INFORMED CONSENT FORM

Study: "Conservative management of CIN2 lesions and evaluation of biomarkers for the identification of CIN2 lesions with a high probability of spontaneous regression"

I undersigned_____

born in_____on_____

resident in_____

telephone_____

I declare

- To have been informed that I have been diagnosed with a cervical lesion called CIN2 and that there is scientific evidence that this lesion can also regress spontaneously;
- To have received exhaustive explanations regarding the research project, which involves the non-immediate treatment of CIN2 lesions but a check-up every six months for two years, to which I declare that I am available;
- To have been informed that if the lesion is found to be persistent or evolving in one of the subsequent checks, the treatment will be carried out immediately;
- I have had sufficient time to carefully read, understand and eventually have additional information on the contents of the information leaflet;
- To be aware that participation is voluntary, with the assurance that refusal to participate will not affect receiving the most suitable treatment;
- To voluntarily participate in the Project and to adhere to the scheduled checks;
- That the biological material obtained with the biopsy or cytological sample can be stored and used subsequently to carry out exclusively tests relating to the purposes of the study in question, i.e. the prevention and treatment of cervical cancers;

- That the data concerning me are strictly confidential and will be used exclusively for the purposes indicated in the project (pursuant to Legislative Decree 196/2003, and subsequent amendments and additions as per the Guarantor's Guidelines for the processing of personal data within the scope of Clinical Trials - Official Journal 190 of 14 August 2008 and pursuant to the European Regulation for data protection no. 679/2016) and as per any other prescription/authorisation of the Guarantor itself, and which will be processed in such a way as to guarantee the confidentiality of my identity;
- That the data concerning me will only be disclosed in a strictly anonymous form, for example through scientific publications and scientific conferences;

- That it is my right to have access to the documentation concerning me and to the evaluation expressed by the Provincial Ethics Committee, which I can contact if I deem it appropriate;

- That a copy of the informed consent and the documentation I have read will remain in my possession;

- That for any problem or further information I can contact the screening program secretariat by calling……..

Therefore,

I AGREE

FREELY, SPONTANEOUSLY AND IN FULL CONSCIENCE TO PARTICIPATE IN THE RESEARCH PROJECT PROPOSED TO ME and I consent to the processing of my personal data for the purposes of the project, within the limits and with the methods indicated in the information above, provided to me pursuant to art. 13 of Legislative Decree 196/2003 and pursuant to the European Data Protection Regulation no. 679/2016.

I also declare that I am aware of the possibility of revoking this consent at any time.

Date_____________ Legible signature of the participant _________________________

Colposcopist gynecologist (name, surname, legible signature):

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OR

I DO NOT AGREE

FREELY, SPONTANEOUSLY AND IN FULL CONSCIENCE TO PARTICIPATE IN THE RESEARCH PROJECT PROPOSED TO ME.

Date_____________ Legible signature of the participant _________________________

Colposcopist gynecologist (name, surname, legible signature):

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Participating Center:____