Introduction

The purpose of this report is to provide information on the research carried out under a licence from the Human Fertilisation and Embryology Authority (HFEA) at UK centres in 2010, together with arrangements for licensing and regulating such research.

The HFEA was set up in 1991 by the Human Fertilisation and Embryology Act 1990 in order to regulate assisted conception and human embryo research. The HFEA also regulates the storage of gametes (sperm and eggs) and embryos. The HFEA has a duty to produce a Code of Practice, which gives guidelines to clinics about the proper conduct of licensed activities, explains its role, and provides advice and information to patients, donors and clinics.

Prior to the HFEA being set up, Parliament asked Dame Mary Warnock to chair an inquiry into human fertilisation and embryology. The report of this inquiry (‘the Warnock Report’), recommended that ‘if the public is to have confidence that [the HFEA] is an independent body, which is not to be unduly influenced by sectional interests, its members must be wide-ranging and in particular the lay interest should be well established’.

How the Authority licenses research projects

The HFEA’s decision-making process when considering research applications is governed by law. The Authority must first determine whether the research proposal passes the necessity test and the intended purpose test.

Under the Human Fertilisation and Embryology Act 1990 (as amended) (‘the HF&E Act’), a licence may not be granted unless the Authority is satisfied that any proposed use of human embryos is necessary for the purpose of the research; and an

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1The Human Fertilisation and Embryology Act 1990 was amended in 2008 when the Human Fertilisation and Embryology Act 2008 was introduced into UK law.

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Table 1
Research purposes
Schedule 2 to the HF&E Act 1990 (as amended)

*Increasing knowledge about serious disease or other serious conditions

*Developing treatments for serious diseases or other serious medical conditions

*Increasing knowledge about the causes of congenital diseases

*Promoting the advances in the treatment of infertility

*Increasing knowledge about the causes of miscarriages

*Developing more efficient techniques of contraception

*Developing methods for detecting gene, chromosome or mitochondrion abnormalities in embryos before implantation

*Increasing knowledge about the development of embryos
activity cannot be authorised unless it appears to the Authority to be necessary or desirable for a research purpose accepted by Parliament (Table 1 shows the purposes for which research using embryos is currently permitted).

Essentially the role of the HFEA is to ensure that the application is lawful; that patients or donors have given properly informed consent and that the use of embryos is justified. For these reasons, the scientists applying for a research licence are asked to provide a lot of information about the research they wish to carry out and why the research could not be done on animal embryos or other types of cells. The scientists also have to send the leaflets which will be given to patients / donors to explain the research before they ask them to consent to the use of their embryos, or their eggs or sperm if they are to be used to create embryos, in research. This information together with the leaflets are closely scrutinised by the Authority and often scientists are asked to make amendments, especially to the leaflets to be given to patients/donors.

To assist the Authority in making these decisions, it takes independent advice by subjecting each research application to external peer review by suitably qualified and independent scientists. The HFEA has a panel of national and international experts in the field of reproductive technologies and infertility for this purpose. The peer review covers the following specific areas:

• whether the research fulfils the categories for which embryo research is permitted;
• the importance of the research in the field;
• whether the research has been done before;
• whether the use of human embryos is justified.

All research applications are considered by a dedicated Research Licence Committee of the Authority. In accordance with the recommendations made in the Warnock Report and to ensure that decisions on whether a research licence should be granted is not unduly influenced by the interests of scientists, this Committee is chaired by a lay member of the Authority. The Research Licence Committee is guided by a published systematic ‘decision tree’ (a copy of this decision tree can be found at: http://www.hfea.gov.uk/docs/2010-10_LC_ELP_Decision_Trees.pdf ). This is intended to increase the transparency of decision making and to ensure that applications are dealt with in a fair and consistent manner.

It can take up to three months to decide whether a research licence should be granted. The Authority has a moral and ethical duty to ensure that human embryos are used in research only where it is absolutely necessary. Moreover, decisions on the suitability of research projects are continually informed by progress in scientific research worldwide and it is the purpose of the Authority’s expert Scientific and Clinical Advances Advisory Committee to ensure it is aware of new developments. For these reasons applications are subject to vigorous scrutiny that does take time and does require applicants to prove that it is necessary to use human embryos in their proposed research.

Where a research licence is granted, the research can only be carried out for up to three years (paragraph 3(8) of schedule 2 to the HF&E Act (as amended)). After this time, if the scientists wish to continue their research then they must apply for another
licensure. Applications to renew a research licence are subjected to the same level of
detailed scrutiny as an application for new research licence.

By law, each scientific project using human embryos must have its own licence from
the HFEA. Therefore, a centre holding a research licence for a particular project is
not allowed to carry out research using human embryos in another area of research
without first obtaining a new, separate, licence from the HFEA.

**Provision of information about research licensed by the HFEA**

When the HFEA receives an application for a research licence, a summary of the
proposed research project is published on the HFEA website ([http://www.hfea.gov.uk/167.html](http://www.hfea.gov.uk/167.html)). A summary of all research projects currently licensed by the HFEA is available on the HFEA website ([http://www.hfea.gov.uk/166.html](http://www.hfea.gov.uk/166.html)) as well as the reports of inspection visits to research centres ([http://guide.hfea.gov.uk/guide/AdvancedSearch.aspx](http://guide.hfea.gov.uk/guide/AdvancedSearch.aspx)).

**Summary of licensed research projects and embryo usage**

In 2010 a total of 24 research projects were being conducted under a licence from
the HFEA. This research was carried out at 23 centres. A list of all the research
projects licensed by the HFEA in 2010 is attached at Appendix 1 to this report.

The HF&E Act permits the Authority to license research for eight purposes (see Table
1). Figure 1 shows the purposes under which the 24 projects of research are
licensed (a research project may be licensed under more than one purpose).

Eighteen of the 24 projects (75%) were licensed because the Authority was satisfied
that the research would increase knowledge about the development of embryos and
50% (12 out of 24) of research projects were licensed because the research would
promote advances in the treatment of fertility. Ten of the 24 projects (42%) were
licensed because the research would increase knowledge about serious disease or
other serious conditions and 12 of the 24 projects (50%) were licensed because the
research would develop treatment for serious disease or other serious medical
conditions.
The purposes for which UK scientists are permitted, by law, to carry out research are quite broad. For example, research that helps develop treatments for serious disease may involve creating human embryonic stem cells or developing new methods that would help patients avoid passing on a genetic disease to their children. Figure 2 shows the broad areas of research carried out under the licences currently issued by the HFEA.
Egg Activation
Two projects (R0172 and R0161) are licensed by the Authority to examine the activation of eggs. At fertilisation a sperm must enter an egg; the sperm stimulates the egg to begin cell divisions and development. As a human sperm approaches the egg it undergoes an event called the acrosome reaction (AR), which is thought to be necessary for successful fertilisation. In the female reproductive tract or in the laboratory this reaction is thought to be induced by interaction between the sperm and the zona pellucida (ZP), a sticky coat surrounding the egg. Despite the crucial role of the acrosome reaction in fertilisation, very little is known about what happens as a sperm moves through the outer egg coat.

One of the licensed projects (R0172) is using advanced fluorescent imaging (microscopy) techniques to examine in detail the events occurring as human sperm and egg interact. The second project (R0161) is investigating how sperm stimulate eggs to begin cell division and development. The researchers have identified a protein, Phospholipase C zeta (PLCzeta), that, when injected into eggs, stimulates them to begin development.

The results of these research projects will give new insight into the very early events occurring in fertilisation, which may lead to the development of new treatments to help couples where the sperm lacks the ability to activate the egg and hence normal fertilisation cannot take place.

Embryo development and implantation
The selection of embryos for use in treatment is mainly based on their morphology – how they look when examined under a microscope and on how rapidly they develop. Little is known about how human embryos are formed and what makes some embryos ‘healthier’ than others.

Four projects (17%) involve the study of early embryo development (R0026; R0067; R011 & R0155). The aim of these projects is to carry out a detailed examination of the development of the early human embryo. One research project (R0067) is studying how an embryo obtains and uses the nutrients it requires; for example, sugars and amino acids (the building blocks of proteins). The research has shown that embryos which developed well in culture take up fewer amino acids from the culture media than embryos which failed to develop normally. Furthermore, embryos which were ‘quieter’ metabolically were more likely to give rise to a pregnancy following embryo transfer. The researchers are now hoping to translate these biological findings into a diagnostic test which could be used to select ‘quiet’ embryos for transfer in order to allow the transfer of single, healthy embryos with a high chance of giving rise to a pregnancy whilst minimising the risks of multiple births.

Another research project (R0111) is studying how normal embryos develop in the laboratory in order to improve the way embryos are cultured and increase the success rates of assisted conception. Although most couples undergoing IVF treatment will have fertilised embryos, many good quality embryos fail to implant when transferred into the woman’s womb. Scientists are looking at genes and proteins which control cell death in embryos, and the ability of cells in the embryo to
stick to one another, and make contact with the wall of the womb, in order to implant and develop. The researchers have used in vitro models to study a group of proteins (Rho GTPases) which control a number of cellular processes, including how cells adhere to one another. The researchers have found that if some of these proteins are switched off, the implantation of embryos is improved. The researchers have also found that the lining of a woman’s womb (the endometrium) plays a role in whether an embryo implants or not. They have discovered that a normal endometrium is able to discriminate between normal and abnormal embryos and prevent abnormal embryos from implanting. By studying in vitro models of implantation, researchers are hoping to develop new therapies for preventing implantation failures.

**Genetic testing**

Five projects (21%) involve the development of techniques to detect serious genetic conditions in embryos (R0075; R0113; R0169; R0177 & R0186). Preimplantation genetic diagnosis (PGD) is a technique that enables people with a specific inherited condition in their family to avoid passing it on to their children. PGD involves checking the genes of embryos created through IVF for this genetic condition. PGD has been used to detect numerical and structural chromosomal abnormalities, the identification of sex for sex-linked diseases and the detection of specific genetic defects that occur in single gene disorders such as cystic fibrosis.

During PGD, one or two cells are removed from an embryo created by in vitro fertilization (IVF) and a diagnostic test carried out on these cells. The aim of the test is to determine whether the cells have the genetic disease or chromosome abnormality. If the cell(s) are found to be free of the genetic disease or chromosome abnormality, then the embryo(s), from which the cells were removed, can be replaced in the uterus (womb) with the hope that they will implant and form a pregnancy. If successful then the baby should not be affected by the disease tested for.

In order to carry out PGD it is necessary to remove one or two cells from an embryo which has been allowed to develop for three days: the embryos have about eight cells at this stage of development. This process is called embryo biopsy and involves forming a hole in the outer shell (zona pellucida) of the embryo. One of the most common methods uses a small amount of acid to dissolve a small section of the zona pellucida in order to remove one or two cells from the embryo using a tiny needle (about five times smaller than a human hair). There have been some concerns about this method as embryos are very sensitive to the environment in which they develop and any culture solution that is either too acidic or too alkaline may stop embryos developing normally.

Another method is to use a laser to form a hole in the zona pellucida. This avoids the use of acid, but expensive equipment is needed and there is a possibility that the light from the laser may damage the cells in the embryo. One of the research projects licensed by the HFEA (R0177) has been testing a new method for removing cells from an embryo and comparing this method with the use of acid or a laser to form a hole in the outer coat of the embryo. The new method is called enucleation and involves puncturing the zona pellucida with a needle and removing the nucleus
of the cell with the same needle. The researchers have compared the three methods of carrying out embryo biopsy (acid, laser and enucleation) and have found that embryos which had been biopsied using enucleation have a high potential for continued development when compared to using the other methods of embryo biopsy. In addition, enucleation gave sufficient genetic material to allow the scientists to carry out the genetic diagnosis.

Preimplantation genetic haplotyping (PGH) is a new technique which enables embryos to be screened for a wider range of diseases. PGD relies on the identification of the presence or absence of a specific mutation associated with the genetic disease, whereas PGH can be used where the precise mutation is not known or cannot be identified. Instead of looking for a specific mutation, PGH scans the cell, taken from a developing embryo, for the broader genetic signature associated with the disease.

By using PGH it may be possible for many more families affected by genetic diseases to undergo genetic testing in order to have children who do not have the genetic disorder. For example, couples who are affected by X-linked genetic diseases such as Duchenne Muscular Dystrophy, where female children do not have the disease but on average half of all male children will have the disease, might then be able to undergo genetic testing and not only be able to have a female embryo transferred but an unaffected male embryo. Until now these couples could only select female embryos for use in IVF treatment. This new technique is now being used in the provision of treatment services in the UK.

**Mitochondrial disease**

Mitochondria are small complex structures which exist in virtually every cell of the body (except red blood cells). They are like small batteries, producing most of the energy which all our cells need to live and grow. Mitochondrial diseases are chronic, genetic disorders that occur when mitochondria fail to produce enough energy. About 3500 people in the UK are affected by mitochondrial disease, which can affect almost every part of the body, with symptoms including muscle weakness and pain, loss of sight and hearing, learning difficulties, seizures, diabetes, heart, liver and kidney disease and breathing difficulties. In the most severe cases, they lead to death in early childhood. The structure and behaviour of mitochondria is controlled not just by DNA contained within the nucleus of the cell but by DNA contained in the mitochondria themselves, known as mitochondrial DNA (mtDNA).

Cells contain thousands of mitochondria and each carries a small piece of DNA which contains 13 protein-coding genes that are needed for normal activities. This compares with 23,000 genes in the chromosomal DNA located in the nucleus of the cell. The inheritance of mtDNA is via mitochondria contained in the egg. Thus mitochondrial genes are inherited only through the mother. Some women are carriers of defective mitochondrial genes; they carry both normal and damaged mitochondrial genes and can pass potentially serious diseases on to their children.

Two projects (R0149 & R0152) are licensed to carry out research into mitochondrial disease.
At present it is not possible to predict which women, who are carriers of mitochondrial diseases, will pass these diseases to their children. Therefore, one of the projects (R0149), licensed by the HFEA, is testing cells taken from the embryos of couples who are at risk of passing on mitochondrial diseases to find out whether it is possible to predict whether or not a baby is likely to be affected with the mitochondrial disorder. This depends on the quantity of normal and abnormal mitochondrial DNA in each cell of the embryo. The researchers have developed a technique for identifying defects in mitochondrial DNA in human embryos created by IVF. This will allow the selection of non-affected embryos using preimplantation genetic diagnosis (PGD) prior to transfer into the woman.

The aim of the second project (R0152) is to see if it is possible to prevent the transmission of mitochondrial disease by transferring the genetic material from the fertilised egg of couples at risk of passing on mitochondrial disease into a healthy early stage embryo donated by another couple. Shortly after a sperm has fertilised an egg, two structures form; these are called pronuclei. One pronucleus contains the mother’s genes and the other contains the father’s genes. Eventually these pronuclei merge to form the embryo’s nucleus containing a unique genetic make-up. This research project has shown that it is possible to transfer the pronuclei containing the chromosomal DNA of a human embryo into a donor egg which has had its nuclear DNA removed with minimal amounts of mitochondria transferred to the donor egg. A proportion of these embryos developed in the laboratory for six to eight days.

**Vitrification**

Vitrification comes from the Latin word vitrum, meaning glass. In the context of freezing eggs and embryos, vitrification is the process whereby the solution containing the eggs or embryos is cooled so quickly that the structure of the water molecules does not have time to form ice crystals and instantaneously solidifies into a glass-like structure.

One centre is licensed to study vitrification (R0187). The aim of this research is to combine the techniques of culturing embryos for five to six days to the blastocyst stage with biopsy and vitrification, in an attempt to indentify the most efficient method of freezing embryos for those patients who may need preimplantation genetic diagnosis (PGD).

Embryo biopsy can be performed at different stages of embryo development: at the cleavage stage, when the embryo is 3 days old, or at the blastocyt stage which usually takes place at day five or six. Vitrification has been shown to offer increased freeze/thaw survival rates over the more conventional ‘slow’ freezing protocols currently in use for blastocysts. This study may help to discover whether vitrification is a better method of freezing biopsied embryos and at which stage it is better to biopsy the embryos to achieve the highest freeze/thaw survival rates.

**Human embryonic stem cell lines**

Stem cell science is becoming a very active area of research. Figure 2 shows that 12 (50%) of the research projects we license involve the derivation of human embryonic stem cell lines (R0115; R0133; R0136; R0142; R0143; R0152; R0162; R0171; R0174; R0178 & R0184). Human embryonic stem cells are useful for studying a
wide range of diseases in the laboratory. These stem cells could, in the future, be used to develop new therapies for serious diseases such as diabetes, Alzheimer’s or Parkinson’s disease.

Embryonic stem cells are derived from early embryos and have the ability to form all the cells of the body (for example, nerve cells, muscle cells and heart cells). The majority of embryonic stem cells are derived from embryos donated for research by patients undergoing treatment at assisted conception units. To grow embryonic stem cells, the cells from a five- or six-day embryo (the blastocyst) are transferred into a dish that contains a small amount nutrient culture medium. The cells from the blastocyst spread out over the surface of the dish and start to divide. The surface of the dish is usually coated with a type of skin cells called fibroblasts which may either be derived from a mouse or a human. This coating of fibroblasts is called a feeder layer and serves two purposes; one is to provide a sticky surface to which the embryonic cells can attach and secondly, to release nutrients into the culture medium so that the embryonic cells can continue to grow and divide.

If the embryonic cells divide for a prolonged period of time and stay pluripotent - that is, maintain the ability to become any cell of the body - then these cells are called an embryonic stem cell line. It is these stem cell lines which may be used to study diseases or be used to develop treatments and drugs.

Although several embryonic stem cell lines have been developed, they are mainly for research and cannot be used to treat patients as they have not been grown under the strict conditions needed for safe human use. Several of the projects are looking at ways to derive human embryonic stem cell lines under conditions whereby the resulting stem cell line could be used clinically.

Generating embryonic stem cell lines is a complex process and not all cells taken from an embryo will go on to become a stem cell line. Therefore a number of projects are studying ways to increase the success rate of generating human embryonic stem cell lines.

To date 35 human embryonic stem cell lines, derived in the UK, have been banked in the UK Stem Cell Bank and 15 of these lines are available for release. The other 20 lines have either completed the banking process and are currently undergoing quality control testing, prior to being released, or are in the process of being banked. A further eight human embryonic stem cell lines, derived under licence from the HFEA, have been approved for banking (by the Steering Committee for the UK Stem Cell Bank and the Use of Stem Cell Lines) but have yet to be deposited in the Stem Cell Bank.
Use of embryos in research

The HF&E Act requires that, prior to donating embryos to research, patients must give their consent to the use of any embryo created using their gametes. It is imperative that embryos (or gametes donated to produce embryos) for research are freely given and that people donating them have made an informed choice. For this reason, licensed centres must have safeguards in place to ensure that if a patient decides to donate gametes and/or embryos for use in research, this donation must not affect their treatment in any way. Centres must ensure that a designated individual who is not involved in the research project is available to discuss the implications of donation with the prospective donor.

The HFEA has introduced additional requirements for licensed centres using embryos to derive human embryonic stem cell lines. Patients donating sperm, eggs or embryos to these research projects must be given information so that they understand fully the implications of this type of research, including the permanent nature of stem cell lines.

The majority of embryos used in research projects are donated by patients undergoing fertility treatment. These embryos are either unsuitable for use in treatment or the patients may decide they do not wish to cryopreserve (freeze) their spare embryos. In addition, patients who have had embryos cryopreserved for future use sometimes decide that they no longer wish or are no longer able to use these embryos in treatment services (for example, IVF may have been successful for them), and consent to their embryos being used instead in a research project.

It is a condition of all research licences which authorise the use of embryos to derive embryonic stem cell lines to deposit a sample of these lines in the UK Stem Cell Bank (see Table 2), so that they may be used by other scientists in many different types of research. Over time, fewer embryos will need to be used for making stem cell lines once enough lines, of a suitable quality, have been deposited in the UK Stem Cell Bank.

Figure 3 shows the number of embryos donated, created and used in licensed research project between 1 January 2010 and 31 December 2010. Over 6000 embryos were donated for use in research; 94% of these donated embryos were received and or thawed for use in research and 76% were used in the course of carrying out licensed research. Some of the embryos donated for use in research but were not received or thawed during 2010 may still be in storage at a treatment centre or the patients donating the embryos may have withdrawn their consent to the embryos being used in research.
Four projects licensed by the HFEA also create embryos in order to carry out the research. One of these projects is studying egg activation which involves fertilising eggs to look at the processes needed for successful fertilisation.
Appendix 1

Research Centres / Projects licensed by the HFEA between 1 January and 31 December 2010

Birmingham Women’s Hospital (Centre 0119) & Institute of Biomedical Research (Centre 0209)
Human gamete interaction and signalling (R0172 / R0173)

Birmingham Women’s Hospital (Centre 0119)
Genetic screening of the preimplantation embryo (R0186)

CARE, Nottingham (Centre 0101)
A novel protocol for extracting cells during embryo biopsy without the use of acid Tyrodes (R0177)

Centre for Human Development, Stem Cells and Regeneration / Division of Human Genetics, University of Southampton (Centre 0251)
Environmental sensitivity of the human preimplantation embryo (R0142)

Centre for Reproductive Medicine, Coventry (Centre 0013)
Indicators of oocyte and embryo development (R0155)

Guys Hospital, London (Centre 0102)
Improving methods for preimplantation genetic diagnosis of inherited genetic disease and predicting embryo quality (R0075)
Developing criteria for estimating quality of stem cells derived from human embryos (R0133)

Hull IVF Unit (Centre 0021)
Biochemistry of early human embryos (R0067)

Human Genetics and Embryology Laboratories, University College London (Centre 0245)
Genetic profiling for infertility and development of novel preimplantation diagnosis (R0113)

Institute of Biomedical Research (Centre 0209)
Derivation of GMP human embryonic stem cells (R0184)

Institute of Reproductive and Development Biology, Imperial College London (Centre 0249)
Comparative studies on human embryonic stem cells and stem cells derived from male germ cells (R0174)

IVF Hammersmith (Centre 0078)
The vitrification of blastocysts following biopsy at the early-cleavage stage or blastocyst stage of embryo development – A pilot study (R0187)
London Fertility Centre (Centre 0088)
Analysis of chromosomes in human preimplantation embryos using Fluorescence In Situ Hybridisation (FISH) and Comparative Genomic Hybridisation (CGH) (R0169)

Manchester Fertility Services Ltd. (Centre 0033), St Mary’s Hospital, Manchester (Centre 0067) and University of Manchester (Centre 0175)
In vitro development and implantation of normal human preimplantation embryos and comparison with uni- or poly-pronucleate pre-embryos (R0026)
Derivation of human embryonic stem cell lines from embryos created from clinically unused oocytes or abnormally fertilised embryos (R0170/171)

Newcastle Fertility Centre at Life (Centre 0017)
Pluripotency reprogramming and mitochondrial biology during early human development (R0152)
Mitochondrial DNA disorders: is there a way to prevent transmission? (R0153)

Oxford Fertility Unit (Centre 0035) and University of Oxford, Department of Obstetrics and Gynaecology (Centre 0311)
Development of a model to study implantation in the human (R0111)
To derive human embryonic stem cells and trophoblast cell lines (R0143)
To develop preimplantation genetic diagnosis (PGD) for mitochondrial DNA disease (R0149)

Roslin Cells Limited (Centre 0202)
Platform technologies underpinning human embryonic stem cell derivation (R0136)

Section of Reproductive & Developmental Medicine, University of Sheffield (Centre 0191) and Centre for Stem Cell Biology (Alfred Denny), Sheffield (Centre 0312)
Development of human embryonic stem cell lines to Good Manufacturing Practice for treatment of degenerative diseases and conditions (R0115)

University of Cambridge (Centre 0246)
Derivation of stem cells from human surplus embryos: the development of human embryonic stem cell (hES) cultures, characterisation of factors necessary for maintaining pluripotency and specific differentiation towards transplantable tissues (R0162)

Wales Heart Research Institute (Centre 0319)
Investigation into the role of sperm PLC- zeta in human oocyte activation (R0161)

Wellcome Trust Centre for Stem Cell Research, University of Cambridge (Centre 0252)
Derivation of pluripotent human embryo cell lines (R0178)
# Use of embryos in research in 2010

Table 1: The number of embryos donated, received, used and created at each licensed research centre in 2010

<table>
<thead>
<tr>
<th>Centre No.</th>
<th>Project No.</th>
<th>No. of embryos donated</th>
<th>No. of embryos received / thawed</th>
<th>No. of embryos used</th>
<th>No. of embryos allowed to perish</th>
<th>No. of embryos created</th>
<th>No. of created embryos used</th>
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<td>Centre for Reproductive Medicine, Coventry</td>
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<td>No. of embryos created</td>
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* The information relating to research project R0187 was submitted as part of a end of project report form and covers the time period 01/01/2010 → 29/01/2011