

DIRECTIONS GIVEN UNDER THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Directions on Reporting Adverse Incidents

These Directions are:	Ref: D.2007/3
Section of the Act providing for these Directions:	GENERAL DIRECTIONS Section 12(d) and (g) of the 1990 Act
These Directions come into force on:	5 th July 2007
These Directions remain in force:	Until revoked

1. These Directions revoke D.2004/3.
2. Each licensed centre must report all adverse incidents (which includes serious adverse events and serious adverse reactions), and all near misses to the HFEA.
3. The Person Responsible (PR) or senior colleague in the PR's absence must notify the Director of Regulation or nominated representative that an adverse incident has occurred or has been identified as having occurred with 12 working hours of the identification of the incident.
4. The initial notification must include:
 - (a) identification of the Centre,
 - (b) report identification,
 - (c) date of initial notification/report,
 - (d) individual affected (Patient or Donor),
 - (e) date of suspected adverse incident,

- (f) details of gametes or embryos involved in the serious adverse incident,
 - (g) type of suspected adverse incident(s) including the transmission of infectious agents.
5. This must be followed by a confirmation report including, items 4 (a) – (c) above and:
 - i. date of confirmation report,
 - ii. confirmation of the type of reaction(s) or a change in type of reaction(s),
 - iii. outcome of investigation and final conclusions.
 6. Each licensed centre must complete an Incident Report Form. The completed form should be faxed or emailed to the HFEA within 24 working hours of the incident taking place.
 7. All breaches of the HFEA Act and/or breaches of the HFEA Code of Practice must be reported as adverse incidents to the HFEA.

Meaning of terms

8. In these Directions, the terms listed have the meaning shown:

“Adverse Incident” means any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed centre including serious adverse events and serious adverse reactions.

“Serious adverse event” means an untoward occurrence associated with the procurement, testing, processing, storage or distribution of gametes or embryos that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for a donor of gametes or a person who receives treatment, or which might result in, or prolong, hospitalisation or morbidity. Any type of gamete or embryo misidentification or mix up shall be considered to be a serious adverse event.

“Serious adverse reaction” means an unintended response, including a communicable disease, in a patient or donor associated with the procurement or human application of gametes and embryos that is fatal, life-threatening,

disabling, incapacitating or which might result in, or prolongs, hospitalisation or morbidity.

“Near miss” means any occurrence, which but for luck, skill or judgement would, in all probability, have become an incident.

A handwritten signature in black ink, appearing to read "Shubay Khan" with a small mark to the right.

Date: 22nd May 2007

Chair