

Guidance supplementary to Chair's Letter CH(10)05 and amended Directions 0005 and 0007

Category A – Patients registered and treated before October 2009

Situation regarding their data

Subject to the conditions set out in the 2010 Regulations, patient and partner data may be disclosed for research purposes unless dissent from disclosure has been expressed.

Situation regarding child's data

Data about people born as a consequence of treatment may be disclosed for research purposes unless a parent or guardian (for anyone under 16) or the adult born as a consequence of treatment has dissented from disclosure.

Situation regarding consent

Consent to disclosure has been presumed, subject to the conditions set out in the 2010 Regulations. Individuals may dissent from disclosure by completing an opt-out form available on the HFEA website <https://portal.hfea.gov.uk/OptOut/Default.aspx>.

Forms used/to be used

Mandatory: Old HFEA registration form [paper or EDI depending on time of registration].

Category B – Patients registered before October 2009 and treated between October 2009 and April 2010

Situation regarding their data

Because this category of patients were not asked to fill in a CD form when they returned for treatment, the HFEA has decided to presume that they have dissented from the disclosure of all their data for research purposes.

Situation regarding child's data

This exclusion will be extended to data about any child born as a consequence of treatment received during this 1 October 2009 to 30 April 2010 period.

Situation regarding consent

While there is an assumption that individuals have dissented from the disclosure of their information, a CD form can be filled in retrospectively although this is not mandatory.

Forms used/to be used

Mandatory: Old HFEA registration form [paper or EDI depending on time of registration].

Optional: CD form **and** Consent Variation form

Category C – Patients registered before October 2009 and treated since 1 May 2010

Situation regarding their data

From 1 May 2010, anyone receiving treatment, regardless of the date they registered, will be required to complete a CD form. The preferences they express on this form will govern how their data is managed and whether or not it is disclosed for research purposes.

Situation regarding child's data

The preferences patients and partners express about their own data on CD forms will be extended to any child born as a consequence of treatment. However, if after the birth of the child, parents decide that they wish their child's data to be handled differently to their own, they must put in writing their revised preferences and mail this to their clinic. If a patient or partner wishes to amend preferences about their own data they are required to complete a new CD form.

Situation regarding consent

Preferences expressed in CD forms will be applied to all data unless revised preferences about children are communicated in writing to clinics.

Forms used/to be used

Mandatory at registration: Old HFEA registration form [paper or EDI depending on time of registration], CD form [paper], Consent Variation form [EDI].

Mandatory if patient/partner preferences revised: CD form [paper], Consent Variation form [EDI].

Mandatory if child preferences expressed are different to patient/partner preferences:

Letter to clinic identifying patient/partner, name and dob of child [paper to be stored with consent forms], Consent Variation form.

Category D – Patients registered and treated since 1 October 2010**Situation regarding their data**

The CD form must be completed. The preferences they express on this form will govern how their data is managed and whether or not it is disclosed for research purposes.

Situation regarding child's data

The preferences patients and partners express about their own data on CD forms will be extended to any child born as a consequence of treatment. However, if after the birth of the child, parents decide that they wish their child's data to be handled differently to their own, they must put in writing their revised preferences and mail this to their clinic. If a patient or partner wishes to amend preferences about their own data they are required to complete a new CD form.

Situation regarding consent

Preferences expressed in CD forms will be applied to all data unless revised preferences about children are communicated in writing to clinics.

Forms used/to be used

Mandatory at registration: New HFEA registration form [EDI], CD form [paper].

Mandatory if patient/partner preferences revised: CD form [paper], correction to registration form [EDI].

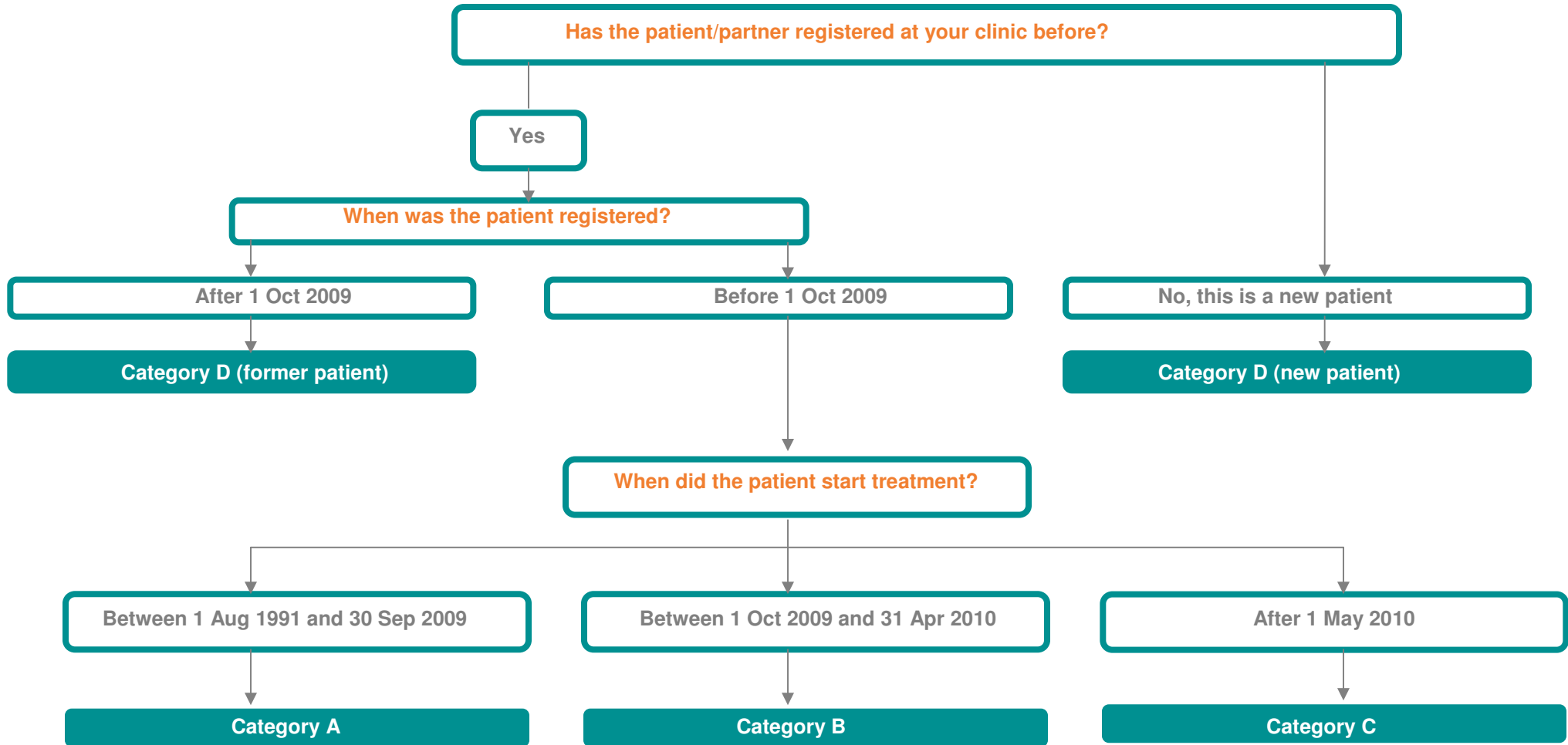
Mandatory if child preferences expressed are different to patient/partner preferences:

Letter to clinic identifying patient/partner, name and dob of child [paper to be stored with consent forms], Consent Variation form.

Consent arrangements for disclosure of information for research purposes

Decision tree for clinic staff

This decision tree can be used to decide which HFEA forms must be completed and what information a patient/partner should be given in relation to consent arrangements for disclosure of information for research purposes. The first key question in the decision tree is *was the patient or partner registered at your clinic?* The second key question is *when did the patient start treatment?* This date should be that of the first HFEA Intention to treat form.



Categories

Category A

PATIENT/PARTNER DATA: Consent to disclosure has been presumed. Patients/partners should be informed of the option to dissent from disclosure by completing an opt-out form available on the HFEA website <https://portal.hfea.gov.uk/OptOut/Default.aspx>

CHILD DATA: Data about people born as a consequence of treatment may be disclosed for research purposes unless a parent or guardian (for anyone under 16) or the adult born as a consequence of treatment has dissented from disclosure.

Category B

PATIENT/PARTNER DATA: Dissent to disclosure has been presumed. Patients/partners may be informed of the option to consent to disclosure by completing a CD form. Their consent must be communicated to the HFEA via the HFEA Consent Variation form [EDI].

CHILD DATA: Data about people born as a consequence of treatment may not be disclosed for research purposes unless a parent or guardian (for anyone under 16) or the adult born as a consequence of treatment has consented to disclosure.

Category C

PATIENT/PARTNER DATA: The patient/partner must complete a CD form. The preferences they express must be communicated to the HFEA via the Consent Variation form [EDI].

CHILD DATA: The preferences patients and partners express about their own data on CD forms will be extended to any child born as a consequence of treatment.

Category D (new patient)

PATIENT/PARTNER DATA: The patient/partner must complete a CD form. The preferences they express must be communicated to the HFEA via the HFEA registration form [EDI].

CHILD DATA: The preferences patients and partners express about their own data on CD forms will be extended to any child born as a consequence of treatment.

Category D (former patient)

PATIENT/PARTNER DATA: No action is needed. The patient/partner will have completed a CD form and the preferences they expressed will have been communicated to the HFEA via the HFEA registration form [EDI].

CHILD DATA: The preferences patients and partners express about their own data on CD forms will be extended to any child born as a consequence of treatment.