Update on the implementation of two EU Directives

In the June 2017 edition of Clinic Focus we informed you that the process of transposing the EU Directives on the import and coding of gametes and embryos into UK had been suspended. As a result, we paused the work on implementation until we received further information from the Department of Health.

On 18 December 2017, the regulations amending the Human Fertilisation & Embryology Act 1990 were laid in Parliament. The Human Fertilisation and Embryology (Amendment) Regulations 2018 can be found here. If approved by Parliament we expect the new rules to apply from April 2018.

We will be issuing guidance on the Directives by April. The Authority will be considering the relevant documents on 8 March 2018 and the guidance will then be incorporated into the Code of Practice when it is next updated in October 2018. We recognise that centres will have less time than usual to prepare for these Directives and we will therefore be taking a proportionate approach in the first few months.

Import

If a UK clinic wants to import gametes/embryos from outside of the EU, EEA and Gibraltar, they will need to establish a relationship with the overseas clinic and assess that it is suitable and meets the standards of the EU Tissue and Cells Directive. The UK clinic then applies to the HFEA for authorisation of the importing relationship.
The HFEA then decides whether to authorise the import and issues a certificate. Further imports from that specific overseas clinic can take place without further oversight – however if the UK clinic decided to change the type of cell (sperm, eggs or embryos) they imported, they would need to notify the HFEA and we would need to consider an application for a new importing relationship and issue a new certificate. If the UK clinic wanted to import from a different overseas clinic, they would have to seek a new authorisation.

Coding

The coding Directive covers the application of a Single European Code (SEC) to donated (non-partner) tissues and cells being transported within the UK, EU, EEA or Gibraltar to ensure clear labelling, identification and traceability of tissues and cells within the EU.

To meet the requirements set out in the Directive, UK-licensed clinics will need to apply a SEC to all donated eggs, sperm and embryos distributed for use in treatment by other centres within the UK, EU, EEA or Gibraltar. Please note that where label size precludes inclusion of the SEC on the container label, the SEC must appear on accompanying documentation.

Exemptions:

- donated eggs, sperm and embryos that stay at the same UK-licensed centre after being imported.

Transitional arrangements:

- donated eggs, sperm and embryos stored prior to 29/10/2016 and released for circulation by 29/10/2021 provided that full traceability is ensured by alternative means.

We had intended to introduce the SEC alongside the implementation of our new data submission system later this year. However, the decision by the Department of Health to introduce the Regulations into Parliament at this time means that the SEC will need to take effect from April 2018. We will provide further details on implementation during March 2018.

If you have any questions or comments about the implementation of the EU Directives, please contact Niamh Marren at niamh.marren@hfea.gov.uk or Chris Hall at chris.hall@hfea.gov.uk.

You can read the full Chair’s letter relating to the EU directives on the Clinic Portal.

HFEA updates

Clinic Focus is changing

Over the next few months we will be rolling out a new format Clinic Focus,

There’s still time to have your say on the next edition of the Code of Practice

We will be launching a new edition of the Code of Practice in October 2018 and
which will require some action from you as we will be using a new distribution system.

We are switching from our own inhouse system for producing and distributing Clinic Focus to a UK based third party email marketing platform called Wired, which some of you might be aware of as they also support other Government Departments with their own email communications.

The new Clinic Focus will still provide you with important updates, actions and news relating to the HFEA and the wider fertility sector, however the new model will integrate more with the Clinic Portal which is also receiving some updates.

Due to data protection regulation, everyone except clinic PR’s will need to manually sign up to the new Clinic Focus distribution list. In recognition of this, we are making the sign-up process as quick and seamless as possible. We will let you know as soon as the information on how to sign-up is available.

There will be a period of overlap between switching to the new platform and discontinuing the current one to ensure that our vital communications between us and you are not disrupted as we make this change. More information on this and the rest of the clinic focus update will be communicated in the next few months.

If you have any questions, please email them to jack.briggs@hfea.gov.uk.

need you to help us shape our thinking about the main proposed changes to guidance, and the structure and usability of the Code.

We need your input on areas of our guidance including leadership, emotional support and information to be provided to patients. If you haven’t signed up already, there’s still time to attend one of our workshops in London, Edinburgh, Manchester or Bristol.

You can register to attend your nearest workshop by going to the Eventbrite page and giving your details by 16 January.

London – Tuesday 13 February
Bristol – Tuesday 20 February
Edinburgh – Thursday 22 February
Manchester – Tuesday 27 February

Your role in advancing research - can you help?

As most research wouldn’t be possible without collaboration between centres, we have launched a new page on the Clinic Portal to help clinics and researchers establish partnerships to recruit donors to provide gametes or embryos for use in

Annual Conference 2018 - save the date

This year’s HFEA annual conference will take place on Thursday 15 March 2018 at Church house in Westminster.

Next month we will open registration, as well as providing more details on
research.

You can read the full list of HFEA licensed research projects that are actively looking for clinic partners on our website, to help identify potential donors. It includes details about the projects, the types of research materials needed, any support or resources available to help recruit donors and the project contact.

There are currently four projects listed and we will add to this as more researchers participate. If you are interested in establishing a partnership with one or more of these research groups, please get in touch directly with the project contact.

Editorial statement
Clinic Focus is the official electronic newsletter of the Human Fertilisation and Embryology Authority, is produced by the editorial team of the HFEA and provides a monthly roundup of news and information for clinics and their staff working in the field of fertility treatment.

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Would you like to contribute to Clinic Focus?
We welcome suggestions from clinics for subjects we cover each month. If there is anything that you would like to see featured in a future issue of Clinic Focus please let us know by contacting us at clinicfocus@hfea.gov.uk

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