

## INFORMED CONSENT FORM

**Name of the Project:** “Alternative strategy for the early detection and prevention of cervical cancer. Introduction of the HPV Test in the primary screening in Opesilandia.”

**Purpose:** To improve the early detection of cervical cancer through the introduction of the HPV test in the primary examination of women between the ages of 30-59 years of age in Opesilandia.

**Background:** The HPV test is a remarkably sensitive method for detecting the leading cause of cervical cancer, which is the Human Papilloma Virus (HPV). It is important to know that cervical cancer is extremely frequent in Opesilandia, that many women die because of this disease and that it can be cured if the precancerous lesions are diagnosed on time and treated immediately.

**Procedures:** The study will consist in the sampling of cervix material for Pap and HPV tests, taken by trained health workers from the Family Health Units in the five hospitals in Opesilandia. A specialized physician at the Clinic for Tumors of the Ministry of Health will perform a colposcopy and a biopsy in all of those women with a positive result by Pap and/or HPV test, in order to analyze if they do or do not have a precancerous injury. If it is confirmed that there is an injury, these women will be treated immediately. A selected group of women with negative Pap and HPV tests will also be given a colposcopy and if there is an injury there will also be confirmation and treatment. All participants will be asked to answer a questionnaire, in order to know the risk factors for cervical cancer.

**Risks:** There are no risks of participation in this study, and the discomfort caused by the sampling of the Pap, the HPV test and the colposcopy is minimal. The biopsy is painless and it can cause minimal bleeding that will be treated immediately by the specialized physician. Very rarely, complications may occur after the procedure, in which case the patient will be seen at the specialties polyclinic in her neighborhood.

**Benefits:** If you choose to participate in the study you will have: 1) Free access to all the diagnosis procedures: Pap test, HPV test, colposcopy, biopsy; 2) Diagnosis to find about your state of health; 3) Free treatment if you are a carrier of a precancerous injury; 4) More information on cervical cancer, its consequences and how to prevent it

Your participation will help scientific research, since the results of this study will be used to assess its applicability in other areas of the nation, so that more women can benefit and thus improve the prevention and control of cervical cancer in Opesilandia.

**Confidentiality:** The identity of each participant will be confidential and her name will not appear in any report of this study. All the data and results of the study will remain confidential and they will not be disclosed to any one other than the coordinators of the study or the regulating authorities. All the data will be processed in the form of codes and will be stored in a computer with restricted access to researchers of this study.

**Alternatives:** You can choose not to participate in this study.

**Who to contact:** For any questions or issues related to this study, you can contact the Department of Public Health and Epidemiology.

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I ..... (Name(s) and Last name(s))

Have read the information given to me

Have been able to ask questions regarding the study

Have received enough information on the study and its benefits

Have spoken with ..... (Name of investigator)

ID No.....

I understand that my participation is voluntary.

I freely consent to participate in the investigation

Date...../...../.....

Signature of participant .....

ID No.....