CONSENT CHECKLIST FOR LICENSED ACTIVITIES USING EXCESS ART EMBRYOS

In the first instance, this document is to be used by applicants and HRECs when developing the consent process and documents which are submitted as part of the licence application.

After licence issue, licence holders are required to ensure that consent processes and documents continue to comply with the requirements of this checklist.

General Description of Process for Obtaining Consent: Important Issues

This checklist has been developed to assist applicants and associated Human Research Ethics Committees (HRECs) to develop consent processes for the use of excess ART embryos that are in accordance with the:

- The *Research Involving Human Embryos Act 2002* (RIHE Act) as amended;
- The Research Involving Human Embryos Regulations 2017 (RIHER) as amended;
- The *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) as amended;
- The *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (ART Guidelines); and
- The *National Statement on Ethical Conduct in Human Research 2007* incorporating all updates as at May 2015 (NS).

For more information on "proper consent" see the *Consent checklist for other licensed research* and *Additional information on obtaining consent*.

When approving a research proposal that requires a licence issued by the NHMRC Licensing Committee, HRECs must review the entire consent process as it relates to the proposed project or activity and provide written advice to the NHMRC Licensing Committee regarding their approval and evaluation of the research project / activity.

All applications for a licence to conduct research, training or quality assurance activities involving the use of excess ART embryos must contain a general description of the process for obtaining participant consent and must include the proposed patient information statement and consent forms.

The NHMRC Licensing Committee does not prescribe the language or format of the information and documents provided to embryo donors. However, the NHMRC Licensing Committee considers that the items listed in the checklist are important elements in the process for obtaining "proper consent". Consequently it requires that applicants attach a completed checklist to the application and recommends that HRECs use the checklist when evaluating the consent process.

The consent process consists of ***TWO*** stages and a description of the process for obtaining consent should address these stages:

- **Stage 1** - Declaration that the embryos are excess ART embryos (Declaration of Excess); and
- **Stage 2** - Provision of information to participants regarding the specific project / activity (Participant Information) and consent given by responsible persons[1] for a specific project / activity (Proper Consent).

It is important for applicants and their HRECs to ensure that the consent process:

- is consistent with the documents listed above,
- provides participants with appropriate information at a level they can understand,

[1] In accordance with the RIHE Act, the definition of 'responsible persons' includes the gamete donor and their spouse. As such, consent is required from a gamete donor's partner if the use is under a licence. This differs to the 2017 ART guidelines which do not require consent from the donor's partner for use in treatment.

- uses terminology in the consent documents and consent information that is consistent with that used in the legislation, and
- records consent appropriately.

Consent that is obtained from participants must be:

- fully informed,
- voluntary and free from coercion,
- specific to the project / activity,
- recorded in writing, and
- given by person/s competent to do so.

General Issues

Item*	Requirement	Basis for this requirement	✓ ✗ N/A
1	The process for obtaining consent has been developed after consideration of and in accordance with:		
	a. The *Research Involving Human Embryos Act 2002* (Commonwealth) (https://www.legislation.gov.au/Details/C2016C00968)	Legislation that establishes a regulatory framework for Australian research that involves human embryos	
	b. The Research Involving Human Embryos Regulations 2017 (Commonwealth) (https://www.legislation.gov.au/Details/F2017L01213)	Legislation that establishes a regulatory framework for Australian research that involves human embryos	
	c. The *Prohibition of Human Cloning for Reproduction Act 2002* (Commonwealth) (https://www.legislation.gov.au/Details/C2017C00306)	Legislation that establishes a regulatory framework for Australian research that involves human embryos	
	d. The *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2017* (https://www.nhmrc.gov.au/guidelines-publications/e79)	RIHE Act paragraph 21(4)(c) and RIHER Part 1	
	e. The *National Statement on Ethical Conduct in Human Research 2007* – Updated May 2015 (https://www.nhmrc.gov.au/guidelines-publications/e72)	RIHE Act paragraph 21(4)(c) and RIHER Part 1	
2	The licence application includes a timeline and a description of the process for obtaining proper consent that includes relevant stages in the treatment process and stages in the use of the embryo for licensed activities.	ART Guidelines 13.16	
3	The process for obtaining consent for involvement in the research is clearly separated from clinical care.	ART Guidelines 4.5, 11.5, 13.16	
4	Consent must be fully informed: Responsible persons are given information regarding the project / activity. Researchers should provide an oral explanation, supported by written information in plain language. Responsible persons are given sufficient time to consider the information.	ART Guidelines 13.16, 13.18.1	

5	Consent of responsible persons must be voluntary and not subject to any coercion, inducement or influence, including financial.	NS 2.2.1, 2.2.9 & 2.2.10 *and* ART Guidelines 11.5, 13.16 Note the offence provisions of PHCR Act section 21 regarding commercial trade in human embryos	
6	Consent must be given by people competent to do so: - legally competent – the relevant responsible people must be identified and all must give consent - cognitively competent – for example, consent documents must not be signed while a woman is affected by the sedation used during egg retrieval.	RIHE Act section 8, subsection 24(1) ART Guidelines 13.16	
7	Consent must be specific to the project.	ART Guidelines 13.16	
8	Consent must be in writing.	ART Guidelines 13.16	
9	The applicant organisation and its HREC have considered the possibility of any financial outcomes of the research and have agreed that the information provided to responsible persons regarding this issue is appropriate and sufficient.	ART Guidelines 13.18.2	
10	The consent documents acknowledge that participants can place restrictions on their consent and provide information about the types of restrictions that may apply and the consequences (if any) of placing restrictions on the consent.	RIHE Act paragraph 21(3)(a)	
11	The description of the consent process includes a procedure for ensuring that the NHMRC Licensing Committee has been notified that consent has been obtained before an excess ART embryo is used under a licence.	RIHE Act paragraph 24(1)(b), section12	
12	The description of the consent process includes the procedures for recording, notifying the NHMRC Licensing Committee about and observing any restrictions participants place on their consent.	RIHE Act paragraph 24(1)(b), section12	
13	If embryos created using donor gametes may be used in the research, the consent protocol includes a process for identifying *all* responsible persons and ensuring that their consent has been obtained before the embryos are used.	RIHE Act section8, subsection 24(1), section12 ART Guidelines 11.7, 13.16	
14	Embryos must exist before they can be declared to be excess. The consent process cannot rely on an “advance directive” obtained before treatment commences.	RIHE Act section 9	
15	If the licensed activity uses fresh embryos which are unsuitable for implantation the consent process description outlines when information is provided about the project, when the declaration of excess embryos form will be signed, when the consent form will be signed, how the cooling off periods are modified and how consent can be withdrawn within the time constraints imposed by the treatment and research protocols.	RIHE Act subsection 24(8)	

16	With the exception of correction of typing errors and updates to contact details, any amendments after the licence has been issued, have been approved by the HREC and by the NHMRC Licensing Committee before being implemented (unless otherwise permitted by the licence conditions).	RIHE Act paragraph 21(3)(c), ART Guidelines 11.1	
17	The consent process and documents should clearly identify the categories of participants who will be approached to give consent to use of their excess ART embryos in the project. That is, responsible persons are only approached if their embryos are suitable for the licensed activity.	ART Guidelines 11.5, 11.6, 11.7	

*Items are numbered for convenience and do not reflect order of importance.

STAGE 1 - Declaration that the embryo/s are excess ART embryo/s

Checklist for the declaration of excess ART embryo process

When people decide that ART embryos are excess to their reproductive needs, they may have several options: allowing the embryos to succumb, donating the embryos to a research project, or donating the embryos to another couple. The NHMRC Licensing Committee does not regulate the options of allowing embryos to succumb or donation to another couple. Declarations that embryos are excess must be completed by the woman for whom the embryo was created and her spouse (if any) at the time the embryo was created.

NOTE: Gamete donors and their spouses at the time of donation are not involved in this stage of the consent process (RIHE Act, subsection 9(1)).

Item	Requirement	Basis for this requirement	✓ × N/A
1	The declaration precedes and is separate from the request for consent to a specific licensed activity.	ART Guidelines 13.13	
2	The declaration that embryos are excess to the reproductive needs of the people concerned is in writing (e.g. a signed form).	RIHE Act subsection 9(2) ART Guidelines 13.13	

Checklist for the Declaration of Excess ART Embryo Document

Item*	Requirement	Basis for this requirement	✓ × N/A
The declaration form:			
1	contains an explicit statement that the embryos are excess to the reproductive requirements of the persons giving consent;	RIHE Act subsection 9(2) ART Guidelines 7.3.2,13.13	

2	describes the options for the ART embryos that are declared to be excess. The options may include the following:	ART Guidelines 4.1.3	
	a. embryos are allowed to succumb – the document informs person(s) signing the form that this is a binding decision and no further consent will be required		
	b. embryos are donated to other person(s) – the document informs person(s) about the clinic's procedures in this situation.		
	c. the person(s) wish to consider donation of embryos to activities licensed by the NHMRC Licensing Committee - the document informs the person(s) that this is not a final decision and that more information will be provided requesting consent for a specific project. No specific information regarding the licensed activity is to be provided at this time		
	d. the person(s) wish to consider donation of embryos to training or quality assurance activities that do not require a licence issued by the NHMRC Licensing Committee		
	e. other options if applicable;		
3	contains a brief statement/s concerning the consequences of each decision and a process to allow the persons giving consent to indicate their decision / choice;	ART Guidelines 11.5 – 11.7 *and* NS 2.2.1	
4	provides for the names and signatures of those declaring embryos to be excess and the date(s) of signing;	RIHE Act subsection 9 (2)(b)	
5	has provision to record information which identifies which embryos are being declared excess e.g. the date the embryos were created or frozen and the number and, if applicable, characteristics of embryos that are being donated / disposed of. This information can be inserted by the clinic before the forms are sent to the people making the declaration;	RIHE Act paragraph 9 (2)(b) ART Guidelines 13.13	
6	includes the name and / or position, and contact details of counselling services and where to obtain further information regarding the options for stored embryos;	ART Guidelines 4.3 & 4.1.3	
7	states that if the embryos are to be used fresh, they may only be declared excess because they are (a) unsuitable for implantation according to the objective criteria or (b) they have (or will be) determined to be unsuitable for implantation on the basis of PGD results.	RIHE Act section 7	
8	gives a reason for declaring the embryos to be excess (e.g. excess to reproductive needs, unsuitable due to PGD or unsuitable according to the objective criteria)	RIHE Act section 7	

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STAGE 2 – Participant Information Statement to inform Proper Consent & Proper Consent Document

Checklist for the Participant Information Statement to inform proper consent

The participant information statement is provided to potential participants in support of the process to acquire proper (specific) consent for a specific project / activity. All responsible persons should be given an oral explanation of the project / activity and this is to be supported by written information. Responsible persons must be given sufficient time to consider the information they are provided with (ART Guidelines 13.18.1).

Responsible persons are defined as the persons who provided the egg and sperm from which the embryo was created and their partners at the time the gametes were donated and the woman for whom the embryo was created and her partner at the time (RIHE Act section 8)[2].

The participant information statement should not exaggerate claims of the likely benefits of the project / activity but explain why it is necessary.

Item*	Requirement	Basis for this requirement	✓ ✗ N/A
1	The person who approaches the responsible persons is independent of their clinical care and has knowledge of the project and related issues.	ART Guidelines 11.5 & 13.13	
2	Responsible persons should be provided with information about the purpose, methods, demands, risks, potential benefits and possible outcomes of the activity described.	NS 2.2.1, 2.2.2, 2.2.6 *and* ART Guidelines 11.6, 13.18.2	
The participant information:			
3	describes a specific project / activity or group of activities. Consent must be sought to use excess ART embryos for each project / activity included in the licence application;	ART Guidelines 13.17	
4	uses non-technical language as far as possible;	NS 2.2.3, 5.2.16 *and* ART Guidelines 13.18.1	
5	provides information about where and how results of the activity may be published - if applicable. Include a statement that this will be non-identifying information;	ART Guidelines 13.18.2 *and* NS 2.2.6(f), 2.2.6(k)	
6	states that the outcomes of the research will be reported to the NHMRC Licensing Committee;	Standard Condition 3001^	
7	informs responsible persons if researchers or others may benefit financially from the use of their embryos;	NS 2.2.6 (i) *and* ART Guidelines 11.11, 13.18.2	
8	informs responsible persons that they will not benefit financially themselves from donating their embryos;	PHCR Act section 21, NS 2.2.10 *and* ART Guidelines 13.18.2	
9	informs responsible persons that the results of the research, such as the development of a cell-based treatment for a disease may only be realised in the long term;	ART Guidelines 13.21.6	

10	if applicable, includes a statement that the outcomes of the project may not benefit the donor or donor's family and friends directly;		
11	contains a statement that the embryos will be destroyed or damaged by the project / activity, or, if they survive the project / activity, they will be allowed to succumb after the activity, or it may be suggested that the embryos are entered into a further project / activity	NS 2.2.1 *and* ART Guidelines 13.18.2	
12	advises that consent and participation in the licensed activity is voluntary;	NS 2.2.1, 2.2.9 *and* ART Guidelines 11.5, 13.16	
13	advises that the decision of whether or not to donate embryos will not affect the ongoing relationship to clinic if this is still relevant to the responsible persons;	ART Guidelines 11.5 NS 2.2.19	
14	advises that consent can be withdrawn at any time, but that if the embryos have already been used in the activity, they may not be able to be recovered;	NS 2.2.19, 2.2.20 *and* ART Guidelines 13.19	
15	advises that a time for re-consideration (cooling-off period) will be observed before the consent is acted upon and the embryos are used for the activity. The applicable cooling-off period is specified in the participant information statement;	ART Guidelines 13.19	
16	advises the procedure for notifying that consent has been withdrawn;	ART Guidelines 13.19	
17	provides details of access to counseling;	ART Guidelines 11.6	
18	makes it clear that the fate of individual embryos may not be able to be reported to the responsible persons;	ART Guidelines 13.17	
19	includes the name or position and contact details of a person able to provide additional information concerning the project or activity;	NS 2.2.6 *and* ART Guidelines 11.5, 11.6, 13.18.2	
20	advises of a process for raising any concerns about the research and the name or position and contact details of a person to receive complaints;	NS 2.2.6, 5.6 *and* ART Guidelines 13.18.2	
21	provides information about how donor privacy will be protected;	NS 2.2.6, ART Guidelines 13.21.6	
22	informs responsible persons that their personal records may be viewed by NHMRC Inspectors to meet the requirements of the RIHE Act;	ART Guidelines 13.18.2	
23	Informs responsible persons that they may place restrictions on their consent, but that this may mean that their donated material cannot be used, and consequently that their consent will not be accepted	RIHE Act paragraph 21(3)(a), subsection 24(1)	

24	describes the options available and requests advice from the responsible persons about their wishes should any of their excess ART embryos remain unused when the licensed activity ceases. Participants should be asked to indicate whether they wish to be contacted about potential future projects or if their embryos should be disposed of appropriately without additional contact;	Standard Conditions 4201^	
If the project involves the derivation of embryonic stem cells lines the participant information:			

25	includes a statement that, if successful, the cell lines may be maintained for many years, used for many purposes and distributed to other parts of the world and that donors will not have any control over the cell lines;	NS 3.4.1, ART Guidelines 13.17, 13.18.2 NS 3.4.3(g), (h), (i) and(j)	
26	includes a statement to the applicable donors that the cell lines contain their genetic information and that they are, in principle, re-identifiable from their genetic material.	NS 3.5.8(a)	
27	provides information about the likely uses and dissemination of the cell line and informs responsible persons about limitations on their ability to withdraw consent after a cell line has been derived.	NS 3.4.3 (h) and ART Guidelines 13.17	

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^ Standard Conditions of Licence (https://www.nhmrc.gov.au/research/embryo-research-licensing/database-licenc)

Checklist for the Proper Consent Document

The items listed below represent the minimum information required in the consent form. Additional information may be included if required.

Item*	Requirement	Basis for this requirement	
The Proper Consent document:			
1	contains a statement that responsible persons have received / been offered an oral explanation that is supported by written information;	ART Guidelines 13.18.1	
2	specifies the purpose(s) for which the embryo/s will be used (Use the title or provide a brief summary of the project / activity);	ART Guidelines 13.17	
3	contains a statement that consent may be withdrawn but that if embryos have been used in the project / activity, they may not be able to be recovered;	ART Guidelines 13.19	
4	has provision to record information which identifies which embryos are being donated to the project e.g. the date the embryos were created or frozen and the number and, if applicable, characteristics, of embryos in storage. This information can be inserted by the clinic before the forms are sent to the	RIHE Act subsection 24(1) and ART Guidelines 13.16	
5	allows responsible persons to record any restrictions they wish to place on their consent;	RIHE Act subsection 24(1)	
6	makes provision for the responsible persons to indicate their wishes about the options for their excess ART embryos should any of the embryos remain unused when the licensed activity ceases;	Standard Conditions 4201^	
7	contains space for the names and signatures of responsible persons giving consent and the date of signing.	ART Guidelines 13.14, 13.16 and RIHE Act paragraph 9(2)(b)	

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^ Standard Conditions of Licence (https://www.nhmrc.gov.au/research/embryo-research-licensing/database-licenc)