

## Authority paper

Strategic delivery	Setting standards <input type="checkbox"/>	Increasing and informing choice <input checked="" type="checkbox"/>	Demonstrating efficiency, economy and value <input type="checkbox"/>
<b>Paper title</b>	Report of the activities of the HFEA Register Research Panel - Annual Update		
<b>Agenda item</b>	10		
<b>Paper number</b>	[HFEA (21/01/2015) 744]		
<b>Meeting date</b>	21 January 2015		
<b>Author</b>	Suzanne Hodgson		
<b>For information or decision?</b>	For information		
<b>Recommendation</b>	The Authority is asked note the activity of the Register Research Panel.		
<b>Resource implications</b>	None		
<b>Implementation</b>	Immediately		
<b>Communication</b>	Internal communication to members of the Register Research Panel and staff involved in its administration.		
<b>Organisational risk</b>	Low		
<b>Annexes</b>	None		

**1. Authority oversight**

1.1. The HFEA Register Research Panel (RRP) was set up in 2010 after the law changed to allow the disclosure to external researchers of patients' identifying information. Since it was established seven studies have been approved, two of which have now been published in peer reviewed journals. The Authority remains the statutory Oversight Committee and therefore has a duty to exercise oversight of the work of the RRP. This paper fulfils this statutory requirement and has one main purpose:

- To report on the work of the Panel since November 2013

**2. Register Research Panel activity since November 2013**

2.1. Since the last report in November 2013, the Panel has received no new applications, but is expecting two in the next few months. The Panel has sat on two occasions, in September and November 2014 to discuss whether further support can be provided to an ongoing piece of work. Staff have continued to meet and correspond with prospective researchers.

2.2. A new Memorandum of Understanding between the RRP and the Health Research Agency Confidentiality Advisory Group has been signed and will be published on the HFEA website in due course.

2.3. No appeals against RRP decisions have been received so there has not yet been a need to convene the Register Research Review Panel.

**3. Update on studies approved in previous years**

3.1. The approval of these studies was previously reported to the Authority; this is an update on their progress.

**Cancer risk in children born after IVF/ICSI (approved 2010)**

3.2. The results of this study were presented to the Authority in September 2013 by Professor Alastair Sutcliffe and were subsequently published in the New England Journal of Medicine in November 2013. The study found that there was no increase in the overall risk of cancer among children born after assisted conception. While there were increased risks of two rare types of cancer (hepatoblastoma and rhabdomyosarcoma) the absolute risks were small and these types of cancer have been linked to low birth weight.

3.3. This is a hugely important piece of work, robustly answering a question which we know has long concerned patients.

3.4. The study, which won the Clinical Science Award at ESHRE 2013, can be read in full here: <http://www.nejm.org/doi/full/10.1056/NEJMoa1301675>.

**Cancer risk and mortality in women after IVF (approved 2010)**

3.5. The analysis of the data provided by the HFEA is on going, and the results of this study should be published this year.

**Mortality and general health in children born after IVF (approved 2012)**

3.6. The study, merged from two separate applications, has full approval from the RRP but is awaiting internal approval from the HSCIC (who are performing the matching, and have had a backlog recently) before matching can start. This is

expected imminently.

**Effect of ethnicity on the success of assisted reproduction technologies (approved 2012)**

- 3.7. The researchers published a paper based on this study in the British Journal of Obstetrics and Gynaecology in November 2013. They reported that live birth rates following IVF or ICSI treatment were significantly lower in the ethnic minority group compared with white European women. The full study can be read here: <http://onlinelibrary.wiley.com/doi/10.1111/1471-0528.12504/pdf>.

**Development and validation of statistical models to predict pregnancy outcomes following in-vitro fertilization (IVF) treatment (approved 2013)**

- 3.8. Most of the analysis for this study is complete now, the team have reported that they are about to fit a more complex model to the data to predict births accounting for multiple treatment cycles per woman. They will keep the HFEA informed with the results.

**EpiHealth Outcomes Project: The effect of maternal age, embryo cryopreservation and culture on perinatal outcomes and child health (approved 2013)**

- 3.9. The researchers have received the linked data (HFEA data linked with Scottish Morbidity and Birth Records) and their analysis of it should be complete in the first half of this year.

**Summary of current projects**

- 3.10. Although the overall number of studies approved remains lower than we may have hoped when the law was amended, taken together these research projects represent an important body of work which could not have been performed otherwise. The completed studies have been published in internationally respected journals and we fully expect the others to follow suit.
- 3.11. The quality of the work produced demonstrates the value of the data in the Register, and of allowing researchers access to the sensitive but unique information held.

**4. Recommendations**

- 4.1. It is recommended that the Authority in its role as the Oversight Committee:
- 4.2. Notes the report of the RRP activities since November 2013.