board by contacting Dr. Vijai Kumar at 231-2137, address MediCiti Hospital, Secretariat Road, Hyderabad 500063.

If you agree to participate, please sign your name on the next page.

(This section should be completed when the subject is able to read and sign this consent form)

If you have read this document and you have been given the chance to ask any questions now or at a later time, please sign your name below.

PRINT NAME OF SUBJECT: _____

Signature of Subject or Legally Authorized Representative DATE

Signature of Person Obtaining Consent DATE

(This section should be completed when the subject is unable to read or write.)

If this consent has been read and explained to you and you have been given the chance to ask any questions now or at a later time, please sign or make your mark below.

PRINT NAME OF SUBJECT:_____

Subject's Mark or Signature DATE

Signature of Person Obtaining Consent DATE

Signature of Witness DATE
(Must be different that the person obtaining consent.)

Consent for Storage of Biological Specimens

Cervical cell, cervical tissue, urine, and blood samples will be collected during your participation in this study as part of the research aims and your clinical care. We would like to store any part of the specimen that is left over to use for research in the future. We will not contact you before using the stored sample for new research. We will store the samples until the end of the study (10 years from now). After the end of the study, the samples may be stored indefinitely in a biospecimens repository to be made available for future research that is performed after our study has ended, however at that time we will not be able to identify which samples belong to you.

You may agree to any, all, or none of the following conditions for storing and future access of the biologic material that we collect from you as part of your participation in our study.

Do you agree to *(circler 'YES' or 'NO' for each)*:

YES NO Storage of my samples to use for future research on cervical cancer?,

YES NO Without further contact?,
If no, with contact to ask permission to use the sample for a specific study?
YES NO

YES NO With linked, or identifying information?
If no, as an unlinked or unidentifiable specimen (cannot be traced back to me)? **YES NO**

YES NO Storage of my samples for future studies not related to cervical cancer?,

YES NO Without further contact?,
If no, with contact to ask permission to use the sample for a specific study?
YES NO

YES NO With linked, or identifying information?
If no, as an unlinked or unidentifiable specimen (cannot be traced back to me)? **YES NO**

After completion of specimen storage consent form, obtain signatures separately for this consent on the following page.

You can change your mind at any time; if you want to withdraw your samples from storage, contact Dr. Meenakshi Jain at 256231, 256238 or MOBILE 98482-77076.

If you have read this document and you have been given the chance to ask any questions about storing your specimens now or at a later time, please sign your name below.

PRINT NAME OF SUBJECT: _____

Signature of Subject or Legally Authorized Representative DATE

Signature of Person Obtaining Consent DATE

(This section should be completed when the subject is unable to read or write.)

If this consent has been read and explained to you and you have been given the chance to ask any questions about storing your specimens now or at a later time, please sign or make your mark below.

PRINT NAME OF SUBJECT:_____

Subject's Mark or Signature DATE

Signature of Person Obtaining Consent DATE

Signature of Witness DATE
(Must be different that the person obtaining consent.)

Barcode: _____

ENROLLMENT QUESTIONNAIRE

Study ID:

Name:

Date of Enrollment Visit: __ __/__ __/__ __
DAY MONTH YEAR

Study ID _____

Barcode _____

CATCH (Community Access to Cervical Health)
ENROLLMENT QUESTIONNAIRE

DATE OF INTERVIEW: __ __/__ __/__ __

START TIME: __ __:__ __

SECTION A. INTRODUCTION

Thank you for agreeing to participate in this project. You will make a very important contribution in our efforts to identify the best method to screen for cervical cancer in your community. During this interview, I will ask you some questions about your health in the past, as well as some questions about your general lifestyle. Sometimes, I may ask questions that relate only to specific periods of your life, like your health in the past year. It is important that you try to answer these questions as accurately as you can. Please also remember that the answers you give during this interview will be kept strictly confidential.

A1. First, how have you been feeling during the last month? (WRITE DOWN EXACT RESPONSE)

Study ID _____

Barcode _____

SECTION B. DEMOGRAPHICS

B1. What village do you live in?

_____ VILLAGE NAME

B2. Do you know your date of birth?

__ __ / __ __ / __ __
day month year

B3. How old are you?

_____ AGE IN YEARS
_____ (0.5) DON'T KNOW

B4. Have you ever attended school?

_____ (01) YES
_____ (00) NO; **GO TO B5**

B4a. What was the highest level of school you completed? _____

B5. What is your occupation? _____

B6. I am going to ask you about your religion, are you…

_____ (00) NO RELIGION
_____ (01) HINDU
_____ (02) MUSLIM
_____ (03) SIKH
_____ (04) CHRISTIAN
_____ (05) OTHER (SPECIFY _____)

B7. What is the total monthly income of your family?

_____ RUPEES
_____ (0.5) DON'T KNOW

B8. How many family members are there in your house? _____

B9. How many rooms are there in your house (excluding the toilet)? _____

Study ID _____

Barcode _____

B10. Do you have an inside toilet in your household?

_____ (01) YES
_____ (00) NO

B11. Do you have running water in your household?

_____ (01) YES
_____ (00) NO

B12. I am going to ask you about your marital status, are you…

_____ (00) SINGLE (never married); **GO TO B14**
_____ (01) MARRIED
_____ (02) DIVORCED
_____ (03) SEPARATED
_____ (04) WIDOWED

B12a. How long since you were married?

_____ YEARS
_____ (0.5) DON'T KNOW

B12b. How old were you when you were married?

_____ AGE IN YEARS
_____ (0.5) DON'T KNOW

B12c. How old were you when you first lived with your husband (i.e., at shobodum)?

_____ AGE IN YEARS
_____ (0.5) DON'T KNOW

B13. What is the occupation of your husband? _____

B14. Do you do most of your cooking indoors or outdoors?

_____ (01) INDOORS
_____ (00) OUTDOORS

B15. What type of cooking fuel do you use?

_____ (00) WOOD
_____ (01) GAS
_____ (02) CHARCOAL
_____ (03) KEROSENE OIL
_____ (04) COWDUNG CAKES
_____ (05) ELECTRIC HEATER

Study ID _____

Barcode _____

SECTION C. MEDICAL HISTORY

Next, I would like to ask you some questions about your medical history.

C1. Have you ever had a Pap smear, that is, a test for cervical cancer?

_____ (01) YES
_____ (00) NO; **GO TO SECTION C6**
_____ (0.5) DON'T KNOW; **GO TO SECTION C6**

C2. On what date did you have that Pap smear? If you can't remember exactly, just give me your best guess.

__ __ / __ __ / __ __
day month year

C3. At what hospital did you have the Pap smear taken?

_____
Name of clinic or hospital

_____
Location of clinic or hospital (city)

C4. Were you told that the Pap smear was abnormal?

_____ (01) YES
_____ (00) NO; **GO TO SECTION C6**
_____ (0.5) CAN'T REMEMBER

C5. Did you receive treatment for your abnormal smear?

_____ (01) YES
_____ (00) NO
_____ (0.5) CAN'T REMEMBER

C6. Do you have a vaginal discharge?

_____ (01) YES
_____ (00) NO
_____ (0.5) DON'T KNOW

Study ID _____

Barcode _____

C7. Do you have any other significant gynecologic symptoms? (for example, bleeding after intercourse, bleeding between menstrual periods, pain in lower abdomen, vulvar itching?)

_____ (00) NO
_____ (01) YES; **SPECIFY _____**

C8. Are you currently using any medication?

_____ (00) NO
_____ (01) YES; **SPECIFY IN BOX PROVIDED**

_____
_____
_____
_____

Study ID _____

Barcode _____

SECTION D. SMOKING HISTORY

D1. Have you ever used tobacco-related products (*like cigarettes, pan masala, bidi, tobacco powder, hookah, gutka, etc)*?

_____ (01) YES
_____ (00) NO; **GO TO D8**

	(a)Cigarette	(b) Bidi	(c) Pan Masala	(d) Tobacco Powder	(e) hooka	(f) gutka	(g) Other (specify) _____
D2. Have you ever used…	____(01) Yes ____(00) No **(Go to D2b)**	____(01) Yes ____(00) No **(Go to D2c)**	____(01) Yes ____(00) No **(Go to D2d)**	____(01) Yes ____(00) No **(Go to D2e)**	____(01) Yes ____(02) No **(Go to D2f)**	____(01) Yes ____(02) No **(Go to D2g)**	____(01) Yes ____(00) No **(Go to D8)**
D3. Have you ever used regularly?	____(01) Yes ____(00) No **(Go to D6a)**	____(01) Yes ____(00) No **(Go to D6b)**	____(01) Yes ____(00) No **(Go to D6c)**	____(01) Yes ____(00) No **(Go to D6d)**	____(01) Yes ____(00) No **(Go to D6e)**	____(01) Yes ____(00) No **(Go to D6f)**	____(01) Yes ____(00) No **(Go to D6g)**
D4. In your lifetime, about how many years did you use regularly?	___ Years ___<1 year	___ Years ___<1 year	___ Years ___<1 year	___Years ___<1 year	___ Years ___<1 year	___Years ___<1 year	___Years ___<1 year
D5. During the years that you used regularly, about how much did you use per day?	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day
D6. Do you current use…?	____(01) Yes ____(00) No **(Go to D2b)**	____(01) Yes ____(00) No **(Go to D2c)**	____(01) Yes ____(00) No **(Go to D2d)**	____(01) Yes ____(00) No **(Go to D2e)**	____(01) Yes ____(00) No **(Go to D2f)**	____(01) Yes ____(00) No **(Go to Dg)**	____(01) Yes ____(00) No **(Go to D8)**
D7. About how much do you currently use per day?	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day	____No/day ____<2/day

Study ID _____

Barcode _____

D8. Have you ever lived with anyone who smoked regularly at home?

_____ (01) YES
_____ (00) NO; **GO TO SECTION E**

D9. Please tell me how this person is related to you. **(PROBE: Was there anyone else?) CHECK ALL THAT APPLY.**

_____ (00) SPOUSE
_____ (01) FATHER
_____ (02) MOTHER
_____ (03) SIBLING
_____ (04) CHILD
_____ (96) OTHER (SPECIFY_____)

D10. Do you currently live with anyone who smokes regularly at home? **(PROBE: Was there anyone else?) CHECK ALL THAT APPLY.**

_____ (00) SPOUSE
_____ (01) FATHER
_____ (02) MOTHER
_____ (03) SIBLING
_____ (04) CHILD
_____ (96) OTHER (SPECIFY_____)

Study ID _____

Barcode _____

SECTION E. REPRODUCTIVE HISTORY

E1. At what age did you first start having your menstrual period?

_____ Age in years
_____ (0.5) DON'T KNOW

E2. Are you still having menstrual periods?

_____ (01) YES
_____ (00) NO; **GO TO E4**

E3. What was the first day of your last menstrual period? **PROMPT WITH CALENDAR**

__ __ / __ __ / __ __; **GO TO E5**
day month year

E4. When did you stop having menstrual periods? **PROMPT WITH CALENDAR**

__ __ / __ __
month year

E5. Have you ever been pregnant?
_____ (01) YES
_____ (02) NO; **GO TO SECTION F1**

E6. How old were you when you were first pregnant?

_____ AGE in years
_____ (0.5) DON'T KNOW

E7. How many times have you been pregnant? **INTERVIEWER, PROMPT TO GET ALL LIVING AND DEAD CHILDREN AND TO REMEMBER MISCARRIAGES/ABORTIONS.**

_____ No. of pregnancies
_____ (0.5) Can't remember

E8. How many of these pregnancies resulted in a live birth?

_____ No. of live births
_____ (0.5) Don't know

E9. How many of these pregnancies resulted in a still birth (baby was not born alive)?

_____ No. of still births
_____ (0.5) Don't know

Study ID _____

Barcode _____

E10. How many miscarriages or abortions have you had?

_____ No. of miscarriages or abortions
_____ (0.5) Don't know

E11. When did you have your last child?

__ __ / __ __ / __ __
day month year

Study ID _____

Barcode _____

SECTION F. CONTRACEPTIVE HISTORY

F1. Have you ever used birth control or family planning?

_____ (01) YES
_____ (00) NO; **GO TO SECTION G1**

F2. Have you ever used oral contraceptives?

_____ (01) YES
_____ (00) NO; **GO TO F3**

F2a. Are you currently using oral contraceptives?

_____ (01) YES
_____ (00) NO

F2b. How long did you use/have you been using oral contraceptives?

_____ No. of YEARS
_____ (0.5) Don't remember

F2c. When did you last use oral contraceptives?

__ __ / __ __
month year

F3. Have you ever used injectable contraceptives?

_____ (01) YES
_____ (00) NO; **GO TO F4**

F3a. Are you currently using injectable contraceptives?

_____ (01) YES
_____ (02) NO

F3b. How long did you use injectable contraceptives?

_____ No. of YEARS
_____ (0.5) Don't remember

F3c. When did you last use injectable contraceptives?

__ __ / __ __
month year
_____ (0.5) Don't remember

Study ID _____

Barcode _____

F4. Have you ever used condoms?

_____ (01) YES
_____ (00) NO; **GO TO F5**

F4a. Do you use condoms every time?

_____ (01) YES
_____ (00) NO

F4b. Are you currently using condoms?

_____ (01) YES
_____ (00) NO

F5. Have you ever used an IUCD (Copper-T)?

_____ (01) YES
_____ (00) NO; **GO TO F6**

F5a. Are you currently using an IUCD?

_____ (01) YES
_____ (00) NO

F6. Have you ever had your tubes tied?

_____ (01) YES
_____ (00) NO; **GO TO F7**

F6a. How old were you when you had your tubes tied?

_____ AGE
_____ (0.5) Can't remember

F7. Have you ever used any other form of birth control?

_____ (01) YES; Specify _____
_____ (00) NO

Study ID _____

Barcode _____

SECTION G. INTERVIEWER REMARKS

G1. STOP TIME: __ __ : __ __

G2. Respondent's cooperation was:

_____ (00) POOR
_____ (01) FAIR
_____ (02) GOOD
_____ (03) VERY GOOD

G3. The quality of this interview, by section is: (Complete for each section. Anytime you circle the code for "UNRELIABLE", indicate the main reason the quality of the information was not good by using a code from the categories listed below.)

	UNRELIABLE	GENERALLY RELIABLE	HIGH QUALITY	REASON Code
Section A: INTRODUCTION	1	2	3	|__|__|
Section B: DEMOGRAPHICS	1	2	3	|__|__|
Section C: MEDICAL HISTORY	1	2	3	|__|__|
Section D: SMOKING HISTORY	1	2	3	|__|__|
Section E: REPRODUCTIVE HISTORY	1	2	3	|__|__|
Section F: CONTRACEPTIVE HISTORY	1	2	3	|__|__|

CODES FOR MAIN REASON

Did not know enough information regarding the topic	(00)
Did not want to be more specific	(01)
Did not understand or speak language well	(02)
Was bored or uninterested	(03)
Was upset, depressed or angry	(04)
Had poor hearing or speech	(05)
Was confused or distracted by frequent interruptions	(06)
Was inhibited by others around her	(07)
Was embarrassed by the subject matter	(08)
Was emotionally unstable	(09)
Was physically ill	(10)
Other (Specify in COMMENTS SECTION)	(96)

G4. The overall quality of this interview is:

_____ (00) UNRELIABLE
_____ (01) GENERALLY RELIABLE
_____ (02) HIGH QUALITY

COMMENTS:

Study ID _____

Barcode _____

Study ID

_____

ADVERSE EVENTS FORM
CATCH STUDY

1. Date: |__|__|/|__|__|/|__|__|

2. Form No.: |__|__|

3. Name: _____

4. Village _____

5. Age: |__|__|

6. Adverse event:
   - 1 |__| reported by phone after study visit
   - 2 |__| reported in person after study visit
   - 3 |__| reported during study visit

6a. Person reporting the adverse event:
   - 1 |__| participant
   - 2 |__| relative/other (specify
     - _____(Name)
     - _____(Relationship to participant)
     - _____(Contact information)

7. Date of onset of adverse event: |__|__| - |__|__| - |__|__|__|__|
   month day year

8. Symptoms/site	9. Severity: 1 = mild, 2 = moderate, 3 = severe	10. Duration/unit of time 0 = minutes, 1 = hours, 2 = days, 3 = weeks
1 |__| Bleeding/_____	|__|	|__|__|/|__|
2 |__| burning or severe irritation/_____	|__|	|__|__|/|__|
3 |__| dizziness	|__|	|__|__|/|__|
4 |__| fainting	|__|	|__|__|/|__|
5 |__| fever	|__|	|__|__|/|__|
6 |__| hematoma/_____	|__|	|__|__|/|__|
7 |__| infection/_____	|__|	|__|__|/|__|
8 |__| pain/_____	|__|	|__|__|/|__|
9 |__| thermal injury/_____	|__|	|__|__|/|__|
10|__| trauma from speculum/_____	|__|	|__|__|/|__|
11|__| uterine cramping	|__|	|__|__|/|__|
12|__| nausea	|__|	|__|__|/|__|
13|__| other: _____	|__|	|__|__|/|__|
14|__| other: _____	|__|	|__|__|/|__|
15|__| other: _____	|__|	|__|__|/|__|
16|__| other: _____	|__|	|__|__|/|__|

Clinician code and signature: |__|__|__| _____

Study ID

_____

11. Was treatment provided?
1 |__| No
2 |__| Yes

11a. Treatment provided by:
1 |__| Study clinician: Study staff code |__|__|__|__|
2 |__| other (specify) _____

11b. Indicate type of treatment provided:

_____
_____
_____
_____
_____

12. Current patient status:
1 |__| symptoms completely resolved
2 |__| symptoms present but under control
3 |__| participant requires further medical care

13. Indicate which medical procedures were performed during the last CATCH study visit and indicate association of event to those procedures:

Procedure	Association of event to procedure 1 = not related 2 = possibly related 3 = definitely related		
1 |__| Pelvic examination	1	2	3
2 |__| Collection of cells for cytology/HPV tests	1	2	3
3 |__| Colposcopy	1	2	3
4 |__| Colposcopically-directed biopsy	1	2	3
5 |__| ECC	1	2	3
6 |__| LEEP or other excisional treatment	1	2	3
7 |__| Blood collection	1	2	3
8 |__| Self-collected vaginal swab	1	2	3
9 |__| Treatment for GYN condition	1	2	3

14. Comments:

_____
_____
_____
_____
_____

Clinician code and signature: |__|__|__| _____

Study ID

BIOPSY REQUEST AND RESULTS
CATCH Study

1. Date:		2. Visit Number:
3. Name: _____	4. Age:	5. Village: _____
6. Colposcopic impression: 1|__| Normal 2|__| Leukoplakia 3|__| Low grade 4|__| High grade 5|__| Upper limit AW not visible 6|__| Cancer		
7. Procedure performed: 1 |__| Cervical Biopsy 2 |__| LEEP or Cone 3 |__| ECC 4 |__| Others_____		
8. Number of cervical biopsies taken: |___|1 |___|2 |___|3 |___|4		

9. #	a./b. Biopsy Location (copy from CF)	c. Pathology number	e. Block sequence number	f. Total no. of slides	G 1st slide ID	h. 1st slide sequence number	i. 2nd slide ID	j. 2nd slide sequence number	k. 3rd slide ID	l. 3rd slide sequence number
1	a. |__|__| b. |__|	|__|__|__|__|__|	|__|__|__|	|__|	|__|	|__|__|__|	|__|	|__|__|__|	|__|	|__|__|__|
2	a. |__|__| b. |__|	|__|__|__|__|__|	|__|__|__|	|__|	|__|	|__|__|__|	|__|	|__|__|__|	|__|	|__|__|__|
3	a. |__|__| b. |__|	|__|__|__|__|__|	|__|__|__|	|__|	|__|	|__|__|__|	|__|	|__|__|__|	|__|	|__|__|__|
4	a. |__|__| b. |__|	|__|__|__|__|__|	|__|__|__|	|__|	|__|	|__|__|__|	|__|	|__|__|__|	|__|	|__|__|__|

10. Technician code and signature: \|__\|__\|__\|

_____

10. Cross Reference number: \|__\|__\|__\|__\|__\|

Study ID:

COLPOSCOPY
CATCH STUDY

1. Date: 2. Visit Number:

3. Name: _____ 4. Village _____

5. Colposcopy adequacy:
   1 |__| Satisfactory 2 |__| Unsatisfactory

6. Level of new squamo-columnar junction (SCJ):
   1 |__| SCJ completely visible 3 |__| SCJ completely within the canal
   2 |__| SCJ partially within endocervical canal

7. Colposcopic impression: (only one)
   1 |__| Normal 2 |__| Leukoplakia 3 |__| Low grade (Reid score = 0-3)
   4 |__| High grade (Reid score = 4+) 5 |__| upper limit AW not visible 6 |__| Cancer

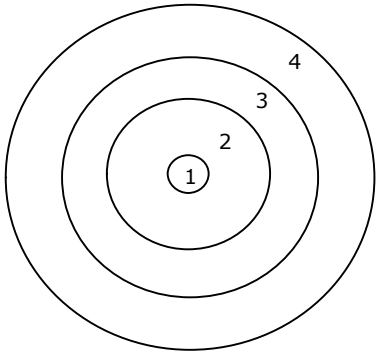
8. Procedure recommended:
   1 |__| Cervical Biopsy 2 |__| LEEP or Cone 3 |__| ECC 4 |__| Others_____
   5 |__| None (Go to #12)

9. Procedure performed:
   1 |__| Cervical Biopsy 2 |__| LEEP or Cone (Go to #12) 3 |__| ECC 4 |__| Others_____
   5 |__| None/refused (Go to #12)

10. Number of cervical biopsies taken: |__| 1 |__| 2 |__|3 |__|4

	Location of the biopsy:	Position on a clock face:	*Distance from the cervix
11_1.	Biopsy #1:	a |__|__|	b |__|
11_2.	Biopsy #2:	a |__|__|	b |__|
11_3.	Biopsy #3:	a |__|__|	b |__|
11_4.	Biopsy #4:	a |__|__|	b |__|

Draw the lesions and the biopsies, and number the biopsies



*Codes for describing the distance from the cervix:

1. In the canal
2. Within the new transformation zone
3. Between the new and old transformation zones
4. Native squamous epithelium

12. How many colposcopy images were taken? |__| 0 |__| 1 |__| 2 (Go to #13)

12a. Comments: _____
_____
_____

13. Procedure details, findings and comments:
_____
_____
_____
_____

Physician code and signature: |__|__|__| _____

Study ID:

Physician code and signature: |__|__|__| _____

Study ID

CYTOLOGY FORM
CATCH STUDY

1. Date:

2. Visit Number:

3. Name: _____

4. Village _____

5. Age:

6. Date received:

7. Date read:

8. Specimen adequacy:
   1 |__| Satisfactory
   2 |__| Satisfactory, but limited by*
   3 |__| Unsatisfactory for evaluation*
   (Do not complete Box __)

8a. *Specify reason
   1 |__| Transformation zone component absent
   2 |__| Scant squamous epithelial component
   3 |__| Partially/totally obscuring inflammation
   4 |__| Obscuring blood
   5 |__| Air-drying artifact
   6 |__| Other: _____

9. Infection (mark all that apply): [Response code 0 if blank, 1 if checked]
   9a |__| HSV
   9b |__| Trichomonas
   9c |__| Candida
   9d |__| Coccobacilli shift in vaginal flora
   9e |__| Other
   9f (specification) _____

10. Epithelial cell diagnosis (Mark all that apply):
1 |__| Negative
2 |__| Reactive cellular changes

11a. Squamous cells
1 |__| ASCUS, NOS

2 |__| ASCUS, favor reactive
3 |__| ASCUS, rule out LSIL
4 |__| ASCUS, metaplastic

5 |__| LSIL, NOS
6 |__| LSIL, cellular changes of HPV
7 |__| LSIL, CIN 1

8 |__| HSIL, NOS
9 |__| HSIL, CIN 2
10 |__| HSIL, CIN 3

11 |__| Invasive squamous cell carcinoma

11b. Glandular Cells
1 |__| Benign endometrial cells in a peri/postmenopausal woman

2 |__| AGUS, NOS
3 |__| Atypical endometrial cells, NOS
4 |__| Atypical endocervical cells, favor reactive
5 |__| Atypical endocervical cells, favor neoplasia

6 |__| Adenocarcinoma in situ (AIS)
7 |__| Adenocarcinoma, NOS
8 |__| Endocervical adenocarcinoma
9 |__| Endometrial adenocarcinoma

10 |__| Other neoplastic:_____
11 |__| Other non-neoplastic:_____

12. Comment:

Pathologist code and signature: |__|__|__| _____

Study ID

HISTOLOGY FORM
CATCH STUDY

1. Date:
2. Visit Number:
3. Name: _____
4. Village _____
5. Age:

6. Pathology number: |__|__|__|__|__|
7. Date processed:
8. Date reviewed:

9. Total number of blocks for case: |__|__|

10. Specimen type and Block designation

11. Diagnosis:

☐ Cervix Biopsy — *enter appropriate code(s)*
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|
Block _____ Position (O'clock) _____ |__|__| |__|__| |__|__|

☐ ECC
Block _____ |__|__| |__|__| |__|__|
Block _____ |__|__| |__|__| |__|__|

☐ Loop or ☐ Cone (If more than 12 blocks, attach additional form)
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|
Block _____ Site _____ |__|__| |__|__| |__|__|

☐ Other, Specify Site _____ & Procedure _____
Block _____ |__|__| |__|__| |__|__|
Block _____ |__|__| |__|__| |__|__|

12. Most severe diagnosis: 01|__|Negative 03|__|Koilo/CIN1 05|__|CIN3 07|__|Invasive
02|__|Atypical metaplasia 04|__|CIN2 06|__|MICRO 96|__|Other

13. Blocks
Cabinet number: |__|__|
Drawer number: |__|__|
Section location: |__|__|

Slides
Cabinet number: |__|__|
Drawer number: |__|__|
Position number: |__|__|

Clinician code and signature: |__|__|__| _____

Study ID

HISTOLOGY FORM
CATCH STUDY

Diagnosis Codes:

Infection (specify in comments)
01 Negative
02 Reactive cellular changes

03 Atypical squamous changes, non-diagnostic
(Specify in comments)

07 LSIL, NOS
08 LSIL, cellular changes of HPV
09 LSIL, CIN 1

10 HSIL, NOS
11 HSIL, CIN 2
12 HSIL, CIN 3

13 Microinvasive squamous cell carcinoma
14 Invasive squamous cell carcinoma

15 Atypical glandular changes, non-diagnostic
(specify in comments)

19 Adenocarcinoma in situ (AIS)
20 Invasive adenocarcinoma, NOS
21 Endocervical adenocarcinoma
22 Endometrial adenocarcinoma

23 Other neoplastic (specify in comments)
24 Other non-neoplastic (specify in comments)

Clinician code and signature: |__|__|__| _____

Study ID

CLINICAL EXAM FORM
CATCH STUDY

1. Date: 2. Visit Number:

3. Name: _____ 4. Village _____

5. Age: 6. Any allergies to medications?
1 |__| Yes (specify _____)
2 |__| No

7. Patient status:
1 |__| Pregnant (defer enrollment)
1a. weeks of gestation |__|__|
2 |__| post-partum
3 |__| post-menopausal
4 |__| abnormal bleeding
5 |__| other: _____

8. External genitalia:
1 |__| normal
2 |__| abnormal*
3 |__| Not done

8a. *If abnormal, indicate findings:
1 |__| erythema
2 |__| edema
3 |__| ulcers
4 |__| vaginal discharge at introitus
5 |__| fissures
6 |__| warts
7 |__| VIN
8 |__| other (specify_____)

9. Vagina :
1 |__| normal
2 |__| abnormal*
3 |__| Not done

9a. *If abnormal, indicate findings:
1 |__| erythema
2 |__| Gartner's duct cysts
3 |__| ulcers
5 |__| fissures
6 |__| warts
7 |__| VAIN
8 |__| other (specify _____)

4 |__| vaginal discharge

a. amount	b. color	c. odor	d. consistency
1|__| minimal	1|__| white	1|__| none	1|__| normal
2|__| moderate	2|__| clear	2|__| foul	2|__| homologous
3|__| profuse	3|__| yellow	3|__| fishy	3|__| curdy
	4|__| brown		4|__| frothy
	5|__| blood		

10. Cervix :
1 |__| normal
2 |__| abnormal*
3 |__| Not done

10a. *If abnormal, indicate findings:
1 |__| erythema
2 |__| edema
3 |__| cervical discharge
10b. **color**
1|__| clear
2|__| opaque white
3|__| translucent white
4|__| yellow/green
5|__| brown
6|__| bloody
4 |__| bleeds easily
5 |__| gross lesions
10c. describe
1|__| Nabothian cysts
2|__| polyp
3|__| ulcer
4|__| leukoplakia
5|__| exophytic lesions
6|__| suspect cancer (triage to colpo)
7|__| other (specify)_____

Gynecologist code and signature: |__|__|__| _____

CLINICAL EXAM FORM
CATCH STUDY

11. Any condition requiring treatment?
    1 |__| No
    2 |__| Yes (indicate diagnosis below, 11a)
        11a. Clinical diagnosis:
            1 |__| atrophic vaginitis
            2 |__| vaginitis (non-specific)
            3 |__| bacterial vaginosis
            4 |__| cervicitis
            5 |__| candidiasis
            6 |__| trichomonas
            7 |__| gonorrhea
            8 |__| herpes lesion
            9 |__| warts
            10 |__| VIN/VAIN
            11 |__| other (specify): _____

12. Was treatment prescribed?
    1 |__| No
    2 |__| Yes
        12a. Indicate type of treatment:
            1 |__| antibiotic (specify:_____)
            2 |__| antiviral (specify:_____)
            3 |__| antifungal (specify:_____)
            4 |__| hormone therapy (specify:_____)
            5 |__| ablative therapy (specify: _____)
            6 |__| other (specify: _____)

13. Can collection of specimens for cytology and HPV testing be completed today?
    1 |__| No, heavy menstrual flow
    2 |__| Yes

14. Pap smear collection:
    1 |__| done, no problem with collection
    2 |__| done, problem with collection (specify: _____)
    3 |__| Not Done (specify reason: _____)

15. HPV sample taken:
    1 |__| done, no problem with collection
    2 |__| done, problem with collection (specify: _____)
    3 |__| Not Done (specify reason: _____)

16. Any complications during the pelvic exam or collection procedures?
    1 |__| No
    2 |__| Yes
        Specify: _____

17. VIA Exam Performed?
    1 |__| No
    2 |__| Yes

Comments:-

Gynecologist code and signature: |__|__|__| _____

Barcode: _____

CATCH STUDY
Community Access to Cervical Health
REFUSAL QUESTIONNAIRE

Study ID:

Name:

Village:

Age: _____ years
_____ (0.5) DON'T KNOW

1. Do you think that cervical cancer can be prevented?
   _____ (01) YES
   _____ (00) NO
   _____ (99) DON'T KNOW

2. Do you think that screening for cervical cancer precursors can prevent cancer?
   _____ (01) YES
   _____ (00) NO
   _____ (99) DON'T KNOW

3. Is there a reason that you do not want to participate in the cervical cancer screening study?
   _____ (01) YES
   _____ (00) NO; **STOP**

4. What is the reason? (Check all the apply)

   _____ (00) No time, inconvenient
   _____ (01) Child care needs
   _____ (02) Fear of cancer diagnosis
   _____ (03) Do not feel screening is important or necessary
   _____ (04) Suspicious of intentions
   _____ (05) Do not trust the doctors
   _____ (06) Afraid that someone will find out about my results
   _____ (07) Did not consent during enrollment
   _____ (08) Other (SPECIFY_____)

Study ID:

Treatment Refusal Form

It has been recommended that I have the following treatment:

☐ LEEP ☐ Hysterectomy ☐ Other _____

I, _____, have received information about the proposed treatment. I have discussed my treatment with Dr. _____ and have been given an opportunity to ask questions and have them answered.

☐ I wish to proceed with the recommended treatment

☐ I do NOT wish to proceed with the recommended treatment but wish to proceed with an alternative treatment _____

☐ I do NOT wish to proceed with the recommended treatment

(This section should be completed when the subject is able to read and sign this consent form)

If you have read this document and you have been given the chance to ask any, please sign your name below.

_____

Signature of Subject or Legally Authorized Representative DATE

_____

Signature of Person Obtaining Consent DATE

Study ID:

(This section should be completed when the subject is unable to read or write.)

If this consent has been read and explained to you and you have been given the chance to ask any questions, please sign or make your mark below.

PRINT NAME OF
SUBJECT:_____

Subject's Mark or Signature DATE

Signature of Person Obtaining Consent DATE

Signature of Witness DATE
(Must be different that the person obtaining consent.)

Study ID

VIA EXAM FORM
CATCH STUDY

1. Date: |__|__|/|__|__|/|__|__| 2. Visit Number: |__|__|

3. Name: _____ 4. Village _____

5. Age: |__|__|

6. Visual Examination Findings: [response 0 if blank; 1 if checked]
   - a |__| Vesicles or ulcers on external genitalia
   - b |__| Excoriation marks on external genitalia, vagina
   - c |__| Cervical polyp
   - d |__| Nabothian follicles
   - e |__| Congenital transformation zone seen

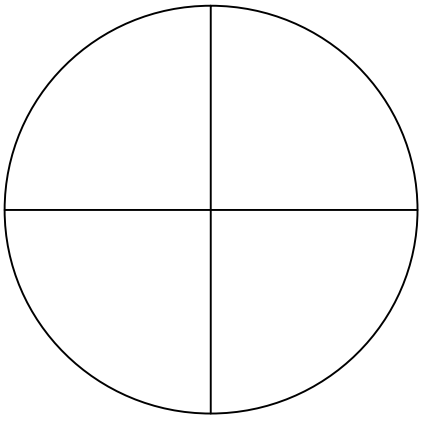
7. Is the complete transformation zone visible?
   - 1 |__| YES
   - 2 |__| NO

8. Findings 1 minute after 5% acetic acid application:
   - 1 |__| NEGATIVE
   - 2 |__| POSITIVE
   - 3 |__| Invasive cancer

9. If VIA is POSITIVE, does the acetowhite lesion extend into the endocervical canal?:
   - 1 |__| YES
   - 2 |__| No

10. If VIA is POSITIVE, how many quandrants on the cervix are involved by the acetowhite lesion(s)?
    - 1 |__| 1 quadrant
    - 2 |__| 2 quadrants
    - 3 |__| 3 quadrants
    - 4 |__| 4 quadrants

11. Indicate the position of the following:



AW: acetowhite lesion
AV: atypical vessels
SCJ: squamocolumnar junction
X: marks the spot that you think requires a biopsy

Gynecologist code and signature: |__|__|__| _____

Study ID

VIA EXAM FORM
CATCH STUDY

12. Reporting the outcome of the VIA (Check all that apply):

12a. VIA negative
1 |__| no acetowhite lesions on the cervix
2 |__| polyps protruding from the cervix with bluish-white acetowhite areas
3 |__| nabothian cysts appearing as button-like areas, as whitish acne, or pimples
4 |__| faint line-like or ill-defined acetowhitening at the squamocolumnar junction
5 |__| shiny, pinkish-white, cloudy-white, bluish-white, faint patchy, or doubtful lesions with ill-defined, indefinite margins, blending with the rest of the cervix
6 |__| angular, irregular, digitating, acetowhite lesions, resembling geographical regions, far away from the transformation zone (satellite lesions)
7 |__| ill-defined, patchy, pale acetowhite areas in the inflamed, unhealthy, ulcerated cervix with bleeding and mucopurulent discharge
8 |__| red spots on the cervix against a pinkish-white background after the application of acetic acid
9 |__| streak-like acetowhitening in the columnar epithelium
10|__| dot-like areas in the endocervix, which are due to grape-like columnar epithelium staining with acetic acid

12b. VIA positive
1 |__| sharp, distinct, well-defined, dense (opaque, dull- or oyster white) acetowhite areas with or without raised margins, abutting the squamocolumnar junction in the transformation zone
2 |__| strikingly dense acetowhite areas in the columnar epithelium
3 |__| condyloma and leukoplakia occurring close to the squamocolumnar junction turning intensely white after application of acetic acid.

12c. Invasive cancer
1 |__| clinically visible ulceroproliferative growth on the cervix that bleeds on touch.

Comments:-

Gynecologist code and signature: |__|__|__| _____