CONSENT CHECKLIST FOR OTHER LICENSED RESEARCH

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 licensable activities which do not involve the use of excess ART embryos. The checklist lists the issues and information that must be considered when developing consent processes and documents for projects that require the use of reproductive material, genetic material, cells or fetal tissue in activities which are licensable according to paragraphs 20(1)(b-f) of the *Research Involving Human Embryos Act 2002*.

The consent processes must reflect the requirements of:

- The *Research Involving Human Embryos Act 2002* (RIHE Act);
- The Research Involving Human Embryos Regulations 2017 (RIHER);
- The *Prohibition of Human Cloning for Reproduction Act 2002 (*PHCR Act);
- 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 licensed research using excess ART embryos* 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 permitted by s.20(1)(b-f) of the RIHE Act must contain a general description of the process for obtaining participant consent and must include the proposed patient information statement and forms. Since these licensable activities may require the use of material from several categories of donors, the consent process and documents should reflect this aspect. Separate information and forms should be provided for each category of donor.

The NHMRC Licensing Committee does not prescribe the language or format of the information and documents provided to 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 complete the checklist for each consent process and attach the completed checklist(s) to the application. The NHMRC Licensing Committee also recommends that HRECs use the checklist when evaluating the consent process.

The consent process should ensure provision of information to participants regarding the specific project / activity (Participant Information) and the obtaining of consent from 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,

[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.

- provides participants with appropriate information at a level they can understand,
- 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.

A description of the Proper Consent process should address the following issues:
- when seeking consent for a specific activity, an oral explanation should be provided and supported by written information. The clinic or research organisation should not accept any signed Proper Consent forms before this occurs,
- the process for observing any restrictions participants place on Proper Consent,
- researchers should always exhibit sensitivity to the needs of the participant/s, and
- processes to allow for withdrawal of consent if desired by the participants.

Information which is common to all categories of human material is provided first. Issues specific to individual categories are noted later.

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(5)	
	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 214(c) and RIHER Part 1(5)	

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 (if applicable) and stages in use of the material in the licensed activity.	ART Guidelines 13.16	
3	The process for obtaining consent for involvement in the research is clearly separated from clinical care.	ART Guidelines 11.5	
4	The consent process and documents should clearly identify the categories of participants who will be approached to give consent for use of their material in the project.	ART Guidelines 11.5, 11.6, 11.7	
5	Consent must be fully informed: Responsible people are given information regarding the project / activity and are given sufficient time to consider the information. Information should be conveyed in appropriate language.	ART Guidelines 11.6, 13.21.6, 13.18.1	
6	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, 13.21.5 Note the offence provisions of PHCR Act section 21 regarding commercial trade in human eggs, human sperm or human embryos and ART Guidelines 13.21.2,13.23.3	
7	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	
8	Consent must be specific to the project	ART Guidelines 13.16	
9	Consent must be in writing	ART Guidelines 4.5.4, 11.7	
10	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 13.21.6	
11	The consent documents must 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)	
12	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 the material is used under a licence.	RIHE Act paragraph 24(1)(b), section 12	
13	The description of the consent process includes the procedures for recording, notifying the NHMRC Licensing Committee and observing any restrictions participants place on their consent.	RIHE Act paragraph 24(1)(b), section 12	
14	Research using human eggs or fetal tissue should be conducted at a location that separates the woman's clinical care from the research.	ART Guidelines 11.5, 13.21.1,13.23.1	

15	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	

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

Participant Information Statement to inform proper consent and proper consent document

Checklist for the Participant Information Statement to inform proper consent

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

Responsible persons in relation to an embryo other than an excess ART embryo are defined as each person whose reproductive material, genetic material or cell was used or is proposed to be used in the creation or use of the embryo. In relation to a human egg, the woman who was the biological donor of the egg is the responsible person (RIHE Act s.8).

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 & 13.21.1, 13.23.1	
2	Responsible persons should be provided with information about the purpose, methods, demands, risks and possible outcomes of the proposed research and a realistic appraisal of its potential benefits.	NS 2.2.1, 2.2.2, 2.2.6 *and* ART Guidelines 13.21.6	
The participant information:			
3	describes a specific project / activity. Consent must be sought to use the donated material for that project / activity;	ART Guidelines 13.21.6	
4	includes a statement that the donated material will not be used for any purpose other than the project/activity for which consent is being asked;	ART Guidelines 13.21.3, 13.21.6	
5	uses appropriate language and graphics to convey accurate clear information including a brief description of the project in lay language and its contribution to the potential benefits of the overall research program;	ART Guidelines 13.21.1, 13.21.6	
6	provides information about where and how results of the activity may be published - if applicable. Includes a statement that this will be non-identifying information;	ART Guidelines 13.18.2, 13.21.9 *and* NS 2.2.6(f), 2.2.6 (k)	
7	states that the outcomes of the research will be reported to the NHMRC Licensing Committee;	Standard Condition 3001^	
8	informs responsible persons if researchers or others may benefit financially from the use of their donated material;	NS 2.2.6(i) *and* ART Guidelines 11.11, 13.21.6, 13.23.9	

Item	Requirement	Basis for this requirement	✓ ✗ N/A
9	informs responsible persons that they will not benefit financially themselves from donating their material;	PHCR Act section 21, NS 2.2.10 *and* ART Guidelines 13.21.6, 13.23.9	
10	informs responsible persons that the results of the research may only be realised in the long term;	ART Guidelines 13.21.6	
11	if applicable, includes a statement that the outcomes of the project may not benefit the donor or donor's family and friends directly;		
12	if applicable, includes a statement that the project will involve the creation of an embryo which will then be destroyed in the course of the activity;		
13	advises that consent and participation in the licensed activity is voluntary;	NS 2.2.1, 2.2.9 *and* ART Guidelines 11.5, 13.21.6	
14	advises that the decision of whether or not to donate their material will not affect clinical care if this is relevant to the responsible persons;	ART Guidelines 11.5	
15	provides a description of how to withdraw consent and advises that consent can be withdrawn at any time up to the time the material is used in the research and that if a stem cell line results, up to the time that the cell line is created. The consequences of withdrawal are also described;	NS 2.2.6(g), 2.2.19, 2.2.20, 3.4.3(h), 3.5.12(f) *and* ART Guidelines 13.21.6, 13.21.8, 13.23.9	
16	if applicable, advises that a specified time for re-consideration (cooling-off period) will be observed before the consent is acted upon and the donated material used for the activity;	ART Guidelines 13.19	
17	provides details of access to counseling;	ART Guidelines 13.21.6, 13.21.15, 13.23.6	
18	if applicable, makes it clear that the fate of the donated material 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 and able to provide information about the outcomes of the research should donors wish to know;	NS 2.2.6 *and* ART Guidelines 11.5, 11.6, 13.21.9	
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	
21	provides information about how donor privacy will be protected;	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 material 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 material should be disposed of appropriately without additional contact.	Standard Conditions 4201^	
If the project involves the creation of embryos for 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, 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)	
	Issues specific to the use of Eggs, Sperm or Cells		
27	Persons other than members of the research team should obtain consent from participants	ART Guidelines 13.21.1	
28	Researchers should be available to discuss the project if requested by the potential participants	ART Guidelines 13.21.1	
29	If genetic screening and disease testing related to gamete or cell donation is to be done, there must be an ethically defensible plan for the disclosure or withholding of such information.	ART Guidelines 13.21.4	
30	A description of the retrieval process for gametes, gonadal tissue or cells, including what will be done, where the procedures will be done and by whom.	ART Guidelines 13.21.6	
31	A statement about the potential risks of retrieving and donating gametes	ART Guidelines 13.21.6	
32	The risks of long-term consequences for fertility of hormonal stimulation of the ovaries and surgical collection of eggs must be disclosed to potential donors.	ART Guidelines 13.21.11	

	Issues specific to use of Fetal cells in licensed research		
33	The request for consent to participate in the research should be separate from the process of deciding to terminate the pregnancy	ART Guidelines 13.23.5	
34	The woman should not be approached for consent for research using fetal cells until after the decision has been made to terminate the pregnancy	ART Guidelines 13.23.5, 13.23.7, NS 4.1.16	
35	The woman should be asked whether, in her decisions about the research, she wishes to involve others such as family members, for whom the research may have implications	ART Guidelines 13.23.4, 13.23.9 *and* NS 4.1.20(a), 4.1.15	
36	The woman should be informed if fetal cells or stem cell lines developed from them will be exported to another country	ART Guidelines 13.23.9	

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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	✓ ✗ N/A
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	clearly indicates the type of material (reproductive material, genetic material or cell) that is being donated;	RIHE Act subsection 20(1) and ART Guidelines 13.21, 13.23	
3	specifies the purpose for which the material will be used (Use the title or provide a brief summary of the project / activity);	ART Guidelines 13.17	
4	If applicable, acknowledges that the project will involve the creation of an embryo which will then be destroyed in the course of the activity;		
5	contains a statement that consent may be withdrawn but that if the material has been used in the project / activity, it cannot not be recovered;	ART Guidelines 13.19	
6	has provision to record information which identifies which material is being donated to the project e.g. the date the material was obtained. This information can be inserted by the licence holder organisation before the forms are sent to the responsible persons;	ART Guidelines 13.16 *and* RIHE Act subsection 24(1)	
7	allows responsible persons to record any restrictions they wish to place on their consent;	RIHE Act subsection 24(1)	
8	makes provision for the responsible persons to indicate their wishes about the options for their donated material if any remains unused when the licensed activity ceases;	Standard Conditions 4201^	
9	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)