

# Licensing Officer – record of consideration

---

## Guy's Hospital (Centre 0102) – Voluntary revocation of licence For Research Project R0133

**22 September 2020**

HFEA, 10 Spring Gardens, SW1A 2BU

Licensing Officer: Clare Ettinghausen

---

### Declaration of interest

- Do you have a conflict of interest in relation to this matter?  
No.

---

### The Licensing Officer had before them

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

---

## 1. Consideration of application

- 1.1** Guy's Hospital is a treatment and research centre. Research project R0133, entitled 'Developing criteria for estimating quality of stem cells derived from human embryos', was first licensed in 2002. The centre also holds a licence for another research project (R0075), which is ongoing.
- 1.2** The Licensing Officer noted that the current licence was issued by Licence Committee in July 2017, for three years, without any additional conditions.
- 1.3** The Licensing Officer noted that the objectives for R0133 were:
- 1) To continue derivation of disease-specific hESC lines on demand.
  - 2) To utilise hESC-derivation technology in the validation of blastocyst quality.
- 1.4** The Licensing Officer noted that a renewal inspection was conducted at the centre on 10 February 2020, at which no non-compliances were observed. Following this, on 15 March 2020, the Person Responsible (PR) informed the centre's inspector that he did not wish to renew the centre's licence for research project R0133 upon expiry. The licence for project R0133 expired on 31 July 2020
- 1.5** The Licensing Officer noted that the PR has confirmed that:
- No gametes or embryos remain in storage at the centre for this research project.
  - Arrangements have been made for the secure storage of patient files and other centre records to be held for a period of 30 years,
  - Arrangements have been made for the retention of records of the numbers of embryos donated to, stored, used and discarded by the project, and of the results and conclusions of the project, for three years.
  - The centre's final HFEA invoice has been paid.
  - The centre's research information and data sheet for 2020 has been provided.
  - The remainder of all stem cell lines (in so far as not used or destroyed as part of or in the course of the research project) have been deposited in the UK Stem Cell Bank or distributed in accordance with any relevant guidelines issued by the UK Stem Cell Bank.
- 1.6** The Licensing Officer noted that General Direction 0002 (3) requires that the HFEA is provided with:
- 1) A provisional report setting out the results and conclusions of the research no later than three months from the end of the project of research for which the licence was granted; and
  - 2) A fully referenced final report with results, conclusions and references to any publications arising from the research project, 12 months from the end of the project for which the licence was granted.

- 1.7** The Licensing Officer noted that the inspectorate recommends the revocation of the centre's research licence for project R0133.
- 

## **2. Decision**

- 2.1** After considering the recommendation of the inspectorate and all supporting documentation, the Licensing Officer agreed to revoke the centre's research licence, for project R0133, with immediate effect.
- 

### **Licensing Officer's signature**

I confirm this is a true and accurate record of my decision.

#### **Signature**



#### **Name**

Clare Ettinghausen

#### **Date**

22 September 2020