Protocol **RCT-PAS**	N° 1751

INFORMED CONSENT

Hysterectomy Vs Partial Myometrial Resection For Placenta Accreta Spectrum (PAS). A Feasibility Study Of A Randomized Controlled Clinical Trial (RCT-PAS)

Principal Investigator: xxxxxxxxxx

Institution name: _____

Introduction:

Abnormally inserted placenta or placenta accreta spectrum (PAS) refers to the abnormal adhesion of the placenta to the uterine walls. According to the degree of invasion of the placenta to the uterus wall, PAS is classified as placenta accreta, increta, and percreta. It occurs in about 1 in every 500 births and can produce, during cesarean section, heavy bleeding, abdominal organ damage, and maternal mortality in very severe cases.

There are two main treatment modalities for placental accreta, the most used modality in the world is hysterectomy (Removing the uterus), however, there is a resective-reconstructive treatment modality in which only the part of the uterus affected by accrete is removed and the rest is preserved, thus performing a less complex surgery.

The best treatment modality for this pathology is still uncertain; evidence suggests that hysterectomy is associated with a higher proportion of surgical complications such as abdominal organ damage, while resective-reconstructive treatment is associated with a lower probability of organ damage.

Current tendency is to perform hysterectomy for patients with more severe PAS, preferring reconstructive resective treatment for patients with less severe PAS; this approach may result in a higher or lower rate of complications from one or another procedure, likely being associated to the degree of invasion of the placenta to the wall of the uterus and not to the treatment modality used.

1. Purpose and procedures:

This is a feasibility study of a clinical trial; a first approach that will allow us to check if all the procedures proposed can be correctly carried out, aiming of help us on planning a definitive clinical trial. Objective of this later clinical trial will be to explore the most appropriate treatment modality for placental accreta.

If you decide to participate in this study, your cesarean section will be done under the highest quality standards, as is currently done. Once the placental accreta is confirmed during surgery, you will be randomized (this means assigned by chance) to one of the intervention groups: obstetric hysterectomy or resective-reconstructive treatment. the chance of being assigned to one group or another is 50% for each group.

There is a chance that you might be assigned to the resective reconstructive treatment group and this procedure could not be technically possible; a hysterectomy will then be necessary. Either procedure will be carried out by the treating medical team.

Additionally, we will store images and videos of your surgery with details of the intraoperative findings for the study purposes.

2. Voluntariness of participation:

Participation in this study is completely voluntary. After reading and listening to all the information provided by the research group and treating physician, you can make the decision to participate or not.

If for any reason you are not eligible for the study, or decide not to participate, this will not affect the adequate and timely treatment of your pathology.

3. Duration:

Your participation will last 42 days, from the moment this Informed Consent is signed, to last telephone contact at D42 of surgical intervention. Total study will approximately last 24 months from the inclusion of the first participant and will be considered finalized when last randomized patient have been contacted at D42 after the surgical intervention.

4. Potential Risks:

The study does not present additional risks to those already inherent to the intervention to be performed and that have been explained by the treating medical team; probable surgical complications will not be increased, quite you decide to participate or not. The treatment that you will receive, if you decide to participate in this study, is most likely the same that you would receive, if you chose not to participate.

5. Potential benefits:

There are no benefits for participating in the study. However, the information we will get from the study will help to improve the treatment of women with placenta accreta spectrum in the future.

6. Confidentiality:

All information collected for the study is confidential. We will not use your full name in any study document; instead un identification number will be assigned to you by the study. Only staff working on this study may have access to your information, which will be safely kept at each of the participants sites. The research group assumes the responsibility of providing you with updated information on the study, so this may affect your decision to continue participating.

7. Payment or additional expenses for patients:

You will not receive any remuneration for participating in the study. Participation in this study is free of charge; no any additional expenses are previewed for you. Any complications arising from your participation in the study will be treated according to the treatment protocols of each hospital, without an additional cost to you.

8. Emergency contact:

If you have any questions, or experience any problem or inconvenience that you consider related to the study, please contact the principal investigator Dr. Xxxxx XXXXX at Telephone No. xxxxxxxxx or the Study Coordinator Xxxxx XXXXX at Telephone No. xxxxxxxxx .If you have any questions regarding this research project or your rights as a Research subject, you should contact the Ethics Committee (Name of Ethics Commeettee), and the President of the Ethics Committee at Telephone No. xxxxxxxxx

9. Data treatment policy:

Personal data management will be treated as by each country law and in accordance with each participant institution policies.

10. Who has reviewed this study?

This study has been reviewed and approved by (Name of Ethics Commeettee), which is responsible for ensuring that all subjects participating in research are treated with dignity and their rights are respected. If you have any questions, you can contact the President of the Ethics Committee at Telephone No. xxxxxxxxx, which is part of an independent group that has reviewed the study.

11. Participant Declaration

I confirm that I have read and understood the text that goes from page No. 01 to page No. 06 of this document, I have had the opportunity to ask questions and all my doubts have been clarified by the principal investigator.

_____	_____
Participant's Name	Participant Signature
_____	_ _ / _ _ _ / _ _ _ _
ID N°	Date (dd/mmm/aaaa)

NOTE: THIS SECTION SHOULD BE FULFILLED ONLY BY WITNESS No 1

_____ Witness Full Name	_____ Signature
_____ ID N°	_ _ / _ _ _ / _ _ _ _ Date (dd / mmm / aaaa)
_____ Address	_____ Relationship with the volunteer

With my signature I certify that I was present during the discussion of the Consent Form, all doubts were satisfactorily resolved and the voluntary participation of the patient.

NOTE: THIS SECTION SHOULD BE FULFILLED ONLY BY WITNESS No 2

_____ Witness Full Name	_____ Signature
_____ ID N°	_ _ / _ _ _ / _ _ _ _ Date (dd / mmm / aaaa)
_____ Address	_____ Relationship with the volunteer

With my signature I certify that I was present during the discussion of the Consent Form, all doubts were satisfactorily resolved and the voluntary participation of the patient.

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NOTE: THIS SECTION SHOULD BE FULFILLED ONLY BY SPOUSE.

_____	_____
Spouse Full Name	Signature
_____	_ _ / _ _ _ / _ _ _ _
ID N°	Date (dd / mmm /aaaa)
_____	
Address	

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Researcher who administered the consent Date (dd /mmm / aaaa)
Full Name

Researcher who administered the consent
Signature