Questions Taken on Notice

1. ***If the central register were transferred to Births, Deaths and Marriages, what is the approximate cost at the moment of running that service?***

The cost to the Private Health Care Unit is now $33,832 for staff costs, or $67,432 if another awareness campaign is undertaken.

Item	***Cost***	*Comment*
0.03 FTE Clerk Grade 3/4 0.25 FTE Clerk 9/10 0.03 FTE Senior Officer Grade 1	$1,868 $27,756 $4,207	Salaries calculated as maximum pay scale +10% on costs, to nearest dollar, drawn from Private Health Care Unit establishment. No additional funding for ART.
Total staff cost	$33,832	
Awareness campaign	$33,600	For 3 month awareness campaign in 2012. Campaign may be repeated annually to promote uptake for voluntary side of register.
Web support	Nil	Nil additional staff required to maintain ART webpages on NSW Health website. Covered by Media Unit establishment.
IT support	Nil	Use existing IT licences (TRIM, Word and Excel) and internal support due to current low volume of data – 200 entries per year. Covered by IT support establishment. Purpose built database to be developed in the long term to accommodate growing volume of data.
Total	**$67,432**	$33,832 if no further awareness campaign

2. ***If an ART provider "goes bust" or otherwise ceases operation, what happens to the records they keep?***

Information about all live donor conceived births after September 2010, of which ART providers are aware, (except for those births caught by the transitional provisions[1]), are recorded on the NSW Health central register, and are kept independently of the ART provider. In addition, section 31(2) of the *Assisted Reproductive Technology Act 2007* requires the ART provider to retain any records required to be kept under section 31 for a period of 50 years after the record is made or such other period as may be prescribed by the regulations. There is no other prescribed time. There is no provision regarding specific arrangements to be made in the case of the cessation of the ART provider.

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[1] If a couple had previously conceived a child using donated eggs or sperm before 1 January 2010 and they want now to conceive another child using the same donor eggs or sperm, the donor's information will NOT be included on the Register if:

- the woman has, before 1 January 2010, already conceived a child as a result of ART treatment using a donated eggs or sperm from the donor; and
- the donated eggs or sperm were obtained before 1 January 2010; and
- the donated eggs or sperm were used to provide ART treatment to a woman before 1 January 2013

While a donor's information in this instance is not mandatory for Register, a donor may decide to include their information voluntarily.

While National Health and Medical Research Council (NHMRC) regulatory recommendations and guidelines are not legislative instruments (s9 (3) *National Health and Medical Research Council Act 1992*), the *Research Involving Human Embryos Act 2002* (RIHE Act) makes accreditation compulsory for most ART facilities. RTAC accreditation is not a mandatory requirement for facilities that provide ART services. However, all ART providers which use human embryos outside a woman's body must be accredited under section 11 of the RIHE Act[2]. Section 8 of the RIHE Act provides:

> "**An accredited ART centre** means a person or body accredited to carry out assisted reproductive technology by:
>
> (a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or
>
> (b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires."

From the commencement of ss10-12 RIHE Act on 19 June 2003, ART providers which use human embryos outside a woman's body must be accredited, and comply with the *Ethical Guidelines on Assisted Reproductive Technology 2004* produced by the NHMRC, and revised in 2007.

The Guidelines require ART providers to make
"

- arrangements to ensure transfer of records to a suitable person or location when a clinic closes or a practitioner ceases to practise (such arrangements should ensure that records stay with the gametes and embryos to which they relate); and
- provision to keep records indefinitely (or at least for the expected lifetime of any persons born)." (p49)

This is a more stringent requirement than exists in the ART Act, and is required for RTAC accreditation, which is in turn required if the ART provider is to comply with the RIHE Act.

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[2] "**S 11 Offence--use of embryo that is not an excess ART embryo**

A person commits an offence if:

the person intentionally uses, outside the body of a woman, a human embryo:

(i) that was created by fertilisation of a human egg by a human sperm; and

(ii) that is not an excess ART embryo; and

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact. "

The effect of this clause is to ensure that there is no loophole for the inappropriate use of ART embryos that are not excess to the needs of the woman (and any spouse) for whom they were created. For example, it would be illegal to use an ART embryo that has not been declared "excess" in the training of ART technicians or to derive embryonic stem cells. (*Research Involving Embryos Bill 2002: Revised Explanatory Memorandum*)

3. ***What is the minimum level of information that was collected in the past and how is that changed now?***

Since the commencement of the RIHE Act, ART providers were to collect "full names (including previous names) and contact details of all participants and, whenever possible, the names of persons born as a result of assisted reproductive technology."(Guidelines p49)

Gamete donors

ART providers were to keep minimum information about gamete donors or gamete providers for donated embryos:

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- name, any previous name, date of birth and most recent address;
- details of past medical history, family history, and any genetic test results that are relevant to the future health of the person conceived by gamete donation (or any subsequent offspring of that person) or the recipient of the donation; and
- details of physical characteristics
- the number of persons born using gametes or embryos provided by the same person(s), the sex of each person born and the number of families into which they have been born."

(Guidelines p50, 51)

To that information required by the Guidelines, the ART Act and Regulation added the recorded items

- place of birth of the donor of a donated gamete,
- any descendent of any donor-conceived offspring, and
- the name of each ART provider who has previously obtained a donated gamete from the donor and the date on which the gamete was obtained.

Stored gametes and embryos

Persons for whom gametes and embryos are stored and persons who use stored gametes are entitled to certainty about the safety and identity of the gametes. Clinics must therefore ensure the safe storage and accurate identification of all gametes.

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- 8.2.1 The identity and location of any gametes or gonadal tissue in storage should be recorded in detail.
- 8.2.2 The labelling method should not be susceptible to unauthorised, undetectable or accidental alteration."

.....

- 8.6.1 The identity, number and location of any embryos in storage should be recorded in detail.
- 8.6.2 The labelling method used should not be susceptible to unauthorised, undetectable or accidental alteration.

(Guidelines p27, 28)

Section 31 of the ART Act further specifies records must be kept in relation to

- the provenance of any such gamete or embryo (including the provenance of the gametes used to create the embryo), and
- the uses that have been made of any such gamete or embryo, including exporting the gamete or embryo from this State or supplying the gamete or embryo to another ART provider, and
- the period during which any such gamete or embryo has been in storage, and
- the identity of each woman who undergoes ART treatment provided by the ART provider and any other prescribed information about the woman, the woman's spouse (if any) and any offspring of the woman.

The Guidelines do not specify records to be kept in relation to storage of gametes or embryos, but the Guidelines do make recommendations about monitoring usage:

"Gametes from one donor should be used in a limited number of families. In deciding the number of families, clinicians should take account of:

- the number of genetic relatives that the persons conceived using the donation will have;
- the risk of a person conceived with donor gametes inadvertently having a sexual relationship with a close genetic relative (with particular reference to the population and ethnic group in which the donation will be used);
- the consent of the donor for the number of families to be created; and
- whether the donor has already donated gametes at another clinic"

(Guidelines p18)

Offspring

Both the ART Regulation and the Guidelines both require

- the full name, sex and date of birth of each offspring born as a result of ART treatment, provided by the ART provider,
- the name of the woman who gave birth to the offspring, and
- if the offspring was born as a result of ART treatment using a donated gamete, the full name and date of birth of the donor of the gamete.

Consent to be obtained

The Guidelines recommended consent forms for the donation of gametes or embryos should include:

- full details of the agreed arrangements for any treatment involving donated gametes or embryos;
- an acknowledgment that each participant (and spouse or partner, if any) has received and understood the information provided about gamete or embryo donation;
- a statement that the gamete or embryo donor understands and acknowledges his or her biological connection to any persons conceived using his or her donated gametes or embryos;
- a statement giving explicit permission to make the specified information available to the recipients and any person conceived through the procedure, respectively;
- a description of the arrangements for responsibility for the gametes or embryos after donation; and
- provision for signature by the participant (and his or her spouse or partner, if any).
- Advice that participants have the right to withdraw or vary their consent at any time.

Potential gamete or embryo donors and gamete or embryo recipients should be given adequate time between provision of information and obtaining consent to allow consideration of the complex issues involved.

Consent forms for the storage of gametes or embryos should include:

- the maximum period of storage; and
- a clearly expressed and witnessed directive as to what should be done with the gametes or embryos if either or both the person(s) for whom they are stored die(s), become(s) incapable of varying or revoking the consent, or fail(s) to give further instructions at the expiry of the maximum period of storage.

The ART Act and Regulation do not add to these requirements.