

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**INFORMATION AND CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

Study Title: “A randomized, triple-blind, placebo-controlled, parallel clinical trial to investigate the safety and efficacy of Papillex® on the regression of abnormal cervical cells caused by HPV”

Sponsor: Papillex Inc.
Protocol Number: 24PXCFF01
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You are invited to participate in a clinical research study exploring how a natural health product may help the regression of abnormal cervical cells caused by Human Papillomavirus (HPV). The regression of abnormal cervical cells means that the cells in the cervix that were not normal have gone back to being healthy.

Participation in this study is strictly voluntary. To make an informed decision about participating in this study, it is important that you understand the potential risks and benefits of the study. This process, known as informed consent, ensures you have all the information needed to decide.

This consent form outlines the study’s purpose, procedures, potential benefits, risks, and how your medical information will be handled. Please review this document carefully. If you have any questions or need clarification, do not hesitate to ask. The study staff can explain words or information that you do not understand and will address all your questions and concerns. Reading this form and talking to the study staff may help you decide whether to take part or not.

Before the study begins, you must sign this consent form. Please take your time to thoroughly read all the details about the study, and feel free to seek additional information if needed. You have access to this form and can review it at your convenience before making a decision. Once signed, you will receive a copy which you should keep for your records. After your consent is obtained, the study assessments will proceed.

Do not sign this form until you fully understand the information provided and feel comfortable with your decision to participate.

If you wish to contact the study staff, please use the phone number or email address provided at the top of this page.

Background And Purpose

Abnormal cervical cells are classified based on where the changes are happening and how serious those changes are. Sometimes, these abnormal cells can go back to normal on their own. However, there is a risk that these cells could develop into cervical cancer. According to the World Health Organization,



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cervical cancer is the fourth most common cancer in women. This is why it's important to detect and manage abnormal cervical cells early.

Currently, removing abnormal cervical cells requires invasive procedures, such as cutting out the cells (excision) or destroying them with heat or cold (ablation). These treatments can lead to risks like infection, bleeding, scarring of the cervix, and potential pregnancy complications. Because of these risks, it's beneficial to explore safer treatment options.

The study product Papillex® is a dietary supplement. Previous research studies suggest that some of the components of Papillex® may help positively improve abnormal cervical cells. However, the specific study product formulation needs further investigation. The objective of this research study is to examine the safety and efficacy (how well the supplement works) of Papillex® on improving abnormal cervical cells caused by HPV.

Study Population

This study will include approximately 60 women aged 25-60 years old with a history of:

- Cervical Intraepithelial Neoplasia (CIN) 1 or 2, based on histology (tissue and cell analysis) diagnosis within the last 18 months and with confirmed abnormal cervical cells based on cytology (cell analysis) within the past 6 months prior to screening, who are not indicated for treatment or are not currently receiving treatment.
- Positive for human papillomavirus (HPV)

How Long Is The Study?

If you are eligible after the screening visit, your participation in this study will last approximately 180` days and will include approximately 6 study visits to the study center.

You will have the option to continue into an open-label extension period for an additional 6 months. Open-label means you will receive the study product if you decide to continue in the open-label extension period. If you decide to continue into the extension period, your participation in this study will last approximately 360 days and will include approximately 7 study visits to the study center.

For the study timeline, list of events, requirements, and procedures for each visit, refer to the “*Study Visit Schedule and Overview*” section of this document.

Important Things To Note

- To determine your eligibility to participate in this study, detailed information about your lifestyle, medications, and medical history will be collected. This information will help determine if you meet the necessary criteria to participate in this study. By signing this consent form, you are not guaranteed to be enrolled in the study. Your participation depends on meeting the study's specific eligibility criteria, which will be determined through a series of questions and assessments.
- If you voluntarily consent to participate in this study, you must agree and be willing to:
 - Complete questionnaires and diaries associated with the study, and to complete all clinic visits, assessments and procedures
 - Provide personal information, including name, date of birth, health card number, and contact information to a medical practitioner for the purpose of scheduling appointments with external healthcare providers and/or retrieving Colposcopy, Pap Smear and/or HPV testing

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- results. Additionally, you authorize the medical practitioner and KGK Science clinic staff to disclose this information to one another for study purposes
- Provide copies of medical records (such as pathology and cytology reports for PAP, HPV, and/or colposcopy records) for eligibility confirmation
 - Maintain current lifestyle habits (diet, physical activity, medications, supplements, and sleep) as much as possible throughout the study
 - Avoid magnetic resonance imaging (MRI), computed tomography (CT), X-ray, or other procedures with contrast (such as iodine and gadolinium) for 48 hours prior to study visits
 - Avoid blood donations 30 days prior to the enrollment visit (Visit 2), during the study, or within 30 days of the last study visit (Visit 6 or Visit 7 if applicable)
- Travel to external healthcare providers may be required for Colposcopy, Pap Smear and/or HPV testing
 - This study will use competitive enrollment. This means that when a target number of participants begin the study (60), all further enrollment will be closed. Therefore, it is possible that you could be in the screening phase, ready to begin the study, and be discontinued without your consent if the target number of participants have already begun the study. If this occurs, you will not be eligible for study compensation.

Study Visit Schedule And Overview

The following table lists the events, requirements, and procedures for each study visit.

List of Abbreviations
<p>HPV = Human Papillomavirus BMI = Body mass Index CBC = Complete blood count QoL = Quality of Life CIN = Cervical Intraepithelial Neoplasia</p>
Visit 1 – Screening (Day -45 to Day -1)
<p><i>Some portions of this visit may occur virtually.</i></p> <ul style="list-style-type: none"> ● Once consent has been obtained, the screening visit will proceed. You will be given a screening number to keep your information confidential ● Information regarding your medical history (including history of HPV vaccination and test results, HPV warts, normal and/or abnormal PAP test results), medications, and current health status will be collected ● Diagnosis of CIN 1 or 2 (within the past 18 months) will be confirmed ● Urine pregnancy test for individuals of child-bearing potential will be performed ● Blood pressure, heart rate, weight and height measurements will be taken (BMI will be calculated) ● Blood samples will be collected (<i>CBC and clinical chemistry [electrolytes (Na, K, Cl), glucose, eGFR, creatinine, AST, ALT, ALP, and bilirubin], HbA1c</i>) ● Abnormal cytology (i.e., abnormal cells from a Pap smear) result within past 6 months will be confirmed. If no cytology test and/or HPV test was completed within the past 6 months, a cytology test and/or HPV test will be performed ● Eligibility for participation in the study will be assessed



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- Your medications, current health status and any side effects or medical problems will be reviewed
- You will complete the QoL questionnaire and Symptoms Checklist
- Urine pregnancy test for individuals of child-bearing potential will be performed
- Blood pressure, heart rate, and weight measurements will be taken (BMI will be calculated)
- Blood samples will be collected (*Vitamin B12, folate, zinc and selenium, T lymphocytes, IFN β*)
- If you still meet all necessary study criteria and are eligible, you will be randomized (assigned to a study group) and enrolled into the study
- You will receive study product and instructions on use
- You will receive your online study diary and instructions on completion

Compliance Touchpoints (Days 22, 67, 112 and 157 with a \pm 3-day window)

- Study staff will contact you to ensure you are taking the study product as required, answer your questions, and review any side effects or medical problems. You will be reminded to record any side effects or medical problems in your study diary

Visit 3 (Day 45 + 2 days)

- You will return unused study product and packaging to confirm you have been taking the study product as directed
- Your study diaries, medications, and any side effects or medical problems will be reviewed
- New study diaries and study product will be provided to you
- Blood pressure, heart rate, and weight measurements will be taken (BMI will be calculated)
- You will complete the QoL questionnaire and Symptoms Checklist

Visit 4 (Day 90 + 3 days)

- You will return unused study product and packaging to confirm you have been taking the study product as directed
- Your study diaries, medications, and any side effects or medical problems will be reviewed
- New study diaries and study product will be provided to you
- Blood pressure, heart rate, and weight measurements will be taken (BMI will be calculated)
- You will complete the QoL questionnaire and Symptoms Checklist
- Blood samples will be collected (*T lymphocytes, IFN β*)

Visit 5 (Day 135 +3 days)

- You will return unused study product and packaging to confirm you have been taking the study product as directed
- Your study diaries, medications, and any side effects or medical problems will be reviewed
- New study diaries and study product will be provided to you
- Blood pressure, heart rate, and weight measurements will be taken (BMI will be calculated)
- You will complete the QoL questionnaire and Symptoms Checklist

**IRB Approved**

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- You will return unused study product and packaging to confirm you have been taking the study product as directed
- Your study diaries, medications, and any side effects or medical problems will be reviewed
- Blood pressure, heart rate, and weight measurements will be taken (BMI will be calculated)
- You will complete the QoL questionnaire and Symptoms Checklist
- Urine pregnancy test for individuals of child-bearing potential will be performed
- A Pap smear and HPV test will be performed. A colposcopy will be performed if applicable.
- Blood samples will be collected (*CBC, clinical chemistry [electrolytes (Na, K, Cl), glucose, eGFR, creatinine, AST, ALT, ALP, and bilirubin], Vitamin B12, folate, zinc, selenium, T lymphocytes, IFN β*)

If your end of study results require further care (such as: if you screen positive for HPV 16,18/45, if you screen positive for other HPV strains and have high grade cytology changes, and/or other potential abnormal findings) you will be directed to follow up with your primary care physician.

You will be given the option to continue into an open-label extension period for an additional 6 months. *

Compliance Touchpoint (Day 270 \pm 3 days)*

- Study staff will contact you to ensure you are taking the study product as required, answer your questions, and review any side effects or medical problems. You will be reminded to record any side effects or medical problems in your study diary

Visit 7 – Follow up (Day 360 \pm 3 days) *

- You will complete study diaries on a weekly basis (or as needed) to record changes in health or medications, any side effects or medical problems, and study product use.
- At the end of the optional open-label extension period, you will complete the QoL questionnaire and Symptoms Checklist.
- Your study diaries, medications, and any side effects or medical problems will be reviewed
- You will return unused study product and packaging to confirm you have been taking the study product as directed

Assessments And Procedures

The following assessments and procedures will be required throughout the study:

Height and Weight

Weight will be measured at all study visits (Visit 1 – Visit 6). Height will be measured only at Visit 1. Your weight and height measurements will be used to calculate your Body Mass Index.

Vital Sign Measurements

Clinic staff will take vital sign measurements including blood pressure and heart rate at each study visit.



THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE***RAND SF-36 (Quality of Life) Questionnaire***

This questionnaire will assess your overall health-related quality of life. This will be done at baseline (Visit 2, Day 0) and all subsequent visits.

Symptoms Checklist

You will be given a list of possible symptoms related to the presence of CIN and will be instructed to check each symptom you have experienced. This will be done at baseline (Visit 2, Day 0) and all subsequent visits.

Urine Samples

Individuals of child-bearing potential will be required to provide a urine sample for a urine pregnancy test at screening (Visit 1), baseline (Visit 2, Day 0), and at the end of the study visit (Visit 6, Day 180 + 3 days). You will be provided with a collection container and instructed on how to provide the sample.

Blood Sample Collection

Blood samples will be collected at screening (Visit 1), baseline (Visit 2, Day 0), Visit 4 (Day 90 + 3 days), and at the end of the study visit (Visit 6, Day 180 + 3 days). If needed, additional blood samples may be collected during the course of the study in order to perform or repeat laboratory tests. The total blood volume collection will be approximately 165 mL (approximately 11 tablespoons), over the period from screening to the end of the study (approximately 225 days). At any study visit, blood volume collected is not expected to be greater than 66 mL (approximately 4.5 tablespoons).

Papanicolaou (Pap) Test, HPV Testing, Colposcopy

If you have not had a Pap smear test within the past six months of Screening, you will undergo a Pap smear test during Screening (Visit 1). At the end of study (Visit 6, Day 180 + 3 days), you will undergo a Pap smear test. Based on the results of the Pap smear and HPV tests, you may be referred for a colposcopy which will be performed by a trained physician/Obstetrician/Gynecologist, based on the standard of care/opinion of the study doctor. Testing for HPV will occur at Screening (Visit 1) (unless you have already been tested within the past six months and can provide a copy of the results) and at the end of the study visit (Visit 6, Day 180 + 3 days).

Study Diary

You will be required to complete online daily study diaries where you will report study product consumption, any side effects or medical problems, and changes in health or medications. If you decide to participate in the extension period, you will be required to complete the study diaries weekly.

Randomization

Randomized means you will be assigned by chance (like drawing numbers from a hat) to a study group. If eligible, you will be enrolled into the study and will be randomized into **1** of **2** groups:

- Papillex[®] group
- Placebo group

This is a triple-blind study, therefore neither you, the study staff, nor the researchers analyzing the data will know which group you have been assigned to. This design ensures that the study's results are unbiased. Neither you nor the study staff can choose which group you are in, ensuring the integrity of the trial. However, if it becomes necessary for your health, the study staff can access this information.



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A placebo is an inactive substance that looks like the study product but has no active/medicinal ingredients. It is used in research to help determine whether the study product has real effects beyond what might happen by chance or expectation. Using a placebo ensures the study results are reliable by reducing bias, as neither participants, study staff, or researchers will know who is receiving the study product.

Medications, Supplements, And Food/Drinks

If you are taking any prescribed medications, you must agree to maintain your dosing regimen during the study, unless otherwise recommended by your general/nurse practitioner. If they recommend any medication or dose changes, please notify the study staff immediately. You should not discontinue your regular medications unless explicitly instructed by your general/nurse practitioner. Stopping regular medications without medical advice to join this study may worsen your health. If you stop your regular medications, inform the study staff immediately.

- If you are taking any prescribed medications and/or treatments which may affect the study outcomes, you may only be assessed for eligibility if you have been taken off these therapies by your general practitioner or nurse practitioner. The study doctor will recommend an appropriate washout period prior to enrollment in the study.
- If you use any of the following health products, supplements, over-the-counter medications, or foods and drinks, you must be willing to stop taking them and undergo the recommended washout period. You must also agree not to consume these items during the study.
 - Dietary supplements that may be used for CIN (e.g., ALA, echinacea) unless on stable dose for three months
 - Dietary supplements that contain any of the ingredients found in the study product (e.g., folate, vitamin C) unless on stable dose for three months
 - Green tea extract (3 days washout)
- For any other health products, supplements, over-the-counter medications, or foods and drinks which may affect the study outcomes, the study doctor will recommend an appropriate washout period prior to enrollment in the study.

Washout Period: This is a period of time recommended by the study doctor to allow restricted substances (such as medications, supplements, drinks, or foods) to clear from the body before the study begins. If you have recently taken or stopped any restricted substances or participated in activities that conflict with the study, a washout period may be required before enrollment.

Birth Control, Pregnancy, And Breastfeeding

- The effect of the study product on pregnancy and breast milk is not known. You must not participate if you are pregnant, breastfeeding or planning to become pregnant during the study.
- Individuals able to become pregnant (*not post-menopausal, have had a menstrual period in the past 1 year, or have not had any of the following surgeries: hysterectomy, bilateral oophorectomy or bilateral tubal occlusion*) must have a negative screening/baseline urine pregnancy test and agree to use a medically approved method of birth control for the duration of the study

Some examples of approved methods of birth control include:

- Hormonal contraceptives including oral contraceptives, hormone birth control patch, vaginal contraceptive ring, injectable contraceptives, hormone implant or intrauterine hormone-releasing system.



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- If you are using hormonal birth control, you must have been using it for at least 3 months prior to screening
- Double-barrier method
- Intrauterine devices (IUD)
- Non-heterosexual lifestyle or agrees to use contraception if planning on changing to heterosexual partner(s)
- Vasectomy of partner as long as the vasectomized partner is the only sexual partner and has received medical assessment that the vasectomy was successful.
- Abstinence and agrees to use contraception if planning on becoming sexually active

If you become pregnant during the study, you must stop taking the study product immediately and contact the study staff. You will be withdrawn from the study and the study doctor will follow up with you until the child's birth, collect information about your pregnancy, its outcome, and the health of your child.

Since the study product is investigational, there may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you become pregnant.

Study Product Information

The study product and placebo will be in the form of a capsule.

Study Product – Papillex®

Medicinal Ingredients	Quantity per day for Papillex®
Mixed carotenoids	1800 mcg
Vitamin C (ascorbic acid)	180 mg
Vitamin E (D-alpha tocopheryl acetate)	80 mg
Folate (Quatrefolic® (6S)-5-Methyletrahydrofolic acid, glucosamine salt)	960 mcg (folic acid equivalent)
Vitamin B12 (methylcobalamin)	4.8 mcg
Zinc (zinc sulfate)	22 mg
Selenium (selenomethionine)	110 mcg
Green Tea Leaf Extract (decaffeinated; 80% catechins, 50% EGCG, 98% polyphenols)	500 mg
Broccoli Sprout Powder (HiActives®) (standardized to ≥5,000 ppm Sulforaphane)	400 mg
Astragalus (astragalus membranaceus) Root Extract (5:1 extract)	200 mg
Natural all-trans-lycopene	7 mg
Reishi Mushroom Extract (fruiting body; 8:1 extract)	100 mg
Non-Medicinal Ingredients: Hypromellose, Rice Flour, Magnesium Stearate	

Placebo

Non-medicinal ingredients: Rice flour and Hypromellose

Directions:

- You will be instructed to take 2 capsules twice a day with food (total of 4 capsules daily)



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- The first 2 capsules should be taken with your first meal of the day and the second 2 capsules should be taken with your last meal of the day.
- If you forget to take the product, you should take it as soon as you remember on the same day.
- Please do not exceed 4 capsules daily.
- Save all unused and open packages and return them to KGK Science Inc. for a determination of compliance.

Alternative Treatments

This study is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the study.

Additional Safeguards

If you need regular medical care for current medical conditions, you should continue with this medical care throughout the study unless otherwise instructed by your regular physician, specialist, or other healthcare professional. For your safety, you must discuss your current medical care with the study staff, as well as changes in medical conditions during the study. In addition, all new medications including supplements and natural health products (NHPs) that are taken during the study must be reported to the study staff.

The study products are intended for your use only as the study participant. They should not be given to anyone else or left in a place where a small child or a pet could accidentally swallow them. All packaging and unused study products are to be returned to the study staff.

Risks To You

Study Product: It is possible that you could have problems or side effects from the study product that nobody knows about yet. There may be unknown risks with taking the study product.

Potential side-effects of taking the study product may include:

- Gastrointestinal disturbance (for example, stomach pain, nausea, loss of appetite, diarrhea, heartburn)
- Liver disturbances (for example, yellowing of skin/eyes, dark urine, sweating, tiredness)
- Musculoskeletal pain (muscles and bones), limb edema (swelling)
- Rash
- Dizziness

During the course of this study, it is possible that your abnormal cells may progress, worsen or become more abnormal. This may alter your management plan for your condition.

Blood Sample Collection: Some risks associated with blood collection may include pain, bruising, and infection at the site. Alcohol swabs and proper blood collection procedures will be followed to minimize the risk of infection. Fainting during a blood draw can occur, though it is not common. Please advise the study staff if you normally faint with blood draws.

Pap Smear Test and Colposcopy: You may experience some discomfort during the Pap smear test and colposcopy. After a Pap smear, you may experience light spotting and after a colposcopy you may experience light cramping or spotting, but these should resolve within a few days.

THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**Could I Have An Allergic Reaction?**

It is possible for people to have allergic reactions to the study product. If you have a serious allergic reaction, you could die. Please read the study ingredients carefully to make sure you are not allergic to any of them. Some effects of an allergic reaction that could be a sign of a life-threatening (anaphylaxis) include:

- Rash
- Difficulty of Breathing
- Wheezing
- Sudden drop in blood pressure (making you feel dizzy or lightheaded)
- Swelling around the mouth, throat, or eyes
- Fast pulse
- Sweating

You should get medical help or go to the emergency room immediately, and then contact the study staff, if you have any of the above-listed effects or any other side effects during the study.

Contact the study staff if you have questions about the signs or symptoms of any side-effects you read about in this consent form. Please inform the study staff right away if you experience any side-effects, problems with your health or the way you feel during the study, whether you think these problems are related to the study products or not. Please contact the study doctor/staff at 519–438–9374 or via email at clinic@kgkscience.com.

Potential Risks From E-Consent

You will be emailed a PDF copy of this signed consent form or provided with a link via email/text message to download a copy of this consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

Withdrawal From The Study

- Your participation in this research is strictly voluntary. You have the right to choose not to be in the study or leave at any time, for any reason, without affecting your relationship with the study staff and without penalty or loss of benefits to which you are otherwise entitled.
- If you discontinue the study for whatever reason, you are expected to return all study materials, such as study product, to the clinic.
- You may be asked to undergo some final visit procedures. These may include returning to the clinic to provide a final blood sample to test your markers of general health and any end-of-study assessments or questionnaires.
- If the study staff finds out any non-study related information that may greatly affect your well-being (for example, information related to your health), they will share it with you immediately.

The Sponsor has the right to stop the study at any time.

The study doctor may also stop your participation in this study at any time without your consent, but the study doctor will tell you why. Reasons for this may include, **but are not limited to:**

- Missing scheduled study visits
- Not taking study product as directed



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- Not completing required assessments or procedures
- Development of medical conditions or serious side-effects that may pose a health risk to you or the study outcomes
- The need for restricted medication(s) during the study
- If you become pregnant during the study

New Findings

Any significant findings that become available during the study which may influence your continued participation in the study will be disclosed to you as soon as possible.

Benefits

- While there may be no immediate benefit to you, the results of this study will provide some of the required scientific evidence for the study products in this clinical research study.
- Your participation in this study supports the research that is required to ensure the science behind the study products.

Costs To You

- All the tests, study products, examinations, and medical care required as part of this study are provided at no cost to you, the public health plan, or your private medical insurance. All costs will be paid for by the Sponsor of this study.
- You, the public health plan, or your personal medical insurance (if any) should continue to pay for expenses for your current medical care and/or prescriptions. These expenses will not be paid as part of your participation in this study.
- The Sponsor of this study is paying your study doctor for the time, effort, and expenses to conduct this study.

Compensation For Participation

For your time and participation in the study, you will be compensated a total of \$750 if you complete the entire study and all associated requirements.

You will receive your compensation after completion of the study on a Clincard, which can be used like a prepaid Mastercard. It can be used anywhere that accepts Mastercard, or the funds can be withdrawn from an ATM (ATM fees apply). Processing times may apply before funds become available on your Clincard.

If you are enrolled (completed visit 2 and received study product), the compensation breakdown is as follows:

- Screening Visit 1: \$0
- Visit 2: \$100
- Visit 3: \$125
- Visit 4: \$150
- Visit 5: \$175
- Visit 6: \$200

If you choose to continue and complete the open-label extension for an additional 6 months, and attend Visit 7 at the clinic, you will receive additional compensation of \$250.



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Once enrolled, for any case in which you or the study doctor determine you cannot complete all the study visits and assessments, you will receive compensation for the visits you have completed. An early termination visit will be requested where you will bring back all study related materials and be requested to complete some blood work and visit procedures if you consent to doing so. If you complete the early termination visit, you will be compensated \$50.

Compensation And Treatment For Injury

In case of an injury or illness suffered while, and solely as a result of participating in this study, you will receive appropriate medical care. The Sponsor will cover necessary medical costs not covered by the provincial health plan or your private medical insurance (if any). By signing and dating this form, you are not giving up your legal rights, nor releasing the study doctor or Sponsors from their legal and professional obligations. Be aware that the provincial health plan or your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

Confidentiality Of Records

- Staff at KGK Science (the contract research organization managing this study) will keep all your medical information confidential to the extent permitted by law.
- All research data (health information, past medical history, and test results from this study) will be kept in a locked file. Forms on which your information is entered will not contain your name (except for the study intake form and/or external requisitions if applicable)
- Any of your personal information that is stored electronically will be password protected, accessible only to authorized personnel and coded wherever possible. Electronic data may be stored on secure servers which are physically located in Canada and/or the United States.
- You will not be identified in any publication that might result from the study.
- Unless required by law, only the following may have access to confidential study data (not your personal information) at the study site:
 - The study doctor and study staff
 - The Sponsor (including its monitors and auditors)
 - Members of the Research Ethics Board (REB) - Univo REB (an independent ethics committee that reviewed the ethical aspects of this study to help ensure that the rights and welfare of participants are protected and that the study is carried out in an ethical manner)
 - Government regulatory authorities including Health Canada and other foreign regulatory agencies
- While the Sponsor will not have access to your personal identifying information, the study doctor, study staff, monitors, auditors, IRB, and regulatory authorities may review study records, which could include your personal identifying information (such as the signed consent form) for compliance and verification purposes.
- Study records will be kept by the sponsor as required by Canadian clinical trial regulations (currently a minimum of 15 years from the date of completion of the study)
- Information from this study will be submitted to the Sponsor. Information sent from the study site will not contain your name.
- You have the right to check your study records and request changes if the information is incorrect.
- While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy.
- As part of this research, you may be required to use one or more of the following: a phone or web app/ site, an electronic study diary (eDiary), or a device that tracks information about you. While



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using these, information about you may be collected and shared with the researchers or people outside of the study. This data might include personal health information, location, call logs, text message history, web browsing history, or social media use. A complete description of the data collection and sharing for an app, eDiary, or device can commonly be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy or instructions about how to access this information from the study staff.

- While the Terms of Use, End User License Agreement, or Privacy Policy may include statements limiting your rights if you are harmed as a result of your use of the app, eDiary, or device in this study, you do not release the investigator, sponsor, institution, or agents for responsibilities from mistakes. You also do not waive any of your rights as a research participant.

By signing and dating the consent form, you give your consent to collect, use and disclose your health information as described above.

A description of this clinical trial will be available on <https://www.ClinicalTrials.gov> as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Future Contact

By participating in this study, you agree that the study staff may contact you in the future should additional information be needed. This contact would only occur if more data specifically related to your participation in this study is required after you have completed the study, or the study has concluded or expired. Any additional information gathered will be handled with the same confidentiality and privacy protections outlined in this consent form. You may choose not to provide additional information if contacted in the future, without any penalty or effect on the care or benefits you receive.

Whom To Contact About This Study

You can contact the study staff via email or by telephone listed on the first page of this document during the study if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The study doctor's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study and please inform the KGK Science study staff.

A research ethics board (REB) is an independent committee that helps to protect the rights and welfare of research participants. If you have any questions about your rights and welfare as a research participant, or have concerns or complaints regarding this research study, please contact Univo REB at (919) 910-7743 or via email at info@univo-group.com



THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE**Voluntary Consent To Participate**

By signing and dating this document I agree that I have been provided enough time to read and consider whether to participate. I have read and understand all pages of the consent form and information it contains regarding the study in a language I understand. I have been given the opportunity to ask all my questions regarding the study with answers to my satisfaction. I understand that I may consult with the study staff, should anything become unclear or if I have further questions.

I volunteer to be in this study at my own free will and without being pressured by study staff, knowing I have the opportunity to withdraw from the study without giving a reason and without affecting my health care. I understand that if I choose to withdraw from the study, I must notify the study staff. The risks involved with participating in this study are clear to me. I agree to follow the study instructions provided to me by the study staff and understand I may not participate in another study while I am enrolled in this study.

It is clear to me that my data derived from this study will be kept anonymous and may be reviewed by the Sponsor, their agents, the Research Ethics Board, Health Canada and other foreign regulatory agencies. I understand that all my personal information will be treated as strictly confidential, except where disclosure is required by law, and will not be made publicly available; however, absolute confidentiality cannot be guaranteed.

By signing and dating this document, I do not waive any of my rights under the law or release the study doctor or Sponsor from their legal and professional obligations.

I know that the study product is for my use only. I will not share it with anyone, and I will store it in a safe place away from children, pets, or others for whom it is not intended.

By signing this consent form, I agree to provide personal information, including name, date of birth, health card number, and contact information to a medical practitioner for the purpose of scheduling appointments with external healthcare providers and/or retrieving Colposcopy, Pap Smear and/or HPV testing results. I authorize the medical practitioner and KGK Science clinic staff to disclose this information to one another for study purposes.

I understand that I will receive a copy of this signed and dated consent form and am expected to keep it for my records.

IN THE EVENT THAT ELECTRONIC CONSENT IS NOT AVAILABLE:

By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had enough time to consider this information, had an opportunity to ask questions, and voluntarily agree to be in this study.

Printed Name of Participant

Signature of Participant

Date (MMM,DD,YYYY)

Time (HH:MM) AM/PM



THIS IS AN IMPORTANT DOCUMENT – KEEP FOR FUTURE REFERENCE

FOR PERSON EXPLAINING CONSENT

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

Printed Name of Person Explaining Consent

Signature of Person Explaining Consent

Date (MMM,DD,YYYY)

Time (HH:MM) AM/PM

FOR ELECTRONIC CONSENT:

For electronic consent, your name, digital signature, date, and time of consenting will be added below by the consenting software. By adding your electronic signature, you consent to the material provided as if you were physically signing a hard copy of this document.

By signing this informed consent document, you acknowledge that you have read and fully understand all pages of the information presented in it, had an opportunity to ask questions, and voluntarily agree to be in this study.

Participant

I voluntarily agree to participate in this study.
↓

Delegated Study Staff

I attest that the participant had enough time to consider this information, had an opportunity to ask questions and voluntarily agreed to be in this study.
↓