

Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Recording and providing information to the Human Fertilisation and Embryology Authority under a research licence

Ref: 0002
Version: 3

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Section 15(2), 12(1)(d) and 12(1)(g)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	1 April 2015

- Centres operating under a research licence granted by the Human Fertilisation and Embryology Authority (HFEA) must maintain a record, in any format, of:
 - the total number of embryos created, used or disposed of during that project of research;
 - the results of the project of research for which the licence was granted; and
 - the conclusions drawn from that project of research
- Licensed centres holding any of the records referred to in paragraph 1(a), 1(b) and 1(c) above must be able to produce hard copies of those records upon request from an HFEA member or employee.
- Centres operating under a research licence granted by the HFEA must provide the HFEA with:
 - a provisional report setting out the results and conclusions of the research, no later than 3 months from the end of the project of research for which the licence was granted; and
 - a fully referenced final report with results, conclusions and references to any publications arising from the research project, 12 months from the end of the project for which the licence was granted.
- Persons responsible for centres licensed by the Authority to carry out research must complete and submit to the Authority an electronic copy of the Research Information and Data Sheet, set out in the Schedule to these Directions and published on the Authority's website, no later than 31 January each year. Before submitting the Research and Information Data Sheet persons responsible must confirm that the information they have provided in the document is true and accurate.

5. Where a member of the Authority requires in writing that the person responsible should submit a further Research Information and Data Sheet in addition to that required by paragraph 4 above, the person responsible must submit the further Research and Information and Data Sheet to the Authority no later than 14 days after the date of the written request.



Gemma Hobcraft **14 January 2015**

Chair of Ethics and Standards Committee in accordance with delegated powers granted by the Human Fertilisation and Embryology Authority on 20 March 2013.

Version control	
Name of Directions:	Recording and providing information to the Human Fertilisation and Embryology Authority under a research licence
Reference number:	0002
Date version 1 issued:	1 October 2009
Date version 2 issued:	6 April 2010
Chair's Letter reference:	CH(10)03
Date version 3 issued:	1 April 2015
Chair's Letter reference:	CH(15)01

Schedule

Research information and data sheet (Jan-Dec [YEAR])

Research project number

Please submit one form per HFEA research project.

Centre name(s):

Centre number(s):

1. Were embryos¹ donated to this research project?

Yes

No

If yes, please provide the following information:

Table 1

	Fresh embryos	Frozen embryos
Number received ² but not yet used ³ for research as of 31 December [previous year]	-----	
Number received between 1 January and 31 December [current year]		
Number disposed of between 1 January and 31 December [current year] prior to being used in research		
Number used between 1 January and 31 December [current year]		
Number received but not yet used for research as of 31 December [current year]	-----	

¹ As defined in Human Fertilisation and Embryology Act 1990 (as amended) section 1.

² An embryo is 'received' when it is under the control of the researchers and its only fate can be research.

³ 'Used' means cultured for research, or thawed with the intention of using for research. An embryo must be 'received' before it can be 'used'.

2. Did you create any embryos⁴ by fertilisation or other means?

Yes No

If yes, please provide the following information:

Table 2

NOTE: Embryos in table 2 should not be included in table 1.

	Fresh embryos	Frozen embryos
Number of embryos created for the research project but not yet used ⁵ as of 31 December [previous year]	-----	
Number created for the research project between 1 January and 31 December [current year]		-----
Number disposed of between 1 January and 31 December [current year] prior to being used in research		
Number used between 1 January and 31 December [current year]		
Number created but not yet used for research as of 31 December [current year]	-----	

⁴ As defined in Human Fertilisation and Embryology Act 1990 (as amended) section 1.

⁵ 'Used' means cultured for research, or thawed with the intention of using for research.

3. Did you create any embryos⁶ by splitting, with the intention of culturing them further and using these as individual embryos for research?

Yes No

If yes, please provide the following information:

Table 3

	Fresh embryos	Frozen embryos
Number of split embryos in storage but not yet used ⁷ as of 31 December [previous year]	-----	
Number of embryos ⁸ split for the research project between 1 January and 31 December [current year]		-----
Total number of embryos ⁹ available as a result of the splitting referred to in the row above		-----
Number disposed of between 1 January and 31 December [current year] prior to being used in research		
Number used between 1 January and 31 December [current year]		
Number in storage but not yet used for research as of 31 December [current year]	-----	

⁶ As defined in Human Fertilisation and Embryology Act 1990 (as amended) section 1.

⁷ 'Used' means cultured for research, or thawed with the intention of using for research.

⁸ The original embryo which was split **should also be logged** in Table 1. Therefore, these embryos should appear in Table 1.

⁹ Once splitting has occurred the resulting embryos **should not be logged** in Table 1. Therefore, do not log these embryos in Table 1.

4. Were any embryos reported on this form donated to another HFEA research project?

Yes No

If yes, please provide the following information:

Table 4

HFEA research project number	Number of embryos donated

5. Did the research involve the derivation of human embryonic stem cell lines?

Yes No

If yes, please state the number of stem cell lines derived in [current year]: