

# Guidance on how to complete the import application form

Below you will find guidelines on what information is needed in each section of the import application form. If you are unsure about what information is needed please contact your inspector for further guidance.

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## 1. General information on the Importing Tissue Establishment (ITE)

- 1.1 Provide the name of the UK centre as it appears on your HFEA licence and the centre number
- 1.3 Provide the address and, if different, the postal address of the UK centre
- 1.4 Provide the website address of the UK centre
- 1.5 If this is the first application the UK centre has made for an import certificate then you need to tick “first time”. However, if this is a second or subsequent application, please tick “renewal”.
- 1.6 Confirm whether the imports that the UK centre is receiving from the third country supplier will be initially stored at your centre.

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## 2. Contact details for the application

- 2.1 Provide the name of the Person Responsible at the UK centre
- 2.2 Provide the telephone number of the Person Responsible
- 2.3 Provide the email address of the Person Responsible
- 2.4 If the Person Responsible is not the Contact Person for this application then the name of the Contact Person needs to be provided. If the Contact Person is the Person Responsible then state “as above”
- 2.5 Provide the telephone number of the Contact Person
- 2.6 Provide the email address of the Contact Person

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## 3. Details of tissues and cells to be imported

- 3.1 If the UK centre is applying for a certificate to allow multiple imports then the UK centre must check the box of each type of tissue and cell that they plan on importing. The same applies if the UK centre is planning to do only a one-off import. Reference to a one-off import is to gametes or embryos imported from a third Country Supplier (TCS) for the purposes of providing services to a particular (named) person or persons on one occasion only. All imports which are not one-off imports are by definition multiple imports.
- 3.2 State the name of the imported tissues and cells
- 3.3 State the trade name of the tissues and cells if different to 3.2
- 3.4 State the name of the third country supplier and the country that the supplier is located in, next to the type of supplier that they are. See the footnote for a discussion of which countries are ‘third countries’ and how this is sensitive to ITE location and the date of import. Imports from TCS in third countries need to be authorised by an ITE import certificate.

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## 4. Annex A

If the UK centre wishes to apply for a certificate for multiple third country suppliers they must complete an Annex A for each third country supplier.

### Details of the third country supplier

- 4.1** Provide the name of the third country supplier.
- 4.2** Provide the name of the contact person at the third country supplier.
- 4.3** Provide the address of the third country supplier.
- 4.4** If the postal address is different from that in 4.3, then you need to provide the postal address also.
- 4.5** Provide the telephone number of the third country supplier, including the international dialling code.
- 4.6** Provide an emergency contact number if different from that provided in 4.5.
- 4.7** Provide an email address for the third country supplier.

### Activities undertaken

- 5.1** The UK centre needs to indicate using the tick boxes, which activities have been undertaken by the third country supplier for each cell or tissue type to be imported. Please also indicate 'not imported' where relevant.
- 5.2** The UK centre needs to indicate using the tick boxes, which activities have been undertaken by third party subcontractors to the third country supplier, for each cell or tissue type to be imported. Please also indicate 'not imported' where relevant.
- 5.3** The UK centre needs to state which activities they will undertake using each tissue or cell type to be imported.
- 5.4** Please state the third countries in which the activities indicated in 5.1 and 5.2 have been carried out per tissue and cell type.

### Documentation to accompany the application

**6** The UK centre must provide the documentation mentioned in 6 along with the application form, indicating using the check boxes that they have done so. Please make sure to provide the documents necessary to support the type of application you are making, be it for a one off import or a multiple import authorisation

For a one off import provide an appropriately completed application form; documentary evidence the third country supplier is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated; and documentary assurance that your centre has not previously import gametes or embryos from the third country supplier for use in treating the person or persons for whom the gametes or embryos are to be imported.

For multiple imports, please provide an appropriately completed application form; documentary evidence the third country supplier is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated; a copy of your written agreement with the third country supplier; a detailed description of the flow of imported tissues and cells from their procurement to their reception at your centre; and a copy of the third country supplier's export authorisation certificate, which should include contact details of the third country's competent authority.

