A Pilot Trial for a Non-Inferiority Trial of Clinician-Collected Versus Patient-Collected Cervical Papanicolaou Smears.

NCT01214330

August 23, 2011

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FWH20100177H

WILFORD HALL MEDICAL CENTER/M IKE O'CALLAGHAN FEDERAL HOSPITAL
INFORMED CONSENT DOCUMENT
(ICD Template Version 6. Jan 08)

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INFORMATION ABOUT THIS CONSENT FORM:

You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Taking part in this study is completely voluntary. You do not have to participate if you don't want to. You do not have to participate in this study in order to get standard medical treatment. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you choose not to participate in this research study, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

PRINCIPAL INVESTIGATOR:

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is LtCol Paul Crawford, MD, Associate Program Director, Nellis Family Medicine Residency, Mike O'Callaghan Federal Hospital, Nellis AFB, NV.

Study Sponsor: R& G Medical
5101 Deer Run Drive
Fort Pierce, FL 34951

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R& G Medical, a for-profit company, is funding this study (the sponsor). The sponsor is providing money to Mike O'Callaghan Federal Hospital (MOFH) and Wilford Hall Medical Center, Lackland Air Force Base, Texas so that the researchers can buy supplies and do lab analysis. Dr. Paul Crawford designed the study and drafted the study plan without influence from the sponsor.

Your participation in this study might provide financial benefit to the corporate sponsor in the long-term.

DESCRIPTION/PURPOSE OF RESEARCH (Why is this study being done?)**:**

You are being asked to consider participation in this research study. The purpose of this study is to
1. Determine whether it is feasible to conduct a full study to determine whether the SoloPap™ cervical cell sample collection kit is as good as a clinician performed Pap test in detecting precancerous cervical lesions in females.
2. Begin to determine patient attitudes regarding ease of use and discomfort using SoloPap

The SoloPap "kit" provides to subjects who would not otherwise have a Pap smear done a convenient and private way to collect samples and ship them to a laboratory for processing. The current study is pilot/pre-cursor study for a larger subsequent study that aims to determine whether SoloPap is truly noninferior to clinician-collected Pap smears in detecting cervical pathology. It will also determine user preference and willingness to perform a self- test.

You have been selected to participate in this study because you are having your regularly scheduled Pap Smear appointment.

This study will enroll approximately 150 subjects.

This study involves the use of an investigational device called SoloPap. This means that the device has not yet been approved by the Food & Drug Administration (FDA) for assisting in cervical cancer screening. However, the FDA has not objected to its use to study its safety and effectiveness.

This study will help find out what effects, good and/or bad, this device has. The safety of this device in humans has been tested in prior research studies; however, some side effects may not yet be known.

PROCEDURES:

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If you decide to take part in this research study, you will be asked to sign this consent form.

During your participation in this study, you will be asked to make approximately __1___ outpatient visits with MOFH Physicians, the Principal Investigator (PI) or study staff.

AND

As a participant, you will undergo the following procedures:

Screening – exams, tests, and/or procedures may be done after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Any procedure described below as "standard care" would be done even if you do not take part in this research study.

- The results of the physical examination done as part of your standard care will be used.
- The clinician-collected Pap smear is considered standard of care and will be given regardless if you are in the study or not--the research procedure will be the self-administering of a Pap smear using the SoloPap Kit

The research procedures will add approximately 15-40 minutes to the length of a routine care visit.

AND
The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you and will discuss other possible options.

When it is determined that you are eligible for the study, you will be assigned to have your study pap smear or your standard of care pap smear based on the option that will allow you to be in the clinic for the least amount of time. Everybody will have both the clinician-collected and self-collected pap smear.

Study Procedures - as a participant, you will undergo the following procedures:

- You will be checked in at the Front Desk as usual.
- An investigator will contact you and explain the study to you.
- You will have the opportunity to participate; if you agree, you will sign the consent form and

be given a copy.
- Either before or after your standard of care pap smear, you will be given an experimental SoloPap kit. You will be directed to a private exam room where you will open the kit, read the directions and perform the self-collected pap smear.
- After dressing, you will give the specimen container to the research assistant or investigator.
- You will be placed in the clinician's standard exam room and be given standard of care pre-pap smear instructions, and standard of care counseling by the clinician.
- You will receive your standard of care pap smear.
- This study will add 15-40 minutes to your standard of care pap smear.
- No additional procedures or visits are required for this study.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:
- You do not follow instructions from the researchers.
- The study is stopped.

If you need a procedure requiring additional informed consent, a separate consent form will be given to you before that procedure.

RISKS OR DISCOMFORTS:

Risks from the overall research plan:

There are minimal risks for participation in this study.

The only additional risk with this study is the self-insertion of the tubular speculum. These risks are similar to those incurred when a woman performs normal personal hygiene tasks such as douching or inserting a tampon, and you might have local pain, redness, bleeding, bruising, or you may develop an infection.

There is also a risk of false-positive screening results. If it appears that the SoloPap Kit is producing consistent false-positive results, the investigator will stop the study and notify the IRB and sponsor immediately.

The survey includes information that is normally collected at your Pap Smear visit and some information about whether you thought the self-collection was better or worse than a clinician collected Pap Smear. Your information will be protected by double password protection and kept as secure as a medical record.

Risks from the specific research procedures (drug(s), interventions, or procedures)
There are some minor risks to taking part in this research study. One risk is that you may have side effects while on the study.

Side effects should be mild.

The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

Side effects from this study will usually go away soon after the intervention.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to procedure that is part of this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks and side effects related to the SoloPap include those which are:

Likely

Likely and not serious 90 subjects out of 100-- The obtaining of the Pap smear in any setting may produce some uterine cramping and spotting. This is a side effect of taking cells from the cervix and surrounding areas such as the endocervical canal, or the passageway between the cervix and the uterine cavity. It is present in many cases and has been historically an acceptable side effect.

Less Likely

Less Likely and not serious 2-4 subjects out of 100-- Self-insertion of the tubular speculum. These risks are similar to those incurred when a woman performs normal personal hygiene tasks such as douching or inserting a tampon, and you might have local pain, redness, bleeding or bruising.

For more information about risks and side effects, ask one of the researchers or study staff.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit on the same day. This visit includes answering 4 questions in a survey. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

There may also be unforeseen risks associated with this or any research study.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

BENEFITS:

The investigators have designed this study to learn if the new treatment is as good as or better than or worse than the most commonly accepted treatments. However, there is no guarantee or promise that you will receive any benefit from this study other than knowing that the information may help future patients.

Society may benefit if the sample collected via the SoloPap collection kit results in the same diagnosis when compared to a normal Pap Smear. Some ways society may benefit include 1) increased availability of Pap Smear testing to women who cannot afford or are afraid of clinician collected Pap Smears, 2) decreased rates of cervical cancer in society or the world and 3) increased availability of Pap Smear testing for military women who are deployed.

COSTS: Will taking part in this study cost anything?

The investigators have designed this study so that there is no cost to you to participate in this study other that what it will cost you to travel to the research appointments.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

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ALTERNATIVES TO PARTICIPATION:

Choosing not to participate in this study is your alternative to volunteering for the study. You can still have your standard of care Pap smear by a clinician.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:

Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, the WHMC Institutional Review Boards, and by R&G Medical (only "de-identified" information will be made available to R&G Medical).

A copy of this consent will be placed in your medical and/or research record. A copy of this consent will be stored by the investigator in a locked cabinet in a locked room. Information collected on this study about you that will affect your medical care will be placed in your medical record. All information about you collected on this study will be kept in an electronic database, which will be double password protected and the access will be restricted to people involved in this study. As soon as possible any link between your identity and the research information will be destroyed. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding your health may be required to be reported to appropriate medical or

command authorities.

ENTITLEMENT TO CARE:

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Wilford Hall Chief, Clinical Research, (210) 292-7069 or Michael O'Callaghan Federal Hospital Risk Manager, 702-653-2527.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

BLOOD & TISSUE SAMPLES:

All specimens kept at WHMC will be handled and disposed of in accordance with federal regulations. Laboratories outside of WHMC will not have WHMC permission to use the samples for any additional research.

VOLUNTARY PARTICIPATION:

The decision to participate in this study is completely voluntary on your part. No one has coerced or intimidated you into participating in this project. You are participating because you want to. The Principal Investigator or one of his/her associates has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If significant new findings develop during the course of this study that may relate to your decision to continue participation, you will be informed.

You may withdraw this consent at any time and discontinue further participation in this study without affecting your eligibility for care or any other benefits to which you are entitled.

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CONTACT INFORMATION:

Principal Investigator (PI):

The principal investigator or a member of Nellis Family Medicine Residency staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Paul Crawford, LtCol, USAF, MC Phone: (702)-653-2970

Institutional Review Board (IRB):

The WHMC Institutional Review Board (IRB), the hospital committee responsible for safeguarding your rights as a research subject, has assigned a member of the IRB, who is not part of the study team, to serve as an outside monitor for this study (this person is the Medical Monitor). If you have any questions about your rights as a research subject, research-related injuries, or any other concerns that can not be addressed by the PI, you can contact the medical monitor, James A. Barker M.D. at (210) 916-7338. Or mail to: 59 CSPG/SGVUS, 2200 Bergquist Dr, Lackland Air Force Base, Texas 78236.

In addition, if you have any comments, questions, concerns or complaints, you may also contact the Chairperson of the IRB, at (210) 916-8251. Or mail to: 59th Medical Wing/CM, 2200 Bergquist Drive, Lackland Air Force Base, Texas 78236.

Your consent to participate in this study is given on a voluntary basis. All oral and written information and discussions about this study have been in English, a language in which you are fluent.

If you agree to participate in this research sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.

A signed copy of this form has been given to you.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

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_____ _____

VOLUNTEER'S PRINTED NAME **DOB**

_____

VOLUNTEER'S ADDRESS (street, city, state, zip)

_____ _____ ____-____-____

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **PHONE NUMBER**

_____

PRINTED NAME OF ADVISING INVESTIGATOR

_____ _____

WITNESS' SIGNATURE **DATE**

(Must witness ALL signatures)

_____

PRINTED NAME OF WITNESS

_____

Subject's Stamp Plate

PRIVACY ACT OF 1974 APPLIES.

DD FORM 2005 FILED IN MILITARY HEALTH RECORD

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