

The HFEA Code of Practice – transposition of existing guidance

The following table shows, the transposition of the measures contained in the existing (6th edition) of the HFEA Code of Practice into the draft (7th edition). In some cases guidance contained in the 6th edition has been rendered among the standards whilst in others, measures have been incorporated within the guidance section with some redrafting to improve clarity and consistency.

Readers will be able to use the table below to track the fate of each provision of the 6th edition, which appears with a brief account of the reasons behind any changes.

<p>What is a 'standard'?</p> <p>The <i>HFEA Standards</i> contains a set of agreed, common specifications for relevant aspects of an assisted conception service (or research project involving the use of human embryos). Conformity to standards may be mandatory (if they express a legal requirement or a condition of licence) or advisory (setting out specifications of good practice). Evidence of conformity with these standards will be sought during an HFEA inspection.</p> <p>What is 'guidance'?</p> <p>HFEA guidance concerns the manner in which licensable activities are expected to be carried out and the functions and responsibilities of licensees discharged. Its purpose is to assist licensees to meet the criteria required by law and specified in the <i>HFEA Standards</i>, and thereby to ensure good practice in the provision of treatment services or the conduct of research. In certain circumstances compliance with the guidance may be taken into account in determining whether a licence should be varied or revoked.</p>

CoP 6	Agreed proposal	Action / outcome
Part 1 – Staff		
1.1	Implicit in standards and <i>passim</i>	None
1.2	New alternate standard on assessment of PRs to be included at 4.1.2	New standard incorporated at S:4.1.2
1.3	Standard sufficient but guidance useful to clarify qualifications. NB under EUTCD PR must have "professional healthcare" background.	Now at 1.1.1
1.4	Alternate specification in standard to identify duties of the PR as set out at s.17 of the 1990 Act for scheme A centres: 4.1.2(d)/1 to cover 1.4.(i) (This should be the 'documented procedure for personnel management' that scheme A centres adopt) -- insert cross reference to 6.2.1 (first para). 4.1.2(d)/2 to cover 1.4.(ii) (This assigns responsibility for scheme A centres to PR rather than 'the centre' for specifications at standard paras 6.3.1; 6.3.2; 6.3.4 & 6.3.5 -- insert x-refs). 4.1.2(d)/3 to cover 1.4.(iii) (This assigns responsibility for scheme A	New specifications drafted for inclusion in standard as indicated.

CoP 6	Agreed proposal	Action / outcome
	centres to PR rather than 'the centre' for specifications at standard para.7.8.4 -- insert x-refs). 4.1.2(d)/4 to cover 1.4.(iv) (This assigns responsibility for scheme A centres to PR). 4.1.2(d)/5 to cover 1.4.(v) (This assigns responsibility for scheme A centres to PR).	
1.5	6.2.1 + professional guidance sufficient	Now at 1.2.1
1.6	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.2.3
1.7	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.2.2
1.8	6.2.1 + revised guidance on personnel with link to professional guidance	Now at 1.3.1
1.9	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.4.2 and 1.4.3
1.10.	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.1
1.11	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.2
1.12.	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.3
1.13	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.4
1.14	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.2
1.15	6.2.1 sufficient	None
1.16	6.2.1 sufficient	None
1.17	6.2.1(e) sufficient	None
1.18	6.2.2 sufficient	None
1.19	6.2.3 sufficient	None
1.1	Implicit in standards and <i>passim</i>	None
1.2	New alternate standard on assessment of PRs to be included at 4.1.2	New standard incorporated at S:4.1.2
1.3	Standard sufficient but guidance useful to clarify qualifications. NB under EUTCD PR must have "professional healthcare" background.	Now at 1.1.1
1.4	Alternate specification in standard to identify duties of the PR as set out at s.17 of the 1990 Act for scheme A centres: 4.1.2(d)/1 to cover 1.4.(i) (This should be the 'documented procedure for personnel management' that scheme A centres adopt) -- insert cross reference to 6.2.1 (first para). 4.1.2(d)/2 to cover 1.4.(ii) (This assigns responsibility for scheme A centres to PR rather than 'the centre' for specifications at standard paras 6.3.1; 6.3.2; 6.3.4 & 6.3.5 -- insert x-refs). 4.1.2(d)3 to cover 1.4.(iii) (This assigns responsibility for scheme A centres to PR rather than 'the centre' for specifications at standard para.7.8.4 -- insert x-refs). 4.1.2(d)/4 to cover 1.4.(iv) (This assigns responsibility for scheme A centres to PR). 4.1.2(d)/5 to cover 1.4.(v) (This assigns responsibility for scheme A centres to PR).	New specifications drafted for inclusion in standard as indicated.
1.5	6.2.1 + professional guidance sufficient	Now at 1.2.1
1.6	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.2.3
1.7	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.2.2

CoP 6	Agreed proposal	Action / outcome
1.8	6.2.1 + revised guidance on personnel with link to professional guidance	Now at 1.3.1
1.9	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.4.2 and 1.4.3
1.10.	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.1
1.11	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.2
1.12.	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.3
1.13	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.4
1.14	6.2.1 + guidance on personnel with link to professional guidance	Now at 1.5.2
1.15	6.2.1 sufficient	None
1.16	6.2.1 sufficient	None
1.17	6.2.1(e) sufficient	None
1.18	6.2.2 sufficient	None
1.19	6.2.3 sufficient	None
Part 2 – Facilities		
2.1	New alternate standard under 4.1.2 required to make this a responsibility of the PR	Standard drafted for inclusion at 4.1.2(d)/2 and 4.1.2(d)/4
2.2	New guidance para.2.1.1 – 2.1.2	Now at 2.1.1-2.1.2
2.3	Duplicates guidance at 8.3	None
2.4	Standard (Part 4) sufficient as drafted – no additional guidance required	None
2.5	Standard 6.3.2 sufficient as drafted – no additional guidance required	None
2.6	Standard 6.3.2 sufficient as drafted – no additional guidance required	None
2.7	Standard 6.3.2 sufficient as drafted – no additional guidance required	None
2.8	Standard 6.3.2 sufficient as drafted – no additional guidance required	None
2.9	Standard 6.3.4 sufficient as drafted – no additional guidance required	None
2.10.	Standard 6.3.4 sufficient as drafted – no additional guidance required	None
2.11	New alternate standard required	Standard drafted for inclusion at 7.8.3/1
2.12	Standards (6.3.1; 7.8.3) sufficient although they don't refer to physical proximity	None
2.13	Standard 6.3.5 sufficient although they don't specifically mention volume	None
2.14	Standard 6.3.5(f) sufficient	None
2.15	Replaced with more specific guidance in CH (04) 03	Incorporate specific guidance from guidance CH (04) 03
2.16 (i)-(iii)	Standard 6.4(f) sufficient	None
2.16 (iv)	Standard 7.8.3 sufficient	None
2.16(v)	Standard 7.3.1 sufficient	None
2.16(vi)	New standard required	Standard drafted

CoP 6	Agreed proposal	Action / outcome
		for inclusion at 7.8.3(d)/1
2.17	Standard 7.7.3 gives sufficient specification to meet this expectation	None
2.18	Standard 6.3.3 adequate	None
2.19	Incorporate in guidance on proper counselling arrangements	Now at 7.1.2
2.20.	Incorporate in guidance on proper counselling arrangements	Now at 7.1.3
2.21	Incorporate into guidance on personnel G 1.4.1	Now at 1.4.1
2.22	Standard 6.3.5 sufficient	none
2.23	Include in new guidance on adverse incidents	Guidance drafted at 14.1.1
2.24	Include in new guidance on adverse incidents	Guidance drafted at 14.1.2
2.25	Include in new guidance on adverse incidents	Guidance drafted at 14.1.3
2.26	Include in new guidance on adverse incidents	Guidance drafted at 14.1.4
2.27	Alternate standard required for scheme A centres	Standard drafted for inclusion at 8.5.1/1
2.28	Standard 8.5.1 sufficient	None
2.29	Alternate standard for scheme A centres at 4.1.2(d)/6 [only way of getting it into the standard is to make it a responsibility of the PR] and guidance at 4.1.1	Standard drafted for inclusion at 4.1.2(d)/6 and guidance incorporated at 4.1.1
2.30.	Standards (<i>passim</i>) sufficient	None
Directions D.2000/3 on satellite and transport IVF		
	Link Directions with standard and guidance	Link S4.2.8 to Directions D.2000/3 and Guidance on use of unlicensed facilities
Chair's letter CH (04) 03 on safety of storage equipment		
	Incorporate into guidance on storage and handling of gametes and embryos. NB 'split sample' requirement should be reviewed.	Now at 9.1.1 and 9.1.2
Directions D.2004/3 on reporting adverse incidents		
	Directions to be amended to conform with requirements of EUTCD	Amend Directions D.2004/3
Part 3 – Welfare of the child and the assessment of those seeking treatment		
3.1	New alternate standard for 1990 Act centres at 7.6.2/1	Standard drafted for inclusion at 7.6.2/1
3.2	Standards (7.1 (generally) & 6.3.1 (premises and facilities)) sufficient	None
3.3	To be covered in the new standard at 7.6.2/1	Standard drafted for inclusion at

CoP 6	Agreed proposal	Action / outcome
		7.6.2/1
3.4	Superseded - see guidance issued with CH (05) 04 (below)	
3.5	Superseded - see guidance issued with CH (05) 04 (below)	
3.6	This is covered in standard 7.5(b) and new guidance 3.5.1	New guidance drafted at 3.5.1
3.7	New guidance drafted in guidance on information for people seeking treatment	Now at 5.3.1(e)
3.8	New standards under 'procurement of gametes' and supporting guidance	New standard at 7.7.1(a-1) and guidance at 9.2.1
3.9	New standards under 'procurement of gametes' and supporting guidance	New standard at 7.7.1(a-1) and guidance at 9.2.2
3.10.	New standards under 'procurement of gametes' and supporting guidance	New standard at 7.7.1(a-1) and guidance at 9.2.2 and 9.2.3
3.11	Superseded - see guidance issued with CH (05) 04 (below)	
3.12	Superseded - see guidance issued with CH (05) 04 (below)	
3.13	Superseded - see guidance issued with CH (05) 04 (below)	
3.14	Superseded - see guidance issued with CH (05) 04 (below)	
3.15	Superseded - see guidance issued with CH (05) 04 (below)	
3.16	Superseded - see guidance issued with CH (05) 04 (below)	
3.17	Superseded - see guidance issued with CH (05) 04 (below)	
3.18	Superseded - see guidance issued with CH (05) 04 (below)	
3.19	Superseded - see guidance issued with CH (05) 04 (below)	
3.20.	Superseded - see guidance issued with CH (05) 04 (below)	
3.21	Superseded - see guidance issued with CH (05) 04 (below)	
3.22	Superseded - see guidance issued with CH (05) 04 (below)	
3.23	Superseded - see guidance issued with CH (05) 04 (below)	
3.24	Superseded - see guidance issued with CH (05) 04 (below)	
3.25	Superseded - see guidance issued with CH (05) 04 (below)	
3.26	Superseded - see guidance issued with CH (05) 04 (below)	
3.27	Superseded - see guidance issued with CH (05) 04 (below)	
3.28	Superseded - see guidance issued with CH (05) 04 (below)	
3.29	Superseded - see guidance issued with CH (05) 04 (below)	
3.30.	Superseded - see guidance issued with CH (05) 04 (below) 0.6	
3.31	Superseded - see guidance issued with CH (05) 04 (below) 0.7	
New WoC guidance CH (05) 04		
3.1	To be incorporated in revised guidance on welfare of the child	Now at 3.1.1
3.2	To be incorporated in revised guidance on welfare of the child	Now at 3.1.1
3.3	To be incorporated in revised guidance on welfare of the child	Now at 3.2.1

CoP 6	Agreed proposal	Action / outcome
3.4	To be incorporated in revised guidance on welfare of the child	Now at 3.2.2
3.5 [3.6]	To be incorporated in revised guidance on welfare of the child	Now at 3.2.3
3.6	To be incorporated in revised guidance on welfare of the child	Now at 3.2.4
3.7	To be incorporated in revised guidance on welfare of the child	Now at 3.3.1
3.8	Content of existing para 3.8 To be incorporate in revised guidance on welfare of the child;	Existing para.3.8 now at 3.3.2; information about genetic inheritance included in new 5.3.1 (information to patients)
3.9	To be incorporated in revised guidance on welfare of the child	Now at 3.3.3
3.10.	To be incorporated in revised guidance on welfare of the child	Now at 3.3.4
3.11	Standard 7.4 and 7.5(c) sufficient	None
3.12	To be incorporated in revised guidance on welfare of the child	Now at 3.4.1
3.13	To be incorporated in revised guidance on welfare of the child	Now at 3.4.2
3.14	To be incorporated in revised guidance on welfare of the child	Now at 3.4.3
3.15	To be incorporated in revised guidance on welfare of the child	Now at 3.4.4
3.16	To be incorporated in revised guidance on welfare of the child	Now at 3.4.5
3.17	To be incorporated in revised guidance on welfare of the child	Now at 3.4.6
3.18	To be incorporated in revised guidance on welfare of the child	Now at 3.4.7
3.19	To be incorporated in revised guidance on welfare of the child	Now at 3.4.8
3.20.	Covered in new standard at 7.6.2/1	Standard drafted for inclusion at 7.6.2/1
3.21	To be incorporated in revised guidance on welfare of the child	Now at 3.5.1
3.24	To be incorporated in revised guidance on welfare of the child	Now at 3.4.8
0.1	To be covered in new guidance on information for people seeking treatment	Now at 5.3.1(e)
0.2	Covered in new standard at 7.6.3/1	Standard drafted for inclusion at 7.6.3/1
0.3	Covered in new standard at 7.6.3/1	Standard drafted for inclusion at 7.6.3/1
0.4	Covered in new standard at 7.6.3/1	Standard drafted for inclusion at 7.6.3/1
0.5	To be covered in new guidance on donors	Now at 4.3.3
0.6	To be covered in guidance on counselling	Now at 7.2.5
0.7	Delete -- covered in general standards on patient care	None
5.6	To be covered in new guidance on information for people seeking treatment	Now at 5.4.6
5.7	To be covered in new guidance on information for people seeking	Now at 5.4.2

CoP 6	Agreed proposal	Action / outcome
	treatment	
5.8	To be covered in new guidance on information for people seeking treatment	Now at 5.4.5
Part 4 – Assessing and screening potential donors		
4.1(i)	Include in revised guidance on recruiting donors	Now at 4.4.1(a)
4.1(ii)	Include in revised guidance on recruiting donors	Now at 4.4.1(b)
4.1(iii)	Include in revised guidance on recruiting donors	Now at 4.6.1
4.1(iv)	Include in revised guidance on recruiting donors	Now at 4.4.1(c)
4.1(v)	Now standard 7.6.3(b)	None
4.1(vi)	Include in revised guidance on recruiting donors	Now at 4.4.1(d)
4.1(vii)	Now standard 7.6.3(d)	None
4.2	New standard at 7.7.1(c)/1	Standard 7.7.1(c)/1 drafted for inclusion
4.3	Include in revised guidance on recruiting donors	Now at 4.11.3
4.4	Include in revised guidance on recruiting donors	Now at 4.7.1
4.5	Include in revised guidance on recruiting donors	Now at 4.7.2
4.6	Include in revised guidance on recruiting donors	Now at 4.7.2
4.7	Include in revised guidance on recruiting donors	Now at 4.6.2
4.8	Section on counselling to be separated from section on suitability as a donor; both to be included in new guidance	Now at 4.8.1 (suitability and 4.5.1 (counselling))
4.9	Redraft standard 7.6.2(f) and include guidance in new guidance on donors omitting expectation that the possibility of donation should be raised by the counsellor as it is often more appropriate that it is raised at an earlier stage during early medical consultation	7.6.2(f) redrafted for inclusion; now at 4.3.1
4.10.	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.2
4.11	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.2
4.12	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.3
4.13	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.4
4.14	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.5
4.15	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.6
4.16	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.7
4.17	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.1
4.18	Move to guidance on information for people seeking treatment	Now at 5.4.3
4.19	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.8

CoP 6	Agreed proposal	Action / outcome
4.20.	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.9
4.21	Include in guidance on donors until new joint screening guidance produced (whereupon to be deleted and replaced with new 4.9.1)	Now at 4.9.10
4.22	Delete note 1 at S:7.6.3 and replace with new standard requiring consideration to be given to suitability of donors and include age limits in new guidance on donors	New standard drafted for inclusion at 7.6.3(f)/1 and new guidance at 4.2.1
4.23	Delete note 1 at S:7.6.3 and replace with new standard requiring consideration to be given to suitability of donors and include age limits in new guidance on donors	New standard drafted for inclusion at 7.6.3(f)/1 and new guidance at 4.2.2
4.24	Delete note 1 at S:7.6.3 and replace with new standard requiring consideration to be given to suitability of donors and include age limits in new guidance on donors	New standard drafted for inclusion at 7.6.3(f)/1 and new guidance at 4.2.3
4.25	Delete note 1 at S:7.6.3 and replace with new standard requiring consideration to be given to suitability of donors and include age limits in new guidance on donors	New standard drafted for inclusion at 7.6.3(f)/1 and new guidance at 4.2.4
4.26	Include in revised guidance on recruiting donors	Now at 4.11.1
4.27	Include in revised guidance on recruiting donors	Now at 4.10.1
4.28	Include in revised guidance on recruiting donors	Now at 4.10.2
4.29	Include in revised guidance on recruiting donors	Now at 4.10.3
4.30.	Include in revised guidance on recruiting donors	Now at 4.10.4
4.31	Include in revised guidance on recruiting donors	Now at 4.10.5
4.32	Include in revised guidance on recruiting donors	Now at 4.3.2
4.33	Include in new guidance on information	Now at 5.5.1

Part 5 – Information

5.1	Standard sufficient in general; distinction between information provision and counselling to be set out in new information guidance	now at 5.1.1
5.2	Standard sufficient	None
5.3	Expectation that there will be an identified contact and that written records will be kept To be included in revised guidance on providing proper information	now at 5.1.2
5.4(i)	To be included in revised guidance on providing proper information	now at 5.3.1(a)
5.4(ii)	To be included in revised guidance on providing proper information	now at 5.3.1(b)
5.4(iii)	To be included in revised guidance on providing proper information	now at 5.3.1(f)
5.4(iv)	To be included in revised guidance on providing proper information	now at 5.10.1(a)
5.4(v)	To be included in revised guidance on providing proper information	now at 5.3.1(e)
5.4(vi)	To be included in revised guidance on providing proper information	now at 5.10.1(b)

CoP 6	Agreed proposal	Action / outcome
5.4(vii)	To be included in revised guidance on providing proper information	now at 5.3.1(f)
5.5(i)	To be included in revised guidance on providing proper information	now at 5.3.1(a)
5.5(ii)	To be included in revised guidance on providing proper information	now at 5.3.1(b)
5.5(iii)	To be included in revised guidance on providing proper information	now at 5.3.1(d)
5.5(iv)	To be included in revised guidance on providing proper information	now at 5.3.1(e)
5.5(v)	To be included in revised guidance on providing proper information	now at 5.3.1(g)
5.5(vi)	To be included in revised guidance on providing proper information	now at 5.3.2
5.5(vii)	To be included in revised guidance on providing proper information	now at 5.3.1(c)
5.5(viii)	To be included in revised guidance on providing proper information	now at 5.3.1(h)
5.5(ix)	To be included in revised guidance on providing proper information	now at 5.3.3 and 5.10.1
5.5(x)	To be included in revised guidance on providing proper information	now at 5.3.1(i)
5.6(i)	To be included in revised guidance on providing proper information	now at 5.4.2(a)
5.6(ii)	To be included in revised guidance on providing proper information	now at 5.4.2(b)
5.6(iii)	To be included in revised guidance on providing proper information	now at 5.4.2(c)
5.6(iv)	To be included in revised guidance on providing proper information	now at 5.4.5(a)
5.6(v)	To be included in revised guidance on providing proper information	now at 5.4.5(b)
5.6(vi)	To be included in revised guidance on providing proper information	now at 5.4.5(c)
5.6(vii)	To be included in revised guidance on providing proper information	now at 5.4.5(d)
5.7(i)	To be included in revised guidance on providing proper information	now at 5.11.1(a)
5.7(ii)	To be included in revised guidance on providing proper information	now at 5.11.1(b)
5.7(iii)	To be included in revised guidance on providing proper information	now at 5.11.1(d)
5.7(iv)	To be included in revised guidance on providing proper information	now at 5.11.1(e)
5.7(v)	To be included in revised guidance on providing proper information	Redrafted, consistently with new legislation, at 5.11.1(h)
5.7(vi)	To be included in revised guidance on providing proper information	Redrafted, consistently with new legislation, at 5.11.1(f)-(h)
5.7(vii)	To be included in revised guidance on providing proper information	now at 5.11.1(j)
5.7(viii)	To be included in revised guidance on providing proper information	now at 5.11.1(k)
5.8(i)	New standard required for research donors under 7/1; guidance To be included in revised guidance on providing proper information	New standard at 7/1.2.2 and guidance now at 5.13.1(a)
5.8(ii)	To be included in revised guidance on providing proper information	Now at 5.13.1(b)
5.8(iii)	To be included in revised guidance on providing proper information	Now at 5.13.1(c)
5.8(iv)	To be included in revised guidance on providing proper information	Now at 5.13.1(d)
5.8(v)	To be included in revised guidance on providing proper information	Now at 5.13.1(e)
5.8(vi)	To be included in revised guidance on providing proper information	Now at 5.13.1(f)

CoP 6	Agreed proposal	Action / outcome
5.8(vii)	To be included in revised guidance on providing proper information	Now at 5.13.1(g)
5.8(viii)	To be included in revised guidance on providing proper information	Now at 5.13.1(h)
5.9(i)	To be included in revised guidance on providing proper information	Now at 5.13.2(a)
5.9(ii)	To be included in revised guidance on providing proper information	Now at 5.13.2(b)
5.9(iii)	To be included in revised guidance on providing proper information	Now at 5.13.2(c)
5.9(iv)	To be included in revised guidance on providing proper information	Now at 5.13.2(d)
5.9(v)	To be included in revised guidance on providing proper information	Now at 5.13.2(e)
5.9(vi)	To be included in revised guidance on providing proper information	Now at 5.13.2(f)
5.10.	To be included in revised guidance on providing proper information	Now at 5.13.3
5.11	To be included in revised guidance on providing proper information	Now at 5.10.2
5.12	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(i)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(ii)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(iii)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(iv)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(v)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.12(vi)	To be included in revised guidance on providing proper information	Now at 5.5.2
5.13	To be included in revised guidance on providing proper information	Now at 5.5.2
5.14	To be included in revised guidance on providing proper information	Now at 5.11.1

Part 6 – Consent

6.1	Standard 7.5 re-drafted; include 6.1 in guidance on consent to examination and treatment	now at 6.2.1
6.2	To be included in revised guidance on obtaining consent	Now at 6.2.1
6.3 (i)	To be included in revised guidance on obtaining consent	Now at 6.2.2
6.3 (ii)	To be included in revised guidance on obtaining consent	Now at 6.2.2
6.3(iii)	To be included in revised guidance on obtaining consent	Now at 6.2.2
6.3 (remainder)	To be included in revised guidance on obtaining consent	Now at 6.2.2
6.4	To be included in revised guidance on obtaining consent	Now at 6.3.1
6.5	To be included in revised guidance on obtaining consent	Now at 6.1.1
6.6	To be included in revised guidance on obtaining consent	Now at 6.1.2
6.7	To be included in revised guidance on obtaining consent	Now at 6.1.3
6.8	To be included in revised guidance on obtaining consent	Now at 6.1.4
6.9	More appropriate in guidance on procuring/ handling gametes with link to consent	Now at 9.1.1
6.10.	To be included in revised guidance on obtaining consent	Now at 6.4.1
6.11	To be included in revised guidance on obtaining consent	Now at 6.4.2
6.12	To be included in revised guidance on obtaining consent	Now at 6.4.3
6.13	To be included in revised guidance on obtaining consent	Now at 6.5.1
6.14	To be included in revised guidance on obtaining consent	Now at 6.6.1

CoP 6	Agreed proposal	Action / outcome
6.15	To be included in revised guidance on obtaining consent	Now at 6.6.1
6.16	This is a condition of storage so move to guidance on storage and handling of gametes and embryos	Now at 9.1.2
6.17	To be included in revised guidance on obtaining consent	Now at 6.6.1
6.18	To be included in revised guidance on obtaining consent	Now at 6.7.1
6.19	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.1.2
6.20.	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.1.2
6.21	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.1.3
6.22	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.1.4
6.23	This is a condition of export so move to new guidance on importing and exporting gametes and embryos	Guidance forthcoming
6.24	To be included in revised guidance on obtaining consent	Now at 5.10.3
6.25	To be included in revised guidance on obtaining consent	Now at 5.10.3
6.26	This is not guidance -- leave out	None
6.27	Not relevant to consent and covered elsewhere -- leave out.	None
6.28	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.2.1
6.29	This is a condition of use so move to revised guidance on use of gametes and embryos in treatment	Now at 8.2.3
6.30.	To be included in revised guidance on obtaining consent	Now at 6.3.3
6.31	To be included in revised guidance on obtaining consent ; replace ambiguous 'beforehand' with 'before the beginning of their treatment'.	Now at 6.2.3
6.32	To be included in revised guidance on obtaining consent	Now at 6.9.1
6.33	To be included in revised guidance on obtaining consent	Now at 6.9.2
6.34	To be included in revised guidance on obtaining consent	Now at 6.9.3
6.35	To be included in revised guidance on obtaining consent	Now at 6.9.4
6.36	Re-draft to clarify and include in revised guidance on obtaining consent	Now at 6.9.5
6.37	To be included in revised guidance on obtaining consent	Incorporated into 6.9.1
6.38	To be included in revised guidance on obtaining consent	Incorporated into 6.9.1
6.39	To be included in revised guidance on obtaining consent	Now at 6.7.4
6.40.	To be included in revised guidance on obtaining consent	Now at 6.7.4
6.41	To be included in revised guidance on obtaining consent	Now at 6.7.5
6.42	To be included in revised guidance on obtaining consent	Now at 6.6.6
6.43	To be included in revised guidance on obtaining consent	Now at 6.6.4
6.44	To be included in revised guidance on obtaining consent	Now at 6.6.4
6.45	To be included in revised guidance on obtaining consent	Now at 6.6.5

CoP 6	Agreed proposal	Action / outcome
6.46	To be included in revised guidance on obtaining consent	Now at 6.6.5
6.47	To be included in revised guidance on obtaining consent	Now at 6.7.1
6.48	To be included in revised guidance on obtaining consent	Now at 6.8.1
6.49	To be included in revised guidance on obtaining consent	Now at 6.8.2
6.50.	To be included in revised guidance on obtaining consent	Now at 6.8.2
6.51	Covered adequately elsewhere (e.g G:8.2.1)	None
6.52	To be included in revised guidance on obtaining consent	Now at 6.8.1
CE letter (03) 02 of 28.11.03 on Deceased Fathers		
	Incorporate into guidance on information and consent	Now at 6.11
Part 7 – Counselling		
Preamble	To be included in revised guidance on provision of proper counselling services	Now at 7.1.1 and 1.4
7.1	To be included in revised guidance on provision of proper counselling services	Now at 7.1.1
7.2(i)-(iii)	To be covered in standard rather than guidance	Covered in standard 7.6.2(b) and (c)
7.2(iv)-(vi)	To be covered in standard rather than guidance	Covered in re-drafted standard 7.6.2 (c)
7.3	Expectation that centres will take refusal of counselling into account is incompatible with revised WoC guidance (and contradicts S:7.6.2(a))	Refer to Professional guidance [BICA]
7.4	Incorporate in standard	Incorporated as new standard 7.6.2(a)/1
7.5	To be included in revised guidance on provision of proper counselling services	Now at 7.2.5
7.6	Covered in S:6.3.3 and professional guidance [BICA]	None
7.7	To be included in revised guidance on provision of proper counselling services	Now at 7.1.1 and 1.4
7.8	To be included in revised guidance on provision of proper counselling services	Now at 7.2.7
7.9	Split guidance relating to initial and subsequent availability and include in revised guidance on provision of proper counselling services	Now at 7.2.2 and 7.2.6
7.10.	Guidance on content of counselling should be given by professional bodies -- include expectation that counselling will follow professional guidelines.	Now at 7.3.1
7.11	Duplicates 7.9. Now at 7.4.2	None
7.12	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.2.1
7.13	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.3.2 and 7.3.3
7.14	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.2.3

CoP 6	Agreed proposal	Action / outcome
7.15	Both HFEA's SEED Report (para 2.7) and HGC's 'Making Babies' report (p.60) recommend that where donor gametes are used, the HFEA should give guidance for people considering donation on factors connected with the selection of donors that are relevant to the welfare of the child and that should be taken into account (e.g. using donors with different ethnic background). This is now included as a new section at 7.3.3(b)	Now at 7.3.3
7.16	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.2.4
7.17	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.4.2
7.18	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.4.3
7.19	Incorporated in standard at 7.6.2(e) with additional guidance at 7.5.1	Incorporated in standard at 7.6.2(e) with additional guidance at 7.5.1
7.20.	To be covered in standard relating to staff training rather than guidance	Incorporated into new standard S:6.2.5(e)
7.21	To be covered in standard relating to counselling with additional guidance	Incorporated into new standard 7.6.2(e) and 7.6.1
7.22	Incorporate into redrafted standard 7.6.2(e) and supplement with revised guidance	New 7.6.2(e) and guidance at 7.6.2
7.23	Covered completely in standard	New 7.6.2(e)
7.24	Similar to 7.9: collapse 7.9 and 7.24 together.	Now at 7.2.7
7.25	To be included in revised guidance on provision of proper counselling services	Now at 7.4.1
7.26	To be included in revised guidance on provision of proper counselling services	Now at 7.4.2
7.27	Incorporate into redrafted standard 7.6.2(e)	Now covered in new standard 7.6.2(e)
7.28	Incorporate into redrafted standard 7.6.2(e)	Now covered in new standard 7.6.2(e)
7.29	To be included in revised guidance on provision of proper counselling services	Now at 7.2.5
7.30.	Relates to qualifications of counsellors and should be incorporated into guidance on personnel	Now at 1.4.4
7.31	Equivalent to guidance at 7.2.1 - 7.2.7; remove duplication	None
7.32	Incorporate into guidance on counselling but replace with reference to revised professional guidance [BICA] when this becomes available	Now at 7.3.4
Part 8 – Use of gametes and embryos		
8.1	Covered adequately by Directions and separate guidance on import and export	Covered in 9.8.1
8.2	Covered adequately by Directions	Covered in 9.8.1

CoP 6	Agreed proposal	Action / outcome
8.3	To be covered in guidance on use of unlicensed facilities	Now in 2.2.1
8.4	Delete -- unworkable requirements which would actually rule out IVF/ ICSI/ cryopreservation/ etc. if properly adhered to. Important aspects adequately covered in new 8.4.1 [ex 8.8].	Covered at 8.3.1
8.5	Delete -- unworkable requirements which would actually rule out IVF/ ICSI/ cryopreservation/ etc. if properly adhered to. Important aspects adequately covered in new 8.4.1 [ex 8.8].	Covered at 8.3.1
8.6	Drafted as a new licence condition	New licence condition 1/1(a)
8.7	Covered in guidance at 8.6.1 and 2.2.5, for example	None
8.8	To be incorporated in guidance on use of gametes and embryos in treatment	Now at 8.3.1
8.9	Drafted as a new licence condition	New licence condition 1/1(b)
8.10.	To be incorporated in guidance on storage and handling of gametes and embryos [termination and disposal]	Now at 9.10.1
8.11	To be incorporated in guidance on storage and handling of gametes and embryos [termination and disposal]	Now at 9.10.2
8.12	To be incorporated in new alternate standard for research centres (new section between sections 7 and 8 of the HFEA standard)	New standard drafted for inclusion at 7/1.1.1
8.13	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.14 (preamble)	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.14(i)	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.14(ii)	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.14(iii)	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.14(iv)	Include in guidance on use of unlicensed services and facilities	Now at 2.3.1
8.15	Adequately covered in standard 6.3.2(c) -- guidance adds nothing to this	None
8.16	Include in guidance on recruiting assessing and screening donors.	Now at 4.3.4
8.17	Drafted as a new licence condition	New licence condition 1/2(a)
8.18	Explanatory only -- omit	None
8.19	Include in guidance on use of unlicensed services and facilities	Now at 8.2.2
8.20.	To be incorporated in guidance on use of gametes and embryos in treatment	Now at 8.5.1
8.21	To be incorporated in guidance on use of gametes and embryos in treatment	Now at 8.5.2
8.22	To be incorporated in guidance on use of gametes and embryos in treatment	Now at 8.5.3
8.23	To be incorporated in guidance on information for those seeking treatment	Now at 5.4.4
8.24	To be incorporated in guidance on use of unlicensed services and facilities	Now at 2.4.1

CoP 6	Agreed proposal	Action / outcome
8.25	To be incorporated in guidance on use of unlicensed services and facilities	Now at 2.4.1
8.26	To be re-drafted as a general obligation for all patients receiving treatment (not merely those undertaking home insemination) although without suggesting that undertaking is enforceable	Now at 5.3.1
8.27	To be incorporated in guidance on use of unlicensed services and facilities	Now at 2.4.2
8.28	To be incorporated in guidance on use of unlicensed services and facilities	Now at 2.4.3
8.29	Duplicates para 8.16: remove duplication	Now at 4.3.4
8.30.	New standard at 7.8.4 (laboratory processes: storage and release of gametes and embryos)	Now at New standard 7.8.4(c)/1
8.31	Superseded -- see CH (06) 01	None
8.32	Superseded -- see CH (06) 01	None
8.33	Covered in Direction D.1991/8 para. 1(e) -- to be included in export guidance.	Covered in new standard 7.8.4(c)/1 and export guidance [forthcoming]
8.34	Superfluous	None
Part 9 – Storage and handling of gametes and embryos		
9.1	Contained in standards (<i>passim</i>)	None
9.2	New standard required	New standard at 7.8.4(b)/1
9.3	Include in guidance on storage and handling of gametes and embryos	Now at 9.7.2
9.4	Include in guidance on storage and handling of gametes and embryos	Now at 9.7.1 Linked to new standard at 7.8.4(b)/1
9.5	Comprehensively covered at standard 6.3.5	None
9.6	Comprehensively covered at standard 6.3.5	None
9.7	Adequately covered at standard 6.3.5(g), 7.8.3(c) and 7.8.4(e)	None
9.8	Adequately covered at standard 6.3.5(g), 7.8.3(c) and 7.8.4(e) and Directions on witnessing	None
9.9	Standard 7.7.7 to be altered to include reference to unauthorised or undetectable alteration	Standard 7.7.7 redrafted.
9.10.	Comprehensively covered at standard 7.3.1	None
9.11	New standard required. NB frequency of review changed to biennial rather than annual.	New standard at 7.8.4(b)/2
9.12	Include in guidance on storage and handling of gametes and embryos	Now at 9.9.1
9.13	Include in guidance on storage and handling of gametes and embryos	Now at 9.9.2
9.14	Covered variously at standard 6.3.5(e); 7.1; 7.7.1(f); 7.7.5; 7.7.6; 7.7.8(f); 7.8.3(c); 7.8.4(d)	None
9.15	Covered at standard 7.7.9(a) read with 7.7.2(c), standard licence condition at HFE Act 1990, s.12(c) and requirements for consent	None

CoP 6	Agreed proposal	Action / outcome
	generally. See also (ambiguous) Directions D.2001/1	
9.16	Covered at standard 7.7.1(f) [quality] and 6.3.5 [security]	None
9.17	Covered at standard 7.7.5; 7.7.6; 7.7.8; 7.7.9	None
Chair's letter CH (04) 03 on safety of equipment used to store gametes and embryos		
local alarms	Include in guidance on storage and handling of gametes and embryos	Now at 9.3.1
auto-dial	Include in guidance on storage and handling of gametes and embryos	Now at 9.3.1
adequate staffing	Include in guidance on storage and handling of gametes and embryos	Now at 9.3.1
adequate spare storage	Include in guidance on storage and handling of gametes and embryos	Now at 9.3.1
Part 10 – Research		
10.1	This is legal requirement rather than guidance and is expressed adequately elsewhere. Cross-reference to legal provision should be linked to relevant standard. No additional guidance required.	Relevant standard (7/1.1.1) to be X-referred to underlying legal provision (s.3)
10.2	This is simply re-states the law as guidance to licence committees. No guidance for researchers.	Relevant standard (7/1.1.1) to be X-referred to underlying legal provision (Schd.2, para.3 as amended)
10.3	This is simply re-states the law as guidance to licence committees. No guidance for researchers.	Relevant standard (7/1.1.1) to be X-referred to underlying legal provision (Schd.2, para.4)
10.4	This simply states general legal prohibitions which are adequately stated elsewhere (and are not peculiar to research).	Relevant standard (7/1.1.1) should be X-referred to underlying legal provision (s.3)
10.5	This is a licence condition -- the guidance does not add anything.	Relevant standard (7/1.2.1) should be X-referred to underlying provision (s.15(4)) and licence condition (2c)
10.6	This is guidance on applying for a licence rather than practice guidance. Therefore does not belong in CoP but should come from Regulation.	None
10.7	As 10.6	None
10.8	This is partly guidance on applying for a licence rather than practice guidance (see 10.6) and partly guidance on constitution of ethics committees (which HFEA issues separately).	None
10.9	Guidance on ethics committees supplied separately by HFEA and DH -- this to be referenced in guidance on applying for a licence rather than	None

CoP 6	Agreed proposal	Action / outcome
	Code	
10.10.	This is information for applicants, not guidance for researchers, therefore does not belong in CoP but should come from Regulation	None
10.11	Draft new standard on disclosure of interests to and link to GMC guidance and guidance on (1) recruiting and (2) obtaining consent from research donors	Items (i), (iii), (iv) and (v) incorporated into new standard 7/1.2.1
10.12	Superfluous	None
Chief Executive's letter CE (05) 01 on reporting of adverse incidents		
Reporting requirements	Part 8 of standard applies to all licensees.	None
Chair's letter CH (06) 01 on outcome of the SEED Review - Directions D.2006/1		
Giving and receiving benefits	Link applicable standard to relevant Direction	Link research standard 7/1.2.1 to D.2006/1 [disbursements to donors]
Part 11 – Records		
11.1	Add new standard relating to accuracy of recording information to standards relating to information and records	New standard at 6.5(a/1)
11.2	Cross references to be inserted as appropriate	Insert cross references as appropriate
11.3	Incorporate into general guidance on general duty of confidentiality	Now at 10.1.1
11.4	Covered in standard 7.2(a) and (b)	None
11.5	Covered in standard 7.2(c)	None
11.6	Covered in standard 7.2(d)	None
11.7		Now at 10.6.1
11.8	To be included in revised guidance on confidentiality and access to confidential information with link to external guidance from Information Commissioner	Now at 10.6.2
11.9	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.6.3
11.10.	Duplicated substantially at 12.2 and 12.3	Now consolidated at 10.4.2
11.11	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.3.1
11.12	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.5.6
11.13 (first sentence to "...outside the centre.")	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.2.1
11.13 (from "If confidentiality is breached...")	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.8.1

CoP 6	Agreed proposal	Action / outcome
to end)		
11.14	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.2.1
11.15	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.2.2
Annex A	Include reference/link to external source of relevant legislation	Include link/reference
Annex B	Include reference/link to external source of relevant legislation	Include link/reference
Chair's letter CH (04) 07 on Disclosure of information relating to gamete donation		
Disclosure to donors and recipients	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.3.1
Chief Executive's letter CE (04) 05 on Freedom of Information Act 2000		
Obligations and exceptions relating to disclosure of information by public bodies	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.7.1-10.7.4
Part 12 – Confidentiality		
12.1	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.1.1 and 10.1.2
12.2	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.4.1-10.4.2
12.3	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.4.2
12.4	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.5.1
12.5	To be incorporated into new guidance on obtaining consent	Now at 6.11.1 & 10.5.2(but para.(iv) at 10.5.3)
12.6	To be incorporated into new guidance on obtaining consent	Now at 10.5.4
12.7	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.5.5
12.8	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.4.3
12.9	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.2.2
12.10.	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.2.2
Chair's letter CH (04) 07 on Disclosure of information relating to gamete donation		
Disclosure to donors and recipients	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.3.1
Chief Executive's letter CE (04) 05 on Freedom of Information Act 2000		
Obligations and	To be included in revised guidance on confidentiality and access to	Now at 10.7.1-

CoP 6	Agreed proposal	Action / outcome
exceptions relating to disclosure of information by public bodies	confidential information	10.7.4
Chair's letter CH (04) 07 on Disclosure of information relating to gamete donation		
Disclosure to donors	To be included in revised guidance on confidentiality and access to confidential information	Now at 10.3.1
Part 13 – Complaints		
13.1	To be included in revised guidance on complaints procedures	Now at 11.3.3
13.2	Form not currently in use--register should be made available to HFEA inspectors during inspection	Revised at 11.3.4
13.3	To be included in revised guidance on complaints procedures	Now at 11.1.1; 11.1.2; 11.2.1 and 11.4.1
13.4	To be included in revised guidance on complaints procedures and linked to guidance on patient information	Now at 5.3.1 and 11.3.2
13.5	To be included in revised guidance on complaints procedures	Now at 11.1.2 and 11.4.2
13.6	To be included in revised guidance on complaints procedures	Now at 11.4.3
Annex A	Include reference / link to external document	Link to NHS guidelines for dealing with patient complaints National Health Service (Complaints) Regulations 2004 (as amended) http://www.dh.gov.uk/PolicyAndGuidance/OrganisationPolicy/ComplaintsPolicy/NHSComplaintsProcedures/fs/en
Annex B	Include reference / link to external documents	Link to (1) The Private and Voluntary Health Care (England) Regulations 2001 and (2) Standards C14-C15 of Independent Health Care: National Minimum Standards (Department of Health)
Part 14 – Preimplantation testing		
14.1	Definition/description -- move to glossary and link to new preimplantation	To be incorporated

CoP 6	Agreed proposal	Action / outcome
	testing guidance	into glossary
14.2	Definition/description -- move to glossary and link to new preimplantation testing guidance	To be incorporated into glossary
14.3	Definition/description -- move to glossary and link to new preimplantation testing guidance	To be incorporated into glossary
14.3/1	Definition/description -- move to glossary and link to new preimplantation testing guidance	To be incorporated into glossary
14.4	Definition/description -- move to glossary and link to new preimplantation testing guidance	To be incorporated into glossary
14.5	This re-states standard licence condition 8(e). Covered by new standard 7.8.3(a)/1	Link/refer new standard 7.87.3(a)/1 to standard licence condition 8(e)
14.6	This re-states standard licence conditions 9(a) and (b)	None
14.7	This is a corollary of standard licence condition 9(a) and (b) and should be included in licensing guidance (i.e. guidance on applying for licences, rather than CoP guidance on conduct of licensable activities)	None
14.8	This is a corollary of standard licence conditions 9(a) and (b) and should be included in licensing guidance rather than CoP	None
14.9	This re-states standard licence condition 8(a). Covered by new standard 7.8.3(c)/1	Link/refer new standard 7.8.3(c)/1 to standard licence condition 8(a)
14.10.	This re-states standard licence condition 8(d). Covered by new standard 7.8.3(a)/1	Link/refer new standard 7.8.3(a)/1 to standard licence condition 8(d)
14.11	This requirement covered by standard 7.8.1 (as amended)	Amend standard 7.8.1 to include reference to embryos or material removed from gametes or embryos in the second paragraph of S7.8.1
14.12	To be included in revised guidance on preimplantation testing	Now at 12.1.1
14.13	More specific than standard 7.6.2(e). To be included in revised guidance on preimplantation testing	Now at 12.2.1
14.14	To be included in revised guidance on preimplantation testing	Now at 12.2.2
14.15	To be included in revised guidance on preimplantation testing	Now at 12.2.3
14.16	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.7.1
14.17	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.7.2
14.18	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.7.3

CoP 6	Agreed proposal	Action / outcome
14.19	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.7.4
14.20.	To be included in revised guidance on preimplantation testing	Now at 12.3.1
14.21	To be deleted following decision at HFEA meeting of 10.05.06	None
14.22	To be included in revised guidance on preimplantation testing	Now at 12.3.2
14.23	To be included in revised guidance on preimplantation testing	Now at 12.3.3
14.24	The purpose of this paragraph is descriptive rather than permissive -- add to relevant section of the guidance on terms	To be incorporated into glossary
14.25	Restates licence condition 10 (e) but to be incorporated in guidance for completeness	Now at 12.4.1
14.26	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.8.1
14.27	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.8.2
14.27/1	To be included in revised guidance on preimplantation testing	Now at 12.5.1
14.27/2	This is guidance on applying for licence rather than guidance on conduct of activities.	To be included in application guidance rather than CoP
14.27/3	To be included in revised guidance on preimplantation testing	Now at 12.5.2
14.27/4	To be included in revised guidance on preimplantation testing	Now at 12.5.2
14.27/5	To be included in revised guidance on preimplantation testing	Now at 12.5.3
14.27/6	Covered adequately by standard 3.2.1	None
14.27/7	To be included in revised guidance on preimplantation testing	Now at 12.2.4
14.27/8	To be included in revised guidance on preimplantation testing (amalgamated with 14.27/7)	Now at 12.2.4
14.27/9	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.9.1
14.27/10	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.9.1
14.27/11	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.9.2
14.27/12	To be incorporated into guidance on providing information (linked to guidance on PGD)	Now at 5.7.4
14.27/13	To be included in revised guidance on preimplantation testing	Now at 12.5.4
14.27/14	To be included in revised guidance on preimplantation testing	Now at 12.5.5
14.27/15	To be included in revised guidance on preimplantation testing	Now at 12.5.6
14.28	General Directions D.2003/1 superseded by Directions D.2004/6 ; Directions D.2004/6 superseded by Directions D.2006/3 -- new standard 7.8.3(a)/1 should link to relevant Directions and Licence Condition LC 8(e).	General guidance now at 9.5.1 with link to relevant Standard, Directions and explanatory letter
14.29	General Directions D.2003/1 superseded by Directions D.2004/6 ; Directions D.2004/6 superseded by Directions D.2006/3 -- new standard	General guidance now at 9.5.1 with

CoP 6	Agreed proposal	Action / outcome
	7.8.3(a)/1 should link to relevant Directions and Licence Condition LC 8(e).	link to relevant Standard, Directions and explanatory letter
14.30.	This relates to qualifications and competence -- to be incorporated into new guidance on personnel	Now at 1.5.7
14.31	To be incorporated into new guidance on procurement, storage and handling of gametes and embryos	Now at 9.5.1
Chair's letter CH (04) 06 on recognition of ICSI / biopsy practitioners		
	Superseded by CH (06) 03	None
Chair's letter CH (05) 03 on regulation of pre-implantation testing		
Guidance on licensing procedure rather than conduct of licensable activities	To be covered in application guidance and adequately enforced through licence conditions 9(a) and (b).	To be included in application guidance
Chair's letter CH (06) 03 on recognition of ICSI / biopsy practitioners		
	Incorporate in licensing inspection process – link applicable standards to relevant Directions	To be covered in guidance on licensing/inspection
Part 15 – Witnessing clinical and laboratory procedures		
Preamble (pp.127-8)	Incorporate into new guidance on witnessing and update list with reference to D.2004/4 (NB To be supplemented by new guidance on use of barcoding and RFID produced by SANT in Autumn 2006)	Now at 13.1.1 and 13.3.1
15.1	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.2	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.3	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.4	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.5	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.6	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.7	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.8	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.9	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
15.10.	Superseded by CH (04) 02 and Directions D.2004/4 (Schedule, para.1).	None
Chair's letter CH (04) 02 on Revised Directions on Witnessing		
list items (i)-(iv)	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.1.2
Directions D.2004/4 on Records of witnessing clinical and laboratory procedures		

CoP 6	Agreed proposal	Action / outcome
1	Irrelevant (for administrative purposes only)	None
2(a)-(d)	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.3.1
Schedule, para.1	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.1
Schedule, para.2	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.2
Schedule, para.3	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.3
Schedule, para.4	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.4
Schedule, para.5	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.5
Schedule, para.6	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.6
Schedule, para.7	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.7
Schedule, para.8	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.8
Schedule, para.9	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.9
Schedule, para.10	To be included in revised guidance on witnessing clinical and laboratory procedures	Now at 13.2.10
Part 16 – Intra-cytoplasmic sperm injection (ICSI)		
Preamble (p.131)	Superfluous explanation -- omit	None
Definitions (pp.131-2)	Consolidate definitions in guidance on usage and interpretation of terms	To be incorporated into glossary
16.1(i)	Covered in standard licence condition 7(c) and guidance on procurement, processing and storage of gametes and embryos	Now at 9.5.1
16.1(ii)	Covered in standard licence condition 7(d) and guidance on procurement, processing and storage of gametes and embryos	Now at 9.5.2
16.1(iii)	CE (97) 04 superseded by CH (04) 06 and then by CH (06) 03-- this provision replaced by Annex A to that letter ('ICSI practitioners') and enforced through paras.2 and 3 of Directions D.2006/2 (replacing D.2004/5). Also covered in guidance on procurement, processing and storage of gametes and embryos.	Now at 9.10.2
16.1(iv)	CE (97) 04 contained detailed guidelines on inspection and standards for ICSI (applications for guidance, indications for clinical application, etc.) The part that corresponds to para.16.1(iv) of the CoP ('Information to be submitted by a centre in support of an initial application to perform ICSI') is essentially licensing guidance (i.e. not to do with the conduct of licensable activities) and was superseded, ultimately by Annex A of CH (06) 03, included in guidance on procurement, processing and storage of gametes and embryos. (NB Last sentence repeats definition in preamble).	Now at 9.5.3
16.2 (i)	Licensing guidance -- superseded by CH (06) 03 and D.2006/2	None
16.2(ii)	Licensing guidance -- superseded by CH (06) 03 and D.2006/2	None

CoP 6	Agreed proposal	Action / outcome
16.2(iii)	Licensing guidance -- superseded by CH (06) 03 and D.2006/2	None
16.2(iv)	Licensing guidance -- superseded by CH (06) 03 and D.2006/2	None
16.3(i)	The first sentence repeats the provision at 16.1(ii) which is superseded by CH (06) 03 -- see Annex A to that letter ('ICSI practitioners')	None
16.3 (2nd para.)	Licensing guidance -- superseded by CH (06) 03 and D.2006/2	None
16.3 (3rd para.)	Retain consistently with blastomere/polar body biopsy practitioners in section on personnel	Now at 1.5.2
16.4(i)	Repeats provision at 16.1(i) which is already covered in standard licence condition 7(c) and guidance on procurement, processing and storage of gametes and embryos	Now at 9.5.1
16.4(ii)	Covered by standard licence condition 7(a) but should be included in guidance on use of gametes and embryos in treatment	Reflected at 8.4.1
16.4(iii)	Covered by standard licence condition 7(a). However recording circumstances in patient notes should be included in guidance rather than as a licence condition and recording for notification to the Authority should be covered by Directions rather than licence condition (i.e. by amendment to Schedule 2 ("Annual record of clinical ICSI") to Directions D.2006/2)	Reflected at 8.4.1
16.4(iv)	Covered by standard licence condition 7(b) but also to be included in guidance on procurement, processing and storage of gametes and embryos (micromanipulation section)	Now at 9.5.3
16.5	To be incorporated into guidance on procurement, processing and storage of gametes and embryos (micromanipulation section)	Now at 9.5.2
16.6	Delete as information is exhaustively included in following paragraph.	Now at 5.6.1
16.7	To be incorporated into guidance on patient information	Now at 5.6.1
Chair's letter CH (04) 06 on changes in procedure for recognising ICSI etc. practitioners		
Annex A ('ICSI practitioners')	Retain consistently with blastomere/polar body biopsy practitioners in section on personnel	Now at 1.5.2
Chair's letter CH (06) 03 on recognition of ICSI / biopsy practitioners		
	Incorporate in licensing inspection process – link applicable standards to relevant Directions	To be covered in guidance on licensing/inspection