[Hospital Logo] **Participant Information Sheet / CONSENT FORM** My Baby's Movements Study	Affix UR Sticker here

Participant Information Sheet/Consent Form
My Baby's Movements Study of pregnant women at or near full term.

[Hospital Name]

Study Title	My Baby's Movements: a stepped wedge cluster randomised controlled trial of maternal awareness of fetal movements during pregnancy.
Short Title	My Baby's Movements.
Project Sponsor	NHMRC.
Chief Principal Investigator	Associate Professor Vicki Flenady.
Co-Principal Investigator	Dr Glenn Gardener.
Site Investigator	
Site Investigator Contact Number	

Part 1 Participant information

Thank you for considering participation in the My Baby's Movements study. This information and consent form explains the study and what taking part involves. Knowing what is involved can help you decide if you want to participate.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or health worker.

If you decide to take part in the study, you will be asked to sign the Consent Form. By signing this, you agree that you:
• Understand what you have read.
• Consent to being involved in the study described.
• Consent to sharing your personal and health information as described.

Pages 3-6 of this document are for you to remove and keep.

1.1 What is the purpose of this study?

The purpose of the study is to reduce the rate of stillbirth in Australia and New Zealand, improve pregnant women's knowledge and awareness of baby's movements and associated health outcomes using information through a mobile phone program. It is important that women receive consistent

and accurate information about baby's movements and what they mean. This program provides women with quality information and supports their awareness of their baby's movements during pregnancy. This study is open to women who are currently pregnant with one baby and are attending antenatal care at participating hospitals. The study will be conducted across multiple hospitals in Australia and New Zealand and has been funded by a National Health and Medical Research Council (NHMRC) Project Grant.

1.2 What does participation in this study involve?

You will be asked to complete a survey about your baby's movements and the information you have previously received about baby's movements. A follow-up survey will be sent out 6 months after birth by mail or email depending on your preference. So that you can be contacted for the follow-up survey, your name and email address, or your postal address will be requested. A pre-paid stamped addressed envelope will be provided if you chose a mail-out version of the survey. Each survey will take roughly 10 minutes to complete. Please note that the surveys will ask you questions about information you may have received on fetal movements, your views and experiences, feelings and expectations about your baby's movements and the birth of your baby. You will also be asked questions about hospital use and your ongoing health.

1.3 Other relevant information about the study

Data will be de-identified, collated and used to inform clinical practice. The results of the study will be published and presented in a variety of forms. In any publication and/or presentation, information will be provided in such a way that no individual participant can be identified. A summary of results will also be made publicly available via the research team's website.

1.4 What if I do not want to be in the study?

Participation is voluntary and you are free to decide whether or not to participate. If you agree to participate you are also free to change your mind at any time and without offering a reason. Declining the project or withdrawing from the study will not affect your routine care, relationships with professional staff or ongoing relationship with your Health Services provider.

1.5 What are the possible risks/benefits of participating?

While many women find thinking about and feeling their baby's movements reassuring some women may feel worried about their baby's movements. If at any time you feel worried, you are encouraged to seek advice from your care providers. Please be aware that you and your baby may not receive any direct benefits from this research.

1.6 What if I want to withdraw after starting the study?

If you do consent to participate, you may withdraw from the study at any time. If you decide to withdraw, please contact the site study coordinator. If you do withdraw, you may be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you.

If you decide to leave the study, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the study can be measured properly and to comply with law. You should be aware that data collected up to the time of withdrawal will form part of the study results. If you do not want your information to be included, you must tell the researchers when withdrawing from the study.

1.7 What happens when the study ends?

Copies of information provided by participants will be kept for 15 years following completion of the study and publication of results. Electronic data will be disposed of securely and any printed copies of research data will be shredded and disposed of.

Part 2 How the study is being conducted?

2.1 What will happen to information about the participant?

Any information about you or your baby collected in this study will remain confidential and will not be disclosed without your permission, except as required by law.

Electronic data will be stored on a secure network database, and is only accessible by approved individuals. Electronic data stored on the network drive will be in password protected folders, only accessible to the research team. Medical information that is routinely collected at hospitals will be de-identified (i.e., names removed) and will only be accessible to the research team. Completed surveys and forms will be securely stored at the coordinating centre at the Mater Research Institute, University of Queensland, Brisbane, Australia.

With your consent, if you live in Australia, Mater Research Institute – The University of Queensland will obtain your Medicare claim data from the Department of Human Services. The Medicare system provides reimbursement for the pharmaceutical benefits schedule (PBS) and medical benefits schedule (MBS) health care costs incurred by individuals within Australia, as well as visits to medical practitioners and specialists. This information will be used to complete a cost-analysis as part of this study.

You can withhold consent for access to your Medicare data, even if you choose to be involved in the other aspects of the study. A standard Medicare form will need to be completed for release of this data.

2.2 Who has reviewed the study?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the appropriate HREC. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

2.3 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you would like any further information concerning this study or if you have any problems which may be related to involvement in the study, contact the Site Study Coordinator.

Site Study Coordinator	
Position	
Phone Number	
Email	

2.4 Complaints

If you have any complaints about any aspect of the study, the way it is being conducted, or if you have any questions about being a research participant in general, and you do not wish to speak to those involved with the research team, please contact the Human Research Ethics Office for your Health Services provider. Details are:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC	
HREC Executive Officer	
Phone Number	
Email	

Local HREC Office contact

Name	
Position	
Phone Number	
Email	

Consent Form – Participant Copy

Study Title	My Baby's Movements: a stepped wedge cluster randomised controlled trial of maternal awareness of fetal movements during pregnancy
Short Title	My Baby's Movements
Project Sponsor	NHMRC
Participant ID	
Chief Principal Investigator	Associate Professor Vicki Flenady
Co-Principal Investigator	Dr Glenn Gardener
Site Investigator	
Site Investigator Contact Number	

Declaration by Participant

1. I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
2. I understand the purposes, procedures and risks of the study described.
3. I have had an opportunity to ask questions and I am satisfied with the answers I have received.
4. I freely agree to take part in this study as described and understand that I am free to withdraw at any time without affecting my care.
5. I understand if I choose to receive the 6-month follow-up survey, that I am required to provide my contact details.
6. I understand that the research project will be carried out according to the principles in the National Health & Medical Research Council Statement on Ethical Conduct in Human Research.
7. I understand that, with my consent, the Mater Research Institute – The University of Queensland will obtain my Medicare data for the purpose of a cost-analysis attached to this study. My Medicare data will be treated as confidential and will not be shared outside this team except as required by law. I understand that a standard consent form issued by Medicare is required to be completed to access my Medicare data.

_____	_____	_____
Your Name (please print)	Your signature	Date

If Required

_____	_____	_____
Witness/Interpreters Name (please print)	Witness/Interpreters signature	Date

Consent Form – Hospital Copy

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_____	_____	_____
Your Name (please print)	Your signature	Date

If Required

_____	_____	_____
Witness/Interpreters Name (please print)	Witness/Interpreters signature	Date

I am happy to receive further contact via:

☐ Email, my email address is: _____@_____

☐ Post, my postal address is:

Contact Name: _____
Address Line 1: _____
Address Line 2: _____
Suburb: _____
City: _____
State: _____ Postcode: _____

Participant ID:

PARTICIPANT CONSENT FORM

Consent to release of Medicare and Pharmaceutical Benefits Scheme (PBS) claims information for the purposes of My Baby's Movements study

Important Information

Complete this form to request the release of personal Medicare claims information and PBS claims information to the My Baby's Movements study.

Any changes to this form must be initialled by the signatory. Incomplete forms may result in the study not being provided with your information. By signing this form, I acknowledge that I have been fully informed and have been provided with information about this study. I have been given an opportunity to ask questions and understand the possibilities of disclosures of my personal information.

PARTICIPANT DETAILS

1. Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name: _____ First given name: _____

Other given name (s): _____

Date of birth: DD/MM/YYYY

2. Medicare card number: _____

3. Permanent address: _____

Postal address (if different to above): _____

AUTHORISATION

4. I authorise the Department of Human Services to provide my:

- ☐ Medicare claims history OR
- ☐ PBS claims history OR
- ☑ **Medicare & PBS claims history**
- ☐ My most recent contact details from the Medicare enrolment database

for the period* DD/MM/YYYY to: DD/MM/YYYY to the My Baby's Movements study.

*Note: The Department of Human Services can only extract 4.5 years of data (prior to the date of extraction). The consent period above may result in multiple extractions.

DECLARATION

I declare that the information on this form is true and correct.

5. Signed: _____ (participant's signature) Dated: DD/MM/YYYY **OR**

6. Signed by _____ (full name) _____ (signature) on behalf of participant

Dated: DD/MM/YYYY

- ☐ Parent (where the participant is under the age of 14 years old*)
- ☐ Legal guardian** (where the participant is under the age of 14 years old*)
- ☐ Power of attorney** ☐ Guardianship order**

* Once a young person has turned 14 years old they must consent to their own information being released.
** Please attach supporting evidence.

APP 5 – PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

Power of attorney – A power of attorney is a document that appoints a person to act on behalf of another person who grants that power. In particular, an enduring power of attorney allows the appointed person to act on behalf of another person even when that person has become mentally incapacitated. The powers under a power of attorney may be unlimited or limited to specific acts.

Guardianship order – A Guardianship order is an order made by a Guardianship Board/Tribunal that appoints a guardian to make decisions for another person. A Guardianship order may be expressed broadly or limited to particular aspects of the care of another person.

A sample of the information that may be included in your Medicare claims history:

Date of service	Date of Processing	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	03/05/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	23/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

* Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date of prescribing	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepham Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	ATC Code	ATC Name
Original	N05 B A 04	Oxazepam
Repeat	N05 B A 01	Diazepam

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012