

EU TISSUES AND CELLS DIRECTIVE

HFEA THIRD PARTY GUIDANCE NOTE

The EU Tissues and Cells Directive (EUTD) covers any service involving donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, for human application. It also extends the Human Fertilisation and Embryology Authority's remit to include the licensing of services involving fresh gametes.

Under the EUTD additional requirements are being introduced for all centres, including the requirement for third party agreements. This guidance note sets out the criteria for establishing when a third party agreement should be held and the requirements relating to these agreements. Please note that all previously issued guidance is superseded by this document.

1. Definitions

The following definitions apply to this document:

Third Party

A third party is a person or entity which provides a product (a service, software, hardware or materials) to a licensed centre that has the potential to affect the quality and safety of gametes or embryos.

Service

A service is the supplying or performance of an activity by one person or entity to another. A service can encompass more than one type of activity, for example sperm preparation as part of the treatment service.

Satellite Centre

Satellite IVF is where the assessment, drug therapy and monitoring take place at the secondary (satellite) centre but the egg retrieval, embryology and embryo replacement are all carried out at the primary (licensed) centre.

Transport Centre

In transport IVF, the assessment, drug therapy, monitoring and egg retrieval takes place at the transport centre but the embryology and embryo replacement takes place at the primary (licensed) centre.

2. Third Party Criteria

Activities that fall into the following two categories should be subject to a third party agreement, unless they are undertaken by a licensed centre.

a) Procurement, testing or processing of gametes or embryos, or both.

Examples

- Laboratories that perform sperm preparation
- Transport and Satellite centres that currently licensed IVF centres work with.
- Off-site centres where the following activities take place:
 - Sperm procurement.
 - Egg collection.

b) Supplying goods or services (including distribution services) which may affect the quality and safety of gametes and embryos.

Examples

- Laboratories that perform blood screening tests.
- Companies that supply equipment and materials that have the potential to impact on quality and safety, e.g. suppliers of culture media.
- Companies that monitor air quality in laboratories.
- Circumstances where the clinical or laboratory premises are leased from a hospital or other institution, e.g. the use of theatre for egg collection under general anaesthetic).
- Courier companies.

If you provide a treatment service you will require a licence under the HFE Act 1990, which is being amended to bring in the requirements of the EUTD. This includes provision of IUI treatment, where sperm preparation is out sourced.

3. Fees

Third party agreements that provide for the procurement, testing or processing of gametes and embryos (category a listed above) will incur an annual fee of £250. This fee is payable for each third party agreement of this type held.

Third party agreements for the supply of services or goods that may impact on the safety or quality of embryos or gametes (category b listed above), but do not include any licensable services, will not incur any fee.

N.B. For IUI centres that work with a sperm preparation laboratory the £250 will be included in the £2950 annual fee. However, for any other relevant third party agreements held fees will be payable.

The third party fee will cover:

- Review of the third party agreement as part of the licence application review process.
- Inspection of a proportion of third party premises during each two year inspection cycle

4. Role and Responsibilities of the Person Responsible (PR)

The PR of a licensed centre with a third party agreement will be responsible for ensuring:

1. All third party agreements held are detailed in the self assessment/application form.
2. Third party fees are paid to the HFEA.
3. The third party has a named person who is accountable to the licensed centre.
4. Standards required by the Directive are met by the third party.
5. Systems are in place to ensure the governance framework and quality management systems are properly implemented.
6. Regular visits to the third party to verify that the licensing framework and systems and processes are working in practice.
7. The HFEA is notified and provided with a report analysing the cause and outcome of any serious adverse event or serious adverse reaction.

Third parties should therefore be selected on their ability to meet the standards laid down by the Directive and their fit with the centres' own quality system.

The Person Responsible of the licensed centre will be under a duty (by virtue of amendments to section 17 of the HFE Act 1990) to secure that the conditions of third party agreements relating to the procurement, testing, processing or distribution of gametes or embryos are complied with. Failure to discharge the duty under section 17 is a ground for revoking or varying the licence.

Furthermore, third party premises must be suitable for the activity entrusted to the third party by the licensed centre. The lack of suitability of third party premises will be a ground for revoking or varying the licence of the licensed centre.

5. Role and Responsibilities of the Third Party

The third party is required to have procedures in place to:

1. Retain records of gametes and embryos to ensure traceability.
2. Notify the PR when a serious adverse event or serious adverse reaction occurs, which may effect the quality or safety of gametes or embryos.
3. Report to the PR any gamete or embryo misidentifications or mix ups.
4. Enable the recall from distribution any gametes and embryos which may be effected by a serious adverse event or serious adverse reaction.

Third party premises may be inspected as part of the licensing process and the investigation of any serious adverse events or serious adverse reactions.

6. Content of the Third Party Agreement


Licensed centres must hold written third party agreements with third parties, which are made in accordance licence conditions issued by the HFEA.


The documentation for third party agreements should also include:

- Full address and named contact details of the third party, and nature of the service to be provided.

- Identify who is responsible for managing the arrangement between the centre and the third party.
- How often the agreement will be reviewed and by whom.
- Summary of the responsibilities of the third party and detailed procedures with regard to each party's respective responsibilities.
- A specification detailing any specific criteria that the service provided by the third party must meet, particularly in relation to quality and safety.
- How any test /diagnostic results are relayed to the commissioning centre, including sign off and confirmation that the result applies to the correct sample.

When Third Party Agreements Apply

You are										
		Currently unlicensed IUI centre	IVF centre	Satellite centre undertaking IUI	Transport centre	Off-site Sperm preparation laboratory	Independent Gynaecologist performing IUI inseminations	Pathology Laboratory e.g blood screening	Transport centre undertaking IUI	Satellite centre
Working with	Currently unlicensed IUI centre	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	N/A	The IUI centre will need a licence under the EUTD and a third party agreement with you (fee included in annual fee).	You will both need a licence under the EUTD.	The IUI centre will need a licence under the EUTD and will need a third party agreement with you (no fee applies).	You will both need a licence under the EUTD.	N/A
	IVF centre	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	The IVF centre will need a third party agreement with you (the fee will apply).	The IVF centre will need a third party agreement with you (the fee will apply).	You will both need a licence under the EUTD.	The IVF centre will need a third party agreement with you (no fee applies).	You will both need a licence under the EUTD.	The IVF centre will need a third party agreement with you (no fee applies).
	Satellite centre undertaking IUI	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	N/A	The satellite centre will need a licence under the EUTD and will need a third party agreement with you (fee included in annual fee).	You will both need a licence under the EUTD.	The satellite will need a licence under the EUTD and will need a third party agreement with you (no fee applies).	You will both need a licence under the EUTD.	N/A
	Transport centre	N/A	You will need a third party agreement with the transport centre (the fee will apply).	N/A	N/A	N/A	N/A	N/A	N/A	N/A

You are										
Working with		Currently unlicensed IUI centre	IVF centre	Satellite centre undertaking IUI	Transport centre	Off-site Sperm preparation laboratory	Independent Gynaecologist performing IUI inseminations	Pathology laboratory	Transport centre undertaking IUI	Satellite centre
	Off-site Sperm preparation laboratory	You will need a licence under the EUTD and a third party agreement with the laboratory (fee included in annual fee).	You will need a third party agreement with the off-site preparation laboratory (the fee will apply).	You will need a licence under the EUTD and a third party agreement with the laboratory (fee included in annual fee).	N/A	N/A – Both services will need a third party agreement with a licensed centre.	You will need a licence under the EUTD and a third party agreement with the laboratory (fee included in annual fee).	N/A – Both services will need a third party agreement with a licensed centre.	You will need a licence under the EUTD and a third party agreement with the laboratory (no fee applies).	N/A
	Independent Gynaecologist performing IUI inseminations	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	You will both need a licence under the EUTD.	N/A	The Gynaecologist will need a licence under the EUTD and a third party agreement with you (fee included in annual fee).	N/A	The Gynaecologist will need a licence under the EUTD and a third party agreement with you (fee included in annual fee).	You will both need a licence under the EUTD.	N/A
	Pathology laboratory e.g. blood screening	You will need a licence under the EUTD and a third party agreement with the laboratory (no fee applies).	You will need a third party agreement with the pathology laboratory (no fee applies).	You will need a licence under the EUTD and a third party agreement with the laboratory (no fee applies).	N/A	N/A – Both services will need a third party agreement with a licensed centre.	You will need a licence under the EUTD and a third party agreement with the laboratory (no fee applies).	N/A	You will need a licence under the EUTD and a third party agreement with the laboratory (no fee applies).	N/A
	Transport centre undertaking IUI	You will both need a licence under the EUTD	You will both need a licence under the EUTD	You will both need a licence under the EUTD	N/A	The transport centre will need a licence under the EUTD and they will need a third party agreement with you (fee included in annual fee).	You will both need a licence under the EUTD.	The transport centre will need a licence under the EUTD and they will need a third party agreement with you (no fee applies).	You will both need a licence under the EUTD	N/A
	Satellite centre	N/A	You will need a third party agreement with the satellite centre (no fee applies).	N/A	N/A	N/A	N/A	N/A	N/A	N/A