

**DIRECTIONS GIVEN UNDER THE
HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990**

Directions on information to be recorded about preimplantation testing procedures	Ref: D 2003/1
These Directions are	GENERAL DIRECTIONS
Section of the Act providing (g) for these Directions	Section 13(2)(f) and 12(d) and of the 1990 Act
These Directions taken effect on:	1st June 2003
These Directions remain in force:	Until revoked

1. Where a practitioner is to undertake polar body or blastomere biopsy for the first time, the Person Responsible at the Licensed Centre concerned must, in advance of the procedure being carried out, notify the Authority in writing of the practitioner's name, the type of biopsy and the date that this is to be carried out ("the first date").
2. The Person Responsible must provide the Authority with the information referred to in Schedule 1 to these Directions in relation to polar body biopsies carried out by each practitioner in respect of the twelve month period following the first date and in respect of each successive period of twelve months. The information is to be provided to the Authority within 28 days of the end of each relevant period of twelve months.
3. The Person Responsible must provide the Authority with the information referred to in Schedule 2 to these Directions in relation to blastomere biopsies carried out by each practitioner in respect of the twelve months period following the first date and in respect of each successive period of twelve months. The information is to be provided to the Authority within 28 days of the end of each relevant period of twelve months.
4. The Person Responsible must record the information referred to in Schedule 3 to these Directions in respect of each treatment cycle involving preimplantation genetic diagnosis of embryos (PGD).
5. The Person Responsible must record the information referred to in Schedule 4 to these Directions in respect of each treatment cycle involving preimplantation screening of embryos for aneuploidy (PGS).

Date: 15 May 2003

Suzi Leather
Chair

TWELVE MONTH RECORD OF POLAR BODY BIOPSY CASES

(To be completed for all Polar Body Biopsy Practitioners)

NAME

CENTRE

CENTRE No.....

Data collection period: From To

No. patients treated	
No. biopsy cycles	
Procedure details	
No. eggs / embryos biopsied	
No. eggs /embryos intact (see definitions)	
No. with 1 st polar bodies only biopsied	
No. of eggs fertilised (rate %)	
No. with 1 st and 2 nd polar bodies biopsied	
No. embryos suitable for transfer after biopsy	
No. grown on to day 5 or 6	
No. of blastocysts (%)	
Outcome	
Biochemical pregnancy	
Clinical pregnancy (FH+ve)	
No. clinical pregnancies per biopsy cycle	
No. clinical pregnancies per ET procedure	

SIGNED.....
 DATE.....
 (Polar Body Practitioner)

SIGNED.....
 DATE.....
 (Person Responsible)

TWELVE MONTH RECORD OF BLASTOMERE BIOPSY CASES

(To be completed for all Blastomere Biopsy Practitioners)

NAME

CENTRE

CENTRE No.....

Data collection period: From To.....

No. patients treated	
No. biopsy cycles	
Procedure details	
No. embryos biopsied	
No. embryos intact (see definitions)	
No. embryos which had 1 cell removed	
No. embryos (1 cell biopsy) damaged	
No. of embryos which had 2 cells removed	
No. of embryos (2 cells biopsy) damaged	
No. embryos greater than 2 cells biopsied	
No. embryos suitable for transfer after biopsy	
No. embryos transferred	
No. grown on to day 5 or 6	
No. blastocysts	
Outcome	
Biochemical pregnancy	
Clinical pregnancies (FH+ve)	
No. clinical pregnancies per biopsy cycle	
No. clinical pregnancies per ET procedure	

SIGNED.....
 DATE.....
 (Blastomere Biopsy Practitioner)

SIGNED.....
 DATE.....
 (Person Responsible)

Centre No:

Form for the recording of PGD data to the HFEA
Information on each cycle of preimplantation genetic diagnosis of embryos

Patient Name and Date of Birth	
Hospital / Clinic Number	
PGD Cycle number and date of commencement	
Indication(s) for testing	
Specific Disease / Disorders tested for	
Details of the tests used e.g. FISH, PCR	
N^o of eggs biopsied and damage rate or N^o of embryos biopsied (number of blastomeres removed and damage rate)	
Results of the analysis for each polar body / blastomere / whether considered suitable for transfer or not	
Number of embryos transferred	
Fate of embryos not transferred	

Please record the following information when known.

Results of prenatal screening, if performed	
Outcome of treatment cycle	

Centre No:

<p>Form for the recording of PGS data to the HFEA</p> <p>Information on each cycle of preimplantation screening of embryos for aneuploidy</p>

Patient Name and Date of Birth	
Hospital / Clinic Number	
PGS Cycle number and date of commencement	
Indication(s) for testing	
Chromosomes tested for	
Details of the tests used	
N° of eggs biopsied and damage rate or N° of embryos biopsied (number of blastomeres removed and damage rate)	
Results of the analysis for each polar body / blastomere / whether considered suitable for transfer or not	
Number of embryos transferred	
Fate of embryos not transferred	

Please record the following information when known.

Results of prenatal screening, if performed	
Outcome of treatment cycle	