

# National Ethics Application Form

Version 2008 - V2.0

**Proposal title:**            **Fetal Virtopsy: The Value of MDCT as an Adjunct to Conventional Investigations in Pregnancy Losses.**

**For submission to:**  
**Women's & Children's Health Network**  
**Human Research Ethics Committee**  
**(EC00197)**

**Name:**    **Dr Sarah Constantine**

**Address:** **Department of Medical Imaging**  
**Women's and Children's Hospital**  
**72 King William Road**  
**North Adelaide SA 5006**  
**AUSTRALIA**

**Contact:** (Bus) **8161 7737**

(AH) -

(Mob) **0418 818 594**

(Fax) **8132 1562**

**Proposal status:**        **Complete**

**Proposal description:**

We aim to investigate the value of MDCT as part of the investigation into fetal abnormalities and pregnancy losses in the 2nd and 3rd trimesters, and early neonatal period. A full body CT scan will be performed on the fetus prior to autopsy. Dr Moore (pathology) and Dr Constantine (radiology) will report the scans together. The results of the CT scan will be compared with the autopsy findings, with the autopsy result considered the "gold standard". We anticipate that MDCT will demonstrate some, but not all the autopsy findings in the fetus. This will enable MDCT to be a useful tool in the investigation of stillbirth and fetal abnormality where autopsy is not possible.

# **Administrative Section**

## **1. TITLE AND SUMMARY OF PROJECT**

### **1.1. Title**

#### **1.1.1 What is the formal title of this research proposal?**

Fetal Virtopsy: The Value of MDCT as an Adjunct to Conventional Investigations in Pregnancy Losses.

#### **1.1.2 What is the short title / acronym of this research proposal (if applicable)?**

Fetal Virtopsy

### **1.2. Description of the project in plain language**

#### **1.2.1 Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.**

We aim to investigate the value of MDCT as part of the investigation into fetal abnormalities and pregnancy losses in the 2nd and 3rd trimesters, and early neonatal period. A full body CT scan will be performed on the fetus prior to autopsy. Dr Moore (pathology) and Dr Constantine (radiology) will report the scans together. The results of the CT scan will be compared with the autopsy findings, with the autopsy result considered the "gold standard". We anticipate that MDCT will demonstrate some, but not all the autopsy findings in the fetus. This will enable MDCT to be a useful tool in the investigation of stillbirth and fetal abnormality where autopsy is not possible.

## 2. RESEARCHERS / INVESTIGATORS

### 2.2. Principal researcher(s) / investigator(s)

2.2.0 How many principal researchers / investigators are there? 1

#### 2.2.1. Principal researcher / investigator 1

##### 2.2.1. Name and contact details

**Name:** Dr Sarah Constantine

**Address:** Department of Medical Imaging  
Women's and Children's Hospital  
72 King William Road  
North Adelaide SA 5006  
AUSTRALIA

**Organisation:** Women's and Children's Hospital

**Area:** Department of Medical Imaging

**Position:** Senior Staff Specialist

**Contact** (Bus) 8161 7737 (AH) -  
(Mob) 0418 818 594 (Fax) 8132 1562

**Email:** sconstantine@internode.on.net

##### 2.2.2... Summary of qualifications and relevant expertise [NS 4.8.7](#) [NS 4.8.15](#)

MBBS  
FRANZCR  
perinatal radiologist

##### 2.2.2... Please declare any general competing interests

nil

##### 2.2.2... Name the site(s) for which this principal researcher / investigator is responsible.

Women's and Children's Hospital

##### 2.2.3 Describe the role of the principal researcher / investigator in this project.

instigation of project  
study design  
reporting CT scans  
data analysis

2.2.4 Is the principal researcher / investigator a student? No

### 2.3. Associate researcher(s) / investigator(s)

2.3.1 How many known associate researchers are there? (You will be asked to give contact details for these associate researchers / investigators at question 2.3.1.1) 1

2.3.2 Do you intend to employ other associate researchers / investigators? No

#### 2.3.1...Associate Researchers / Investigators 1

##### 2.3.1...Name and contact details

**Name:** A/Prof Lynette Moore

**Address:** Department of Surgical Pathology  
Women's and Children's Hospital  
72 King William Road  
North Adelaide SA 5006

**Organisation:** Women's and Children's Hospital

**Area:** Department of Surgical Pathology

**Position:** Department Head

**Contact** (Bus) 8161 7317 (AH) -  
(Mob) - (Fax) 8161 7022

**Email:** Lynette.Moore@health.sa.gov.au

**2.3.1... Summary of qualifications and relevant expertise** [NS 4.8.7](#) [NS 4.8.15](#)

BMBS  
FRCPA

**2.3.1... Please declare any general competing interests**

nil

**2.3.1... Description of the role of the associate researcher / investigator in this project.**

identification of potential participants  
reporting of CT scans  
interpretation of autopsy studies  
data analysis

**2.3.1... Name the site at which the associate researcher / investigator has responsibility.**

Women's and Children's Hospital

**2.3.1... Is this associate researcher / investigator a student?**

No

## 2.4. Contact

Provide the following information for the person making this application to the HREC.

### 2.4.1. Name and contact details

**Name:** Dr Sarah Constantine

**Address:** Department of Medical Imaging  
Women's and Children's Hospital  
72 King William Road  
North Adelaide SA 5006  
AUSTRALIA

**Organisation:** Women's and Children's Hospital

**Area:** Department of Medical Imaging

**Position:** Senior Staff Specialist

**Contact** (Bus) 8161 7737 (AH) -  
(Mob) 0418 818 594 (Fax) 8132 1562

**Email:** sconstantine@internode.on.net

## 2.5. Other personnel relevant to the research project

**2.5.1 How many known other people will play a specified role in the conduct of this research project?** 2

**2.5.1... Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel.**

CT radiographers who will be performing the CT scans

**2.5.2 Is it intended that other people, not yet known, will play a specified role in the conduct of this research project?** No

## 2.6. Certification of researchers / investigators

**2.6.1 Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research?** No

## 2.7. Training of researchers / investigators

**2.7.1 Do the researchers / investigators or others involved in any aspect of this research project require any additional training in order to undertake this research?** No

### 3. RESOURCES

#### 3.1. Project Funding / Support

##### 3.1.1. Indicate how the project will be funded

###### 3.1.1... Type of funding.

[Please note that all fields in any selected funding detail column (with the exception of the code) will need to be completed.]

	By Researchers Department or Organisation
Name of Grant / Sponsor	nil
Amount of funding	nil
Confirmed / Sought	Not Sought
Detail in kind support	nil
Indicate the extent to which the scope of this HREC application and grant are aligned	nil

###### 3.1.1... How will you manage a funding shortfall (if any)?

N/A

3.1.2 Will the project be supported in other ways eg. in-kind support/equipment by an external party eg. sponsor No

#### 3.2. Duality of Interest

3.2.1 Describe any commercialisation or intellectual property implications of the funding/support arrangement.

nil

3.2.2 Does the funding/support provider(s) have a financial interest in the outcome of the research? No

3.2.3 Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research? No

3.2.4 Does any other individual or organisation have an interest in the outcome of this research? No

3.2.5 Are there any restrictions on the publication of results from this research? No

## 4. PRIOR REVIEWS

### 4.1. Ethical review

#### 4.1.0. Duration and location

4.1.0... In how many Australian sites, or site types, will the research be conducted? 1

4.1.0... In how many overseas sites, or site types, will the research be conducted? 0

Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted

#### 4.1.0...Site / Site Type 1

##### 4.1.0... Site / Site Type Name

Women's and Children's Hospital

##### 4.1.0... Site / Site Type Location

Women's and Children's Hospital

72 King William Road

North Adelaide SA 5006

#### 4.1.0...Provide the start and finish dates for the whole of the study including data analysis

Anticipated start date 01/03/2012

Anticipated finish date 01/03/2013

4.1.0... Are there any time-critical aspects of the research project of which an HREC should be aware? No

4.1.1 To how many Australian HRECs (representing site organisations or the researcher's / investigator's organisation) is it intended that this research proposal be submitted? 1

#### 4.1.1...HREC 1

4.1.1... Name of HREC Women's & Children's Health Network Human Research Ethics Committee (EC00197)

#### 4.1.1...Provide the start and finish dates for the research for which this HREC is providing ethical review.

Anticipated start date or date range 01/03/2012

Anticipated finish date or date range 01/03/2012

4.1.1... For how many sites at which the research is to be conducted will this HREC provide ethical review? 1

#### 4.1.1...Site 1

4.1.1... Name of site Women's and Children's Hospital

4.1.1... Which of the researchers / investigators involved in this project will conduct the research at this site?

Principal Researcher(s)

Associate Researcher(s)

Dr Sarah Constantine

A/Prof Lynette Moore

4.1.2 Have you previously submitted an application, whether in NEAF or otherwise, for ethical review of this research project to any other HRECs? No

### 4.3. Peer review

4.3.1 Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process? [NS 1.2](#) Yes

4.3.1... Provide details of the review and the outcome. A copy of the letter / notification, where available, should be attached to this application.

Will be submitted for publication to a peer reviewed journal, may also be presented at radiology and/or pathology conference.

# **Ethical Review Section**

## **Summary**

### **Applicant / Principal Researcher(s)**

**Dr Sarah Constantine**

*MBBS*

*FRANZCR*

*perinatal radiologist*

***Potential conflicts of interest***

*nil*

### **Associate Researcher(s) / Investigator(s)**

**A/Prof Lynette Moore**

*BMBS*

*FRCPA*

***Potential conflicts of interest***

*nil*

## 5. PROJECT

### 5.1. Type of Research

**5.1.1 Tick as many of the following 'types of research' as apply to this project. Your answers will assist HRECs in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 9 of NEAF.**

**This project involves:**

- Research using qualitative methods [NS 3.1](#)
- Research involving the collection and / or use of human samples [NS 3.4](#)
- Research involving ionising radiation [ARPANSA guidelines](#)

**5.1.2 Does the research involve limited disclosure to participants?** [NS 2.3](#) No

**5.1.3 Are the applicants asking the HREC / review body to waive the requirement of consent?** [NS 2.3.5](#) Yes

### 5.2. Research plan

**5.2.1 Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies (4000 character limit).** [NS 1.1](#)

The loss of a pregnancy, whether spontaneous or induced for medical reasons, is a very traumatic event for the parents. In many cases, the reasons for a fetal abnormality or miscarriage are not clear, but can be very important for future pregnancies and patient counselling. Fetal autopsy is performed (with parental consent) as often as possible, but some parents cannot consider autopsy at a very stressful time in their lives, and others cannot consent for cultural or religious reasons. Some of these parents will allow an external examination and x-rays which provide only limited information.

The use of multi-detector computed tomography (MDCT) is well established in forensic science units around the world. To date, there has been very little research into the value of MDCT in fetal deaths. A recent article by O'Donoghue et al. used MDCT as an adjunct to autopsy in the investigation of 3rd trimester stillbirths, finding good correlation between measurements obtained in both settings, although only half their cases underwent formal autopsy.<sup>1</sup>

1. O'Donoghue K, O'Regan KN, Sheridan CP, O'Connor OJ, Benson J, McWilliams S, Moore N, Murphy MJ, Chopra R, Higgins JR, Maher MM. Investigation of the role of computed tomography as an adjunct to autopsy in the evaluation of stillbirth. *Eur J Radiol.* 2011 Apr 29. [Epub ahead of print].

**5.2.2 State the aims of the research and the research question and/or hypotheses, where appropriate.**

We aim to investigate the value of MDCT as part of the investigation into fetal abnormalities and pregnancy losses in the 2nd and 3rd trimesters, and early neonatal period. While we do not propose to replace conventional autopsy, we hope to show a good correlation between radiological and pathological findings, so that we can offer a non-invasive alternative to autopsy where the parents cannot consent to dissection. The cases will be reported by the radiologist and pathologist together, to obtain maximal information in each case.

**5.2.3 Has this project been undertaken previously?** No

### 5.3. Benefits/Risks

**5.3.0 Does the research involve a practice or intervention which is an alternative to a standard practice or intervention?** Yes

**5.3.0... Explain how the practice or intervention differs from standard practice or intervention.**

MDCT is not currently used routinely in the investigation of still births. Plain x-rays and conventional autopsy are the current standard, along with laboratory and genetic testing.

**5.3.2 What expected benefits (if any) will this research have for the wider community?**

We do not propose to replace conventional autopsy, but we hope to show a good correlation between radiological and pathological findings, so that we can offer a non-invasive alternative to autopsy where the parents cannot consent to dissection. Some parents cannot consent to autopsy for cultural or religious reasons.

**5.3.3 What expected benefits (if any) will this research have for participants?** [NS 2.1](#)

We hope that we can provide a non-invasive alternative to conventional autopsy, so the maximal information about a pregnancy loss can be obtained in cases where consent is not given for autopsy. It is important to investigate still births to allow planning for future pregnancies and the prevention of further pregnancy losses

where possible.

**5.3.4 Are there any risks to participants as a result of participation in this research project?** [NS 2.1](#) No

**5.3.5 Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants.** [NS 1.6](#)

All participants are deceased - no discomfort. No harm from a non-invasive CT scan.

**5.3.8 Are there any other risks involved in this research? eg. to the research team, the organisation, others** No

**5.3.9 Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor(s)?** No

**5.3.11 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?** No

## 5.4. Monitoring

Refer to NS 3.3.19 - 3.3.25

**5.4.1 What mechanisms do the researchers / investigators intend to implement to monitor the conduct and progress of the research project?** [NS 5.5](#)

The CT scans will be reported on an ongoing basis, and compared with autopsy results when available. This will enable any problems to be detected on an ongoing basis, rather than at the end of the study.

## 6. PARTICIPANTS

### 6.1. Research participants

6.1.1 The National Statement identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

This question aims to assist you and the HREC to identify and address ethical issues that are likely to arise in your research, if its design will include one or more of these populations. Further, the National Statement recognizes the cultural diversity of Australia's population and the importance of respect for that diversity in the recruitment and involvement of participants. Your answer to this question will guide you to additional questions (if any) relevant to the participants in your study.

**6.1.1 Tick as many of the following 'types of research participants' who will be included because of the project design, or their inclusion is probable, given the diversity of Australia's population. If none apply, please indicate this below.**

	a) Primary intent of research	b) Probable coincidental recruitment
Women who are pregnant and the human foetus <a href="#">NS 4.1</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Children and/or young people (ie. <18 years) <a href="#">NS 4.2</a>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Aboriginal and/or Torres Strait Islander peoples <a href="#">NS 4.7</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

You have indicated that it is probable that

- Women who are pregnant and the human foetus
- Aboriginal and/or Torres Strait Islander peoples

may be coincidentally recruited into this project. The National Statement identifies specific ethical considerations for these groups(s).

**6.1.3... Please explain how you will address these considerations in your proposed research.**

Research is being conducted exclusively on the deceased human fetus, of any race or culture. Consent is obtained from the parents, via an interpreter where necessary, as part of consent for autopsy. If consent cannot be given for autopsy, this is automatic exclusion from this study.

### 6.2. Participant description

**6.2.1 How many participant groups are involved in this research project?** 1

**6.2.2 What is the expected total number of participants in this project at all sites?**  
100

#### 6.2.3. Group 1

**6.2.3... Group name for participants in this group**  
Stillborn human fetuses and early neonatal deaths

**6.2.3... Expected number of participants in this group**  
100

**6.2.3... Age range**  
14 weeks gestation and over

**6.2.3... Other relevant characteristics of this participant group**  
consent given by parent(s) for full autopsy and participation in research

**6.2.3... Why are these characteristics relevant to the aims of the project?**  
As we are using a new technique of imaging in this population, we need a full autopsy to provide a "gold standard" comparison.

### 6.3. Participation experience

**6.3.1 Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader of what the participation will involve.**

When a pregnancy is lost, some parents cannot consent to an autopsy of the child for cultural or religious reasons, or because of emotional distress. By performing a CT scan on stillborn babies of various ages and comparing the results to autopsy findings, we hope we can spare some parents this decision in the future. In this study, a CT scan will be performed before the autopsy, and the results of both investigations will be

compared. The CT scan does not involve any disturbance to the body of the baby. The child is placed on the CT table and the x-rays are taken just as in a living baby, without the use of any needles or contrast.

#### **6.4. Relationship of researchers / investigators to participants**

##### **6.4.1 Specify the nature of any existing relationship or one likely to rise during the research, between the potential participants and any member of the research team or an organisation involved in the research.**

Some fetuses and their mothers will have been/will be patients at the Women's and Children's Hospital.

##### **6.4.2 Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.**

Nil additional to the normal consent process.

##### **6.4.3 Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher / investigator or organisations.**

Nil additional to the normal consent process.

**6.4.4 Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations.?** No

**6.4.5 Is it intended that the interview transcript will be shown or made available to participants?** [3.1.15](#) No

#### **6.5. Recruitment**

##### **6.5.1 What processes will be used to identify potential participants?**

When stillbirths are referred to the Department of Pathology, the parents are taken through the consent process for further investigations. The Department will identify any fetuses of the required age range whose parents have given consent for both autopsy and research, and refer the patient to Medical Imaging for a CT scan.

**6.5.2 Is it proposed to 'screen' or assess the suitability of the potential participants for the study?** No

##### **6.5.3 Describe how initial contact will be made with potential participants.**

As above.

**6.5.3... Do you intend to include both males and females in this study?** Yes

##### **6.5.3... What is the expected ratio of males to females that will be recruited into this study and does this ratio accurately reflect the distribution of the disease, issue or condition within the general community?**

We expect a ratio of close to 1: 1, as stillbirths affect fetuses of both sexes, even though some individual conditions may affect one gender more often than the other.

**6.5.4 Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?** No

**6.5.5 If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?** No

#### **6.6. Consent process**

##### **6.6.4. You have indicated that the project involves research where it is proposed that the HREC qualify or waive the conditions for consent**

**6.6.4... Does the research aim to expose illegal activity?** No

##### **6.6.4... Why is it impracticable to seek consent?**

Consent is already sought as part of the usual consent process for autopsy. The consent form includes a section asking parents to consent for research, which would cover this study.

##### **6.6.4... Why is it thought that participants would have consented?**

If participants consent for research, this should include our study which is purely research based and does not involve any harm to the fetus, nor retention of any fetal tissues. Plain x-rays are already used as part of the normal investigation process into stillbirths, CT is a specialized form of x-ray study.

##### **6.6.4... How is their privacy protected?**

The CT scans will only be available to those involved in this study.

##### **6.6.4... How is their confidentiality protected?**

Each fetus is assigned a laboratory number by the Department of Pathology, this will be used to identify the fetus for the CT scan so that patient names are kept confidential and private.

6.6.4... Will the results of the research have significance for the welfare of participants? No

## 7. PARTICIPANTS SPECIFIC

### 7.2. Children or young people

#### 7.2.1 Why is participation of children or young people indispensable to this research?

#### How has this study been designed to be appropriate for children or young people? [NS 4.2.1](#)

The population of interest is only fetuses and neonates. MDCT has already been shown to be of value in post mortem adults.

#### 7.2.2 Explain why there is no reason to believe that the research participation is not contrary to the best interests of the children or young people. [NS 4.2.13](#) [NS 4.3](#)

There is no invasive component to the CT scan, and as the fetuses are all deceased, there is no concern about radiation dose as there is in living babies.

## 8. CONFIDENTIALITY/PRIVACY

### 8.1. Do privacy guidelines need to be applied in the ethical review of this proposal?

8.1.1 Indicate whether the source of the information about participants which will be used in this research project will involve:

collection directly from the participant

use of information which you or your organisation collected previously for a purpose other than this research project

#### 8.1.1... Information which will be collected for this research project directly from the participant

8.1.1... Describe the information that will be collected directly from participants. Be specific where appropriate.

Information pertinent to the autopsy will be collected and used when the CT scans are reported. Information includes family and pregnancy history such as previous pregnancy losses, inherited diseases known within the family, and exposures or infection during the pregnancy, the results of any prior investigations such as amniocentesis and the pregnancy ultrasounds.

8.1.1... The information collected by the research team about participants will be in the following form(s). Tick more than one box if applicable.

individually identifiable

8.1.1... Give reasons why it is necessary to collect information in individually identifiable or re-identifiable form.

The autopsy is part of the normal clinical care of the patient, and the CT scan is linked to this. No identifiable data will be published, but will need to be collected to enable data analysis.

#### 8.1.1... Information which will be used for this research project which you or your organisation collected previously for a purpose other than this research project

8.1.1...Indicate from which of the following you will be collecting information for this research project and indicate how many databases from each source.

Commonwealth	0
State/Territory	0
Private Sector	0

### 8.2. Using information from participants

8.2.1 Describe how information collected about participants will be used in this project.

The reporting of any radiological investigation is done within the appropriate clinical setting and with review of any previous imaging. As such, the obstetric images and patient history as necessary to provide a meaningful interpretation of the CT scan. This is the main reason for collecting identifiable data. Once the scans are reported and the autopsy finished, no identifiable data is required, but the results of the past imaging etc is still used in data interpretation. For example, we may find that CT scans are not useful in a subgroup who had finding X on their obstetric ultrasound scans, but were useful in those had finding Y. This is why we need to collect this sort of data.

Given that applicants are seeking a waiver of the requirement for consent, your response to this question must explain how the privacy of participants will be protected.

8.2.2 Will any of the information used by the research team be in identified or re-identifiable (coded) form? Yes

8.2.2... Indicate whichever of the following applies to this project:

Information collected for, used in, or generated by, this project will not be used for any other purpose.

8.2.4 List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access. Examples of others are: student supervisors, research monitors, pharmaceutical company monitors .

Dr S Constantine

A/Prof L Moore

Ms M Tregeagle (CT radiographer)

Ms S Fraser (CT radiographer)

### 8.3. Storage of information about participants during and after completion of the project

8.3.1 In what formats will the information be stored during and after the research project? (eg. paper copy,

computer file on floppy disk or CD, audio tape, videotape, film)

The scans will be stored electronically on a computer file.

**8.3.2 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during and after the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)**

The CT radiographers (Ms Tregagle and Fraser) will secure the study data. Each scan will be identified only be gestational age, gender and Pathology number.

Given that applicants are seeking a waiver of the requirement for consent, your response to this question must justify that there is an adequate plan in place to protect the confidentiality of the data.

Given that applicants are seeking a waiver of the requirement for consent, your response to this question must justify that there is an adequate plan in place to protect the confidentiality of the data.

**8.3.5 The information which will be stored at the completion of this project is of the following type(s). Tick more than one box if applicable.**

re-identifiable

**8.3.5... Give reasons why it is necessary to store information in identifiable or potentially identifiable (coded) form.**

If any further questions arise during the project or clinically, we need to be able to identify each fetus to re-examine the scans.

**8.3.5... If the data can be re-identified using a code, specify the security arrangements and access for the code.**

N/A

**8.3.6 For how long will the information be stored after the completion of the project and why has this period been chosen?**

Information will be kept for 10 years. This is in accordance with the NPAAC Guidelines.

[http://www.health.gov.au/internet/main/publishing.nsf/Content/0392138A9970DFD1CA257371000D9200/\\$File](http://www.health.gov.au/internet/main/publishing.nsf/Content/0392138A9970DFD1CA257371000D9200/$File)

**8.3.7 What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher / investigator ceases to be engaged at the current organisation?**

The data will belong to the Women's and Children's Hospital and will remain on campus.

Given that applicants are seeking a waiver of the requirement for consent, your response to this question must justify that there is an adequate plan in place to protect the confidentiality of the data.

Given the this research involves a proposed waiver of consent and the intent of exposing illegal activity [see NS 4.6.1] the HREC must be satisfied that your response to this question has justified that there is sufficient protection of the privacy of the participants.

**8.4. Ownership of the information collected during the research project and resulting from the research project**

**8.4.2 Who is understood to own the information resulting from the research, eg. the final report or published form of the results?**

Women's and Children's Hospital.

**8.4.3 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?** No

**8.5. Disposal of the information**

**8.5.1 Will the information collected for, used in, or generated by this project be disposed of at some stage?** No

**8.6. Reporting individual results to participants and others**

**8.6.1 Is it intended that results of the research that relate to a specific participant be reported to that participant?** No

**8.6.1... Explain/justify why results will not be reported to participants.**

We are not expecting to find information that will not already have been found and reported at autopsy.

**8.6.2 Is the research likely to produce information of personal significance to individual participants?** No

**8.6.3 Will individual participant's results be recorded with their personal records?** No

**8.6.4 Is it intended that results that relate to a specific participant be reported to anyone other than that participant?** No

**8.6.5 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues** No

**8.6.6 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?** No

**8.6.7 How is it intended to disseminate the results of the research? eg report, publication, thesis**  
Publication, perhaps conference submission.

**8.6.8 Will the confidentiality of participants and their data be protected in the dissemination of research results?** Yes

**8.6.8... Explain how confidentiality of participants and their data will be protected in the dissemination of research results**  
All identifying features will be removed from images.

## 9. PROJECT SPECIFIC

### 9.3. Research involving ionising radiation

Applicants should refer to the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice: Exposure of Humans to Ionising Radiation for Research Purposes (RPS 8) (ARPANSA Code). In preparing information for participants applicants should refer to paragraph 2.1.8 specifically.

**9.3.1 Why is it necessary to expose research participants to ionising radiation for this research?** [ARPANSA Code 2.1.7\(a\)](#)

CT scans involve ionising radiation.

**9.3.2 Describe the radiation dose assessment and risk assessment obtained for this research.** [ARPANSA Code 2.1.6](#)

Nil - participants are deceased.

**9.3.3 Has the dose assessment and risk assessment been verified by a medical physicist?** [ARPANSA Code 2.1.6 2.3.2\(a\)](#) No

**9.3.3... Provide an explanation.**  
Participants are deceased.

**9.3.4 Is the use of radiation a novel use?** [ARPANSA Code 2.1.7\(f\)](#) No

**9.3.5 Will the radiation dose exceed the dose limits described in Table 1 to the ARPANSA Code?** No

**9.3.6 Will the research participants include:**  
 Neither

**9.3.7 What precautions will be taken to keep radiation dose and radiation exposure to a minimum?** [ARPANSA Code 2.1.5\(b\), 2.1.7\(d\)](#)

Doses are expected to be similar to those used in living subjects.

**9.3.8 Is the site(s) where the radiation will be used actively involved in a relevant quality assurance program?** [ARPANSA Code 2.1.7 \(c\)](#) Yes

Whenever possible, in the case of research involving the radiation exposure of healthy research participants, participants should be selected who have not previously or are not currently exposed to radiation from research projects (ARPANSA Code 2.1.5(a)). You should consider this requirement when answering question 6.5.2 about the selection of participants.

### 9.5. Research involving the collection and / or use of human samples

You have indicated that the project involves the use of human samples.

**9.5.1 What is the nature of sample/s you plan to use?**

Samples that are taken in the normal course of an autopsy are used for comparison. No extra samples are to be taken.

**9.5.2 What is the source of the sample/s you wish to use? (tick all boxes that apply)**  
 Obtained from, or accessed during, autopsy

**9.5.2... Name the organisation/s from which the tissue sample is being obtained/accessed. Please provide details (if known) on how these samples will be obtained.** [NS 3.4.1 \(a-f\)](#)

Department of Surgical Pathology, Women's and Children's Hospital.

**9.5.2... Indicate the type of autopsy (May be both)**  
 Non-coronial

**9.5.2... How will samples be used? (May be both)**  
 Excised  
 Accessed in situ

**9.5.2... At the time of collection of the sample/s, for which of the following purpose was consent obtained/will be obtained?** Diagnostic, therapeutic or other medical procedure

**9.5.2... Do you propose to obtain third party consent for your use of excised autopsy samples for this research project?** Yes

**9.5.2... Indicate from whom consent will be sought and explain the legal authority for this consent**  
Consent will be obtained from the parents of the fetuses.

**9.5.2... By whom will the sample/s be accessed?** A member of the research team

**9.5.2... Do you propose to obtain third party consent for your access to in situ autopsy samples for this research project?** Yes

**9.5.2... Indicate from whom consent will be sought and explain the legal authority for this consent**  
Consent will be obtained from the parents of the fetuses.

**9.5.3 In what form will the sample(s) be used by the investigators in the conduct of this project?** Identified

**9.5.4 Will the tissue sample(s) used for this project be destroyed once the project is completed?** No

**9.5.4... Explain why the tissue sample/s will not be destroyed; who will have access to them in the future; and whether the tissue samples will be used to establish a tissue bank or genetic register.**  
Routine autopsy samples will be kept in accordance with NPAAC guidelines.

**9.5.5 Does this research involve the development of a cell line?** No

**9.5.6 Provide details of the collection and management of this information source.** [NS 3.4.1 \(a-f\)](#)  
N/A

**9.5.7 Describe how you will ensure that all sample/s used in this project will be stored securely and describe how you will monitor this as well as the use of the sample/s.**  
All samples are kept in a secure laboratory location requiring security card access.

# 10. DECLARATIONS AND SIGNATURES

## 10.1 Project Title

Fetal Virtopsy: The Value of MDCT as an Adjunct to Conventional Investigations in Pregnancy Losses.

## 10.2 Human Research Ethics Committee to which this application is made

Women's & Children's Health Network Human Research Ethics Committee (EC00197)

## 10.3 Signatures and undertakings

### Applicant / Principal Researchers (including students where permitted)

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research Involving Humans.
- the research will be conducted in accordance with the National Statement.
- the research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal NS 5.5.3 including:
  - serious or unexpected adverse effects on participants;
  - proposed changes in the protocol; and
  - unforeseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion NS 5.5.6 see NS 5.5.8(b);
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

### Applicant / Chief Researcher(s) / Principal Researcher(s)

Dr Sarah Constantine  
Women's and Children's Hospital

\_\_\_\_\_  
Signature

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

### Associate Researchers

A/Prof Lynette Moore

\_\_\_\_\_  
Signature

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

### Heads of departments/schools/research organisation

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

\_\_\_\_\_  
Title

\_\_\_\_\_  
First name

\_\_\_\_\_  
Surname

\_\_\_\_\_  
Position

\_\_\_\_\_  
Organisation name

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## 11. ATTACHMENTS

This page and all pages that follow don't need to be submitted to your HREC.

### 11.1 List of Attachments

<b>Core Attachments</b>	<b>Attachments which may be required/appropriate.</b>
Recruitment/invitation	Copy of advertisement, letter of invitation etc
Participant Information	Copy or script for participant Copy or script for parent, legal guardian or person responsible as appropriate
Consent Form	Copy for participant For parent, legal guardian or person responsible as appropriate For, optional components of the project eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome
HREC approvals	Copy of outcome of other HREC reviews

<b>Attachments specific to project or participant group</b>	<b>Attachments which may be required/appropriate.</b>
Research conducted in the workplace or possibly impacting on workplace relationships	Evidence of support/permission from workplace where research will be conducted
Research involving the collection and / or use of human samples	Evidence of support/permission from tissue bank or tissue custodian for proposed access / use of tissue Evidence of having met any legal requirements for use of autopsy or coronial autopsy tissue
Research involving assisted reproductive technologies (ART)	Evidence of having met any legal requirements relevant to the research
Children and/or young people (ie. <18 years)	Information/consent form for parent, legal guardian or person responsible
Aboriginal and/or Torres Strait Islander peoples	Evidence of support / permission of elders and/or other appropriate bodies

## 11.2 Participant information elements

### Core Elements

Provision of information to participants about the following topics should be considered for all research projects.

Core Elements	Issues to consider in participant information
About the project	Full title and / or short title of the project Plain language description of the project Purpose / aim of the project and research methods as appropriate Demands, risks, inconveniences, discomforts of participation in the project Outcomes and benefits of the project Project start, finish, duration
About the investigators / organisation	Researchers conducting the project (including whether student researchers are involved) Organisations which are involved / responsible Organisations which have given approvals Relationship between researchers and participants and organisations
Participant description	How and why participants are chosen How participants are recruited How many participants are to be recruited
Participant experience	What will happen to the participant, what will they have to do, what will they experience? Benefits to individual, community, and contribution to knowledge Risks to individual, community Consequences of participation
Participant options	Alternatives to participation Whether participation may be for part of project or only for whole of project Whether any of the following will be provided: counselling, post research follow-up, or post research access to services, equipment or goods
Participants rights and responsibilities	That participation is voluntary That participants can withdraw, how to withdraw and what consequences may follow Expectations on participants, consequences of non-compliance with the protocol How to seek more information How to raise a concern or make a complaint
Handling of information	How information will be accessed, collected, used, stored, and to whom data will be disclosed Can participants withdraw their information, how, when Confidentiality of information Ownership of information Subsequent use of information Storage and disposal of information
Unlawful conduct	Whether researcher has any obligations to report unlawful conduct of participant
Financial issues	How the project is funded Declaration of any duality of interests Compensation entitlements Costs to participants Payments, reimbursements to participants Commercial application of results
Results	What will participants be told, when and by whom Will individual results be provided What are the consequences of being told or not being told the results of

<b>Core Elements</b>	<b>Issues to consider in participant information</b>
	research How will results be reported / published Ownership of intellectual property and commercial benefits
Cessation	Circumstances under which the participation of an individual might cease Circumstances under which the project might be terminated

**Research Specific Elements**

Provision of information to participants about the following topics should be considered as may be relevant to the research project.

<b>Specific to project or participant group</b>	<b>Additional issues to consider in participant information</b>
Research involving ionising radiation	Explain what radiation is, where appropriate Explain risks using easily understood examples / comparisons, where appropriate Explain specific risks, including to fertility, pregnant women and the foetus, as appropriate
Research involving the collection and / or use of human samples	How samples will be accessed, collected, used, stored, and disposed of Who will have access to samples Can participants withdraw their samples, how, when Ownership of samples Subsequent use of samples including development of cell lines Any legal requirements / constraints on collection or use of samples eg. autopsy, coronial autopsy Any legal requirements regarding consent for use of samples eg. autopsy, coronial autopsy
Research involving assisted reproductive technologies (ART)	Have the consent requirements of the NHMRC ART guidelines (pg 50) been met?
Aboriginal and/or Torres Strait Islander peoples	describe consultation process to date and involvement of leaders whether ATSI status will be recorded