INFORMATION AND CONSENT FORM – Couple version
Services and healthcare for women and their partners during a miscarriage in the emergency room

Research project title	**Toward improved services and care for women and their partners during a miscarriage in the emergency room: Evaluation of the continuum of primary care services.**
Funding agency	**Fonds de recherche en santé du Québec (FRQS)**
Principal Researcher	*Francine de Montigny*, Ph.D. Psychology, Professor of Nursing, Université du Québec en Outaouais
Co-researchers	*Luisa Ciofani*, RN, M.Sc.(A), IBCLC, PNC(C), Associate Director of Nursing – Women's Health Mission, McGill University Health Centre
	Anne-Marie Lanctôt, RN, M.Sc.(A), Nurse Manager – Women's Health Ambulatory Services, McGill University Health Centre

Introduction

We are inviting you to participate in a research study, as you have recently consulted a hospital emergency room doctor or the Early Pregnancy Rapid Access Clinic because you (or your partner) were going through a miscarriage. However, before agreeing to participate in this project or signing the information and consent form, please take the time to read, understand, and carefully consider the information below. We encourage you to address any questions you might find useful to the principal researcher or to any other personnel assigned to the study, and to ask them to explain any word or item of information that is not clear.

Nature and objectives of the study

The purpose of this study, which is being conducted in nine centres in Quebec over a 3-year period, is to examine women and their partners' experience of services received at the emergency room and within the community following a miscarriage, as well as the experience of emergency room health professionals in providing care for these couples. The aim is to identify the best professional practices for women and their partners following the loss of a child in the early stages of pregnancy. To this end, the researchers wish to recruit 200 couples who have experienced a miscarriage in an emergency room, as well as 200 doctors, nurses, and managers working in the emergency room of a Quebec health establishment. There will be 40 to 60 couples recruited at the McGill University Health Centre.

The nine sites for this study include the Royal Victoria hospital of the McGill University Health Centre; CSS Ste. Jerome, St-Eustache and des Sommets; Ste-Justine Hospital; CSSS de l'Outaouais; CSSS Trois Rivières; Centre Mere-Enfant - St. François Hospital (Quebec City); Hôtel Dieu de Levis Hospital; St-Hyancithe Hospital Centre; and CSSS de Chicoutimi.

Nature of the participation being requested

If you agree to participate in the study, after having signed this form, your participation will consist in:

a) Completing a telephone or online survey of about 20 minutes regarding your experience of receiving services in the emergency room and within the community following a miscarriage. You will be asked to complete this survey three times, at 6 to 8 weeks following your miscarriage, then again 6 and 12 months after the miscarriage.

b) If you agree, you might also take part in an individual interview of about 60 to 90 minutes regarding your experience of receiving services in the emergency room during a miscarriage. The interview will be audio-recorded and will take place at your home or any other place of your choosing, between 6 and 8 weeks after your loss.

Voluntary participation and the possibility of withdrawing

Your participation in this research project is voluntary. You are therefore free to refuse to participate. You may also withdraw your participation at any time, without providing any explanation, by informing a member of the research team.

Your decision not to participate in this research project or to withdraw your participation will in no way affect the quality of care and services you are entitled to receive nor on your relationship with the members of the health care team.

If you withdraw from this research project or are withdrawn from the research project, the information already collected from your participation will nonetheless be conserved.

Benefits

Your participation in this research will contribute to adapting and implementing professional practices in Quebec emergency rooms geared toward women and men who go through a miscarriage in Quebec emergency room services. You may derive a personal benefit from participating in the study, as some women and men may find it helpful to talk about their experiences related to miscarriage, but we cannot guarantee it.

Risks and inconveniences

There is no physical risk associated with the procedures involved in this study. However, apart from any inconveniences related to the time needed to participate in the project, you may, as a man or woman, experience discomfort being presented with certain questions of a personal nature. You should not hesitate to bring this up, so that the professionals can offer the necessary support by referring you to various appropriate resources, depending on your situation. You are also free to refrain from answering any questions that make you uncomfortable.

Confidentiality

During your participation in this research project, the principal investigator responsible for the project as well as members of the research team will collect information related to your participation and required to meet the scientific objectives of this research project in a research chart.

All the collected information will remain confidential within the limits of the law. Your identity will be protected by replacing your name with a research code. Only the research team from your hospital, Luisa Ciofani and Anne- Marie Lanctôt will have access to the link between your name and the code.

You have the right to consult the data in the research chart to verify the accuracy of the information and to modify it should that be necessary. However, in order to preserve the integrity of the scientific data of the research project, you may not have access to certain information only once your participation has finished.

In order to verify that the research project is conducted appropriately, and to ensure your protection, the following organizations may consult your research chart as well as your medical record:

- the sponsors of the research project;
- government regulatory bodies;
- the research ethics committees of the hospitals in Quebec participating in this research project or an individual mandated by the committee.

Members of these organizations adhere to a confidentiality policy.

The research findings may be published or may become part of scientific discussions/ meetings but it will not be possible to identify you. The data may also be analyzed in conjunction with related projects or findings may be used to develop future research projects.

The collected and coded research data will be kept in a secure manner for a period of five years after the completion of the study under the responsibility of Dr. Francine de Montigny at the Université du Québec en Outaouais.

Compensation

You will not receive any compensation for participating in this study.

Resource persons

For any information regarding this research project, you may contact Francine de Montigny, the principal researcher, at 1-800-567-1283, extension 2257 (Université du Québec en Outaouais., Gatineau).

At the McGill University Health Centre, you may contact the local investigator, Luisa Ciofani at (514) 934 – 1934 (34372).

Should you have any questions about your rights as a research participant, you may contact the Ombudsman at the MUHC at (514) 934-1934 (35655).