UNIVERSITY OF ALBERTA

Centre of Excellence for Gastrointestinal Inflammation and Immunity Research (CEGIIR)
Division of Gastroenterology
Department of Medicine

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IBD Patients
INFORMATION SHEET & CONSENT

Reproduction, Pregnancy, and Lactation in Inflammatory Bowel Disease
CEGIIR Additional Consent

Principal Investigator: Dr. V. Huang
Sub-Investigator(s): Dr. R. Fedorak, Dr. Kroeker, Dr. L. Dieleman, Dr. K. Goodman, Dr. B. Halloran, Dr. K. Hegadoren, Dr. E. Wine, Dr. H. Hyunh, Dr. A. Mason, Dr. K. Madsen, Dr. E. Elahi

BACKGROUND

Inflammatory bowel disease (IBD) is a chronic disease that affects patients of all ages, especially those in their reproductive years. Women with IBD have concerns regarding their ability to become pregnant, to carry a pregnancy to term, and to have healthy infants. We know that there are many interactions between IBD and pregnancy, and that control of the disease is the best management we have for IBD during pregnancy. However we do not know why some women do well during pregnancy, while others flare. This is important because active IBD during pregnancy is associated with poor pregnancy outcomes (miscarriage, pre term delivery, smaller infants). Patients with IBD require immunosuppressive medications to keep their disease under control. However, maternal IBD, maternal microbiome (bacterial flora), and maternal medications, can affect the fetus and infant, but how everything is related is not well understood. Recently, a few studies have reported low blood cell counts in the infants born to mothers with IBD who are on immunosuppressive medications. However, these studies had no comparison group of infants born to healthy mothers, and it is unclear the effect of maternal IBD and IBD medications on the infant's immune system.

We hope that by following women with IBD before, during, and after pregnancy and analyzing blood, stool, urine, and breast milk samples for certain chemical markers or genes we may be able to better understand and manage IBD during pregnancy.

We hope that by following infants born to women with IBD, and analyzing cord blood, placenta, maternal breast milk, and stool samples for certain chemical markers or bacteria and viruses, as well as blood cell counts, we may be better able to understand the impact of maternal IBD on infants born to women with IBD.

WHY ARE YOU BEING INVITED TO PARTICIPATE?

You are being asked to participate for the following reasons:

a) You have Crohn's disease, ulcerative colitis, or indeterminate colitis.
b) You are considering pregnancy or are pregnant or are breastfeeding.

WHAT DOES THIS INVOLVE?

You will be asked to complete a series of questionnaires, and to provide blood, urine, stool, and other listed samples at each visit. The samples will be stored in the CEGIIR (Centre of Excellence for Gastrointestinal Inflammation and Immunity Research) biobank. They will be analyzed in the future for chemicals and bacteria that may affect reproduction and pregnancy in IBD. By collecting a large number of samples from many people, at different times of reproduction and pregnancy, this allows researchers to analyze samples from several people at one time. Samples will be stored without any personal identifiers attached (this means things like your name

will not be attached to the samples). Samples will be identified by a "code", so researchers will never know that the samples and information about you came from you. This also means that you will not receive any information about the results from the research on the samples. We will maintain a list that links your sample to your name but only certain individuals in the research group will have this link, and they will only use it if you ask to have your samples removed in the future.

You will have the option to consent to some or all aspects of this study.

The study visits will coincide with your routine clinical visits that you will attend as part of the Reproduction, Pregnancy, and Lactation in Inflammatory Bowel Disease Clinic. These include:

1) pre-conception: if you are considering or trying to become pregnant
2) 1st trimester: one visit
3) 2nd trimester: one visit
4) 3rd trimester: one visit
5) Delivery
6) 3 months post-partum
7) 6 months post-partum
8) 12 months post-partum
9) any extra visit(s) that you may require due to a flare of your disease

At each visit, except where noted below, you will be asked for the following:

1) Questionnaires: You will be asked to complete various questionnaires to assess your medical, social, reproductive, and IBD history. These should not take more than 10-15 minutes.

2) Blood samples: You will be asked to provide an additional 30cc of blood at each visit. The expected total blood volume collected for the entire study (From preconception to 12 months post-partum) is 210ml. This can vary depending on what stage you are in at the time of your first visit (baseline visit). This may also vary depending on how many preconception visits are completed, since preconception visits are every 6 months until you become pregnant, or any extra visits due to a flare of your disease.

3) Urine and stool samples: You will be asked to collect urine and stool samples at home and bring them to each visit.

4) Delivery samples: If you consented to provide delivery samples, you would need to inform us of expected delivery date, and when you go to hospital for delivery. We will coordinate with you the collections to occur at your delivery hospital.

- **Cord blood samples:** If you wish to do cord blood banking, please speak with your obstetrician. Samples for this research study will be collected only after clinical samples are obtained. As these research samples will be analyzed and stored for research purposes, results will not be available for clinical use.
- **Placenta samples:** You will be asked for consent to collect placenta samples, taken during delivery. If you consent to participate in this portion, you would need to inform us when you go into labour.
- **Breast milk sample:** You will be asked to provide breast milk sample shortly after delivery (within 48 hours if possible).
- **Neonatal stool sample:** You will be asked to collect stool from your infant after delivery (first stool sample ("meconium") if possible, but within 48 hours)

5) Breast milk samples: You will be asked to collect breast milk samples at home to bring to your post-partum visits (3 months, 6 months, and 12 months postpartum).

6) Neonatal outcomes: You will be asked at 3 months, 6 months, and 12 months post-partum visits for information regarding the health of your child. This includes questionnaires about the growth and development of your child.

7) Neonatal stool samples: You will be asked to collect stool samples from your infant – 3 months, 6 months and 12 months of age. Ideally this would be collected on the same day as your own blood, urine, stool, breast milk collections.

8) Review of medical records: Your signed consent will allow us to access your medical records (including Alberta Netcare) if needed to obtain further details of your medical history.

9) Review of medical records of neonate: your signed consent will allow us to access the medical records (including Alberta Netcare) if needed to obtain further details of your infant's medical outcomes.

The study staff may need to contact you at a later date (within 1 year after completion of the study) for clarification of your medical history or responses to the questions in the questionnaire.

POSSIBLE RISKS

You may experience a small amount of discomfort from having blood samples drawn. However, the blood samples will be collected concurrently with standard of care labs at the time of the clinic visit.

Your infant will not experience discomfort from stool samples as they will be collected from their diapers. As the samples will be stored for future research analysis, including genetic analysis, results will not be available for immediate clinical care. If you have questions or concerns, you may contact the study investigator at the number provided below.

POSSIBLE BENEFITS

You may not benefit directly from this study, but you will help researchers better understand the complex interaction between pregnancy and IBD, and thus help physicians to provide better treatment in the future for pregnant IBD patients, to improve maternal and fetal outcomes.

CONFIDENTIALITY

Personal health records relating to this study will be kept confidential. Any research data collected about you during this study will not identify you by name, only by your initials and a coded number. Your name will not be disclosed outside the research clinic. Any report published as a result of this study will not identify you by name. For this study, the study doctor may need to access your personal health records (including electronic health records from Alberta Netcare) for health information such as past medical history and test results. The health information collected as part of this study will be kept confidential unless release is required by law, and will be used only for the purpose of the research study.

During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta or Health Research Ethics Board.

By signing the consent form you give permission to the study staff to access any personally identifiable health information, which is under the custody of other health care professionals as deemed necessary for the conduct of the research. Study documents and study data will be stored for a minimum of 5 years in secured locked storage of the principal investigator, and on the secured intranet at Division of Gastroenterology at the University of Alberta.

VOLUNTARY PARTICIPATION

You are free to participate in certain parts of the study as you feel comfortable doing. You are free to leave questions blank if you so choose. You are free to withdraw from the research study at any time, and your continuing medical care will not be affected in any way. If you decide to withdraw from the study, any data and

samples already collected from you will still be used for the research, unless you also ask for them to be withdrawn. If the study is not undertaken or if it is discontinued at any time, the quality of your medical care will not be affected. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study you will be promptly informed.

ALTERNATIVES

You do not have to take part in this study to receive care for IBD during pregnancy. If you choose not to be in this study, you will receive the same care and treatment as you normally would and no data or samples will be collected for this study.

REIMBURSEMENT OF EXPENSES

There is no paid reimbursement for participation in this study.

CONTACTS:

If you have any questions about the study, you may contact us at 780-248-1038 or pregibd@ualberta.ca.

The plan for this study has been reviewed for its adherence to ethical guidelines by a Research Ethics Board at the University of Alberta. For questions regarding participant rights and ethical conduct of research, contact the Research Ethics Office at (780) 492-2615.

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CONSENT FORM

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	Yes	No
1) Do you understand that you have been asked to participate in this research study?	☑	☐
2) Have you read and received a copy of the attached Information Sheet?	☑	☐
3) Do you understand the benefits and risks involved in taking part in this research study?	☑	☐
4) Have you had an opportunity to ask questions and discuss this study?	☑	☐
5) Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☑	☐
6) Do you understand the issue of confidentiality, and do you understand that the research team will have access to your medical record, including personally identifiable health information?	☑	☐

Who explained this study to you? Reed

I agree to take part in this study: YES ☑ NO ☐

[redacted]	[redacted]	[redacted]
Signature of Research Participant	*Date*	*Printed Name*

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

[signature]	Nov 2/16	Reed Sutton.
Signature of Investigator or Delegate	*Date*	*Printed Name*

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THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A SIGNED AND DATED COPY GIVEN TO THE RESEARCH PARTICIPANT

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INFANT CONSENT FORM

Reproduction, Pregnancy, and Lactation in Inflammatory Bowel Disease
CEGIIR Additional Consent

Principal Investigator: Dr. V. Huang
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	Yes	No
1) Do you understand that you have been asked to provide consent for your infant to participate in this research study?	☑	☐
2) Have you read and received a copy of the attached Information Sheet?	☑	☐
3) Do you understand the benefits and risks involved in taking part in this research study?	☑	☐
4) Have you had an opportunity to ask questions and discuss this study?	☑	☐
5) Do you understand that you are free to withdraw your infant from the study at any time, without having to give a reason and without affecting your future medical care?	☑	☐
6) Do you understand the issue of confidentiality, and do you understand that the research team will have access to your infant's medical record, including personally identifiable health information?	☑	☐

Who explained this study to you? Reed.

I agree for stool sample collection from my infant: YES ☑ NO ☐

[redacted] [redacted] [redacted]

Signature of Infant's mother *Date* *Printed Name*

I believe that the person signing this form understands what is involved in the study and voluntarily agrees for their infant to participate.

[redacted] Nov 2/16 Reed Sutton.

Signature of Investigator or Delegate *Date* *Printed Name*

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THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A SIGNED AND DATED COPY GIVEN TO THE RESEARCH PARTICIPANT