# Mulligan Concept Intervention for Pregnancy Related Lumbo-Pelvic Pain
# NCT number: TBD

## *Consent Documentation*
**February 7, 2018**

**CONSENT FORM**

Project Title: Mulligan Concept Intervention for Pregnancy Related Pelvic Girdle Pain

The University of Idaho Institutional Review Board has approved this project.

**DESCRIPTION:** You are invited to participate in a research study on Pregnancy Related Pelvic Girdle Pain (PPGP). The purpose of this study is to learn more about PPGP and how the Mulligan Concept, a gentle manual therapy technique, may be used an intervention to treat the pain and dysfunction in women experiencing PPGP.

With your permission, you will be asked about the history of your PPGP and related symptoms. You will undergo a physical examination and fill out a questionnaire that collects information about your experience with PPGP. You will then complete gait analysis, sit-to-stand, and active straight leg raise tasks. Data will be collected about your biomechanical performance and your muscle activity by an 8-camera system and electromyography (EMG) electrodes placed on your skin. The tasks are easy to complete. In total, you will be asked to walk a straight line for 10 steps 6 times, stand up from a chair 6 times, and raise each leg 20 inches off of a treatment table (while laying on your back) 6 times. Each task will be completed in groupings of 3 repetitions, with a period of evaluation and/or treatment between groupings. A clinician, who is a Certified Mulligan Practitioner and Instructor, will perform the evaluation and/or treatment. The session will take no longer than 30 minutes and may include a palpation, pain free and gentle joint mobilizations, and active range of motion. Your entire participation in the study should take approximately 90 minutes of your time.

**RISKS:** There are only mild anticipated risks associated with this study. Few people report some skin irritation from adhesive used to place electrodes on your skin. There are no other known risks to being exposed to the camera or EMG systems. You can suspend or stop your participation at any time without penalty. We do ask that you share the study information with your doctor consult with them before beginning the study. In order to ensure that you have done this, we ask that they also sign this consent form.

**BENEFITS**: You will be supported for your time: $150 + natal support item (e.g., diapers). Apart from participant support, you will also have an opportunity to return after the study has been completed to receive additional treatment at no charge.

**PARTICIPANT'S RIGHTS:** If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time. If you decide to stop at any time, there will be no penalty from your withdrawal. You will still receive $75 for your time. Your identity will not be disclosed in any published or written material resulting from the study.

**Do I have to sign this authorization form? If I sign, can I withdraw from the study later?**

You do not have to sign this form. But if you do not, you will not be able to participate in the research study. If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your information (and to discontinue any other participation in the study) at any time. After any revocation, your information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your academic or personal information in this study, you simply need to express in writing your wishes to Dr. Larkins (contact information below).

**What Personal Information Will Be Used or Disclosed?**

Any information gathered during the study will remain confidential. Only the primary researchers will be able to link your identity to your information. The information you provide will be stored digitally on a secure computer in a private office. The data will be secured by password and encryption. Personal information will be collected by the University of Idaho for tax purposes, in order for you to be provided participant support funds. Information collected for tax purposes will not be linked to study data.

**What is the Mulligan Concept?**

Brian Mulligan, a New Zealand physio (similar to physical therapist in the US), created the Mulligan Concept. The concept is a manual therapy paradigm that includes a clinician applying joint mobilizations and having the patient perform concurrent active, pain free, movement.
Below is an example of a clinician performing a mobilization to the patient's hip.

**Who will be performing the treatment?**

Dr.'s Lynn Reordon and Julie Paolino are practicing physical therapists who specialize in the Mulligan Concept. Lynn and Julie are both Certified Mulligan Practitioners and Instructors of the technique, who travel the world teaching the Mulligan Concept manual therapy techniques. In addition to having Lynn and Julie's expertise, all of the participating researchers have been trained in the Mulligan Concept, and Dr. Larkins is also a Certified Mulligan Practitioner.

**Signature of participant Date**

Questions about this study or about your rights or concerns about this research can be directed to Dr. Lindsay Larkins (lwarren@uidaho.edu) at (208) 885-1022 or the Office of Research Assurances at the University of Idaho (208) 885-6162.

I am 18 years old or older and have reviewed this consent form. I understand and agree to its contents.

Participant Name _____

Participant Signature _____ Date _____

I am the participant's physician and have reviewed this consent form. I understand its contents and agree to their participation in the study.

Provider Name & Credential _____

Provider Signature _____ Date _____

Experimenter Name _____

Experimenter Signature _____ Date _____