# Participant Information Sheet for Biomarker for monitoring Ovarian Reserve

# (2 years of age and over)

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**What is our research study about?**

Our research study will focus on finding out if a newly discovered biomarker will be useful in helping females (aged 2 years and over) undergoing cancer treatment know more about their fertility before and after treatment. We would like to see how this compares with available tests such as Anti Mullerian hormone (AMH) and Follicular Stimulating Hormone (FSH). Parent/caregivers on behalf of their child (children <16 years of age) who agree to have their child participate or females over 16 years of age who eligible to consent for themselves will help by having their own/their child’s blood tests taken before, during and after chemotherapy to measure the new and available biomarkers so that we can compare them and find out if they are more accurate. Bloods will be drawn once at three different time intervals, either via central line or cannula, and include: one day before chemotherapy and then at 3 months, 9 months, 12 months and 1 year following the end of treatment.

**How we measure fertility your/your child’s fertility?**

Female fertility can be determined by two factors- ovarian quantity and ovarian quality. Ovarian quantity refers to the number of oocytes (eggs) remaining in a woman’s ovary. The number of eggs is set before birth and cannot be replenished. The number of eggs declines with age. Ovarian quality refers to the ability of the egg to get fertilized and support a successful pregnancy.

**What is this new fertility test that I should be concerned about for me/my child?**

Current fertility tests measure the number of eggs by detecting blood levels of hormone for example FSH, AMH and/or obtaining an “antral follicle count” (the number of maturing eggs) by vaginal ultrasound (a test used to look at a female's reproductive organs). However, this does not give a direct accurate measure of egg quantity and fertility potential.

Our research study aims to measure ovarian quality by measuring a newly discovered serum (blood) protein that is directly secreted from your/your child’s egg. This may provide a more accurate picture of your/your child’s egg quality and therefore your/her fertility.

**Why is a Biomarker for monitoring ovarian reserve study important for me/my child?**

Current fertility tests only provide a brief picture of your/your child’s fertility potential. We believe our biomarker would assist with providing a more accurate measure of your/your child’s fertility.

**How will this test benefit me/my child and other female cancer patients?**

If this biomarker works as expected, it will allow you to have a better understanding of your/your child’s fertility as we will be able to measure your/your child’s egg quality before and after cancer treatment. This information will help you/your child and other female cancer patient’s make informed decisions about fertility preservation before or after cancer treatment as well as helping you/your child plan for a family in the future.

**Who is responsible for this project?**

Dr Antoinette Anazodo, is a cancer doctor at the Sydney Children’s Hospital and Professor Bill Ledger, Is a fertility doctor at the Royal Hospital for Women in Sydney.

**Are there any risks to me/my child in participating in this research study?**

There is are minimal risks should you decide to or on behalf of your child to participate in this study.

**Pain:**

There is pain associated with the taking of blood tests required. If a central line or cannula is in place, the blood sample collection should not cause any additional discomfort or inconvenience to your/your child.

**Psychological distress:**

If you/your child experiences any sign of psychological distress regarding any aspect of the trial, you/ you and your child will be given the opportunity to speak with your /your child’s treating cancer team’s social worker or psychologist.

**What happens if I/my child suffers injury and complications as a result of this research study?**

There is very little physical risk in agreeing to/on behalf of your child participate in this research study. If you/your child requires treatment or suffers loss as a result of the negligence of any of the parties involved in the study you/your child may be entitled to compensation; the cost of your/your child’s treatment would have to be paid out of such compensation.

**Will participating or saying no affect my/my child’s care?**

No matter what you choose to do, your/your child’s treatment and long-term care will not be affected.

**What information will be collected on my/my child?**

If you decide to consent on behalf of yourself/your child to participate in this study, we will collect the following information for you/your child which will include:

* Demographic information such as age and ethnicity on you/your child;
* Your/your child’s cancer diagnosis and treatment details, including date of diagnosis, type of cancer and stage, date of relapse if relevant and type of treatment (chemotherapy);
* Your/your child’s gynecological and obstetric history prior to cancer treatment, where applicable.

**Will my/my child’s data be stored safely?**

Yes. Your/your child’s data will be stored on a database at the Kids Cancer Centre (KCC) at Sydney Children’s Hospital. Your/your child’s data will be stored on a password protected computer, and access will only be available to research personnel who are involved with the study. After the study is completed, the data will remain stored on a password protected local area network with access limited to research personnel for 7 years after collection.

**How will my/my child’s information be used and reported?**

We will use your/your child’s information when analyzing our data and presenting it in our final report. However no personal or identifiable information of any patient will be reflected in any reports.

**Will my/my child’s privacy and confidentiality be protected?**

Yes, your/your child’s privacy and confidentiality will be maintained at all times. Only research personnel involved in our study will access to your/your child’s medical information.

**Will my/my child have to do anything?**

No. Blood will only be drawn at fixed time periods which have been detailed above (one day before chemotherapy and then at 3 months, 9 months, 12 months and 2years following end of treatment).

**What is the consent process for my/my child to participate?**

After reading this patient information sheet, if you decide that you would like to/on behalf of your child take part in this research study, we would ask you to complete a consent form (on behalf of your child). Please read the consent form and tick the boxes stating that you consent to/on behalf of your child to participate. If you require further information on this study, please speak with the study coordinator or your treating doctor to discuss any matters or concern regarding your/your child’s participation. Your consent will allow us to collect and use your/your child’s information for our study.

**The consent process differs depending on your/your child’s age, based on the following:**

* Patients older than 18 years will be able to provide their own consent
* Patients older than 13 years (but under 18 years old) will be asked to sign a form called an “assent” where they agree to participate and a parent or legal guardian will also need to consent.
* Patients younger than 13 years will require the consent of a parent or legal guardian.

You can withdraw your/your child’s consent to participate at any time. If you decide to withdraw your child’s consent you will be asked to sign a revocation of consent (on behalf of your child).

**Who should I contact if I have concerns about the conduct of this study**

Any person with concerns or complaint about the study should contact the study chief investigator Dr. Antoinette Anazodo: antoinette.anazodo@sesiahs.health.nsw.gov.au