

**Table 1 - Sections of Annex 2 where Annex 1 is referenced.**

<b>Annex 2 Section (line)</b>	<b>Current cross-reference to Annex 1 (to be deleted)</b>	<b>Proposed action:</b>
<b>INTRODUCTION</b>		
Line 17	Annex 1	Delete reference
Line 34	Annex 1	Refer to Principles 6, 7 and 9
<b>INVESTIGATOR</b>		
2.1 Communication with the IRB/IEC (line 48)	Annex 1, section 1.1	Refer to Principle 3.1
2.2 Informed Consent Considerations (line 53)	Annex 1, section 2.8	Refer to Principle 2.2
2.3 Investigational Product Management (line 81)	Annex 1, section 2.10	Delete reference
2.5 Safety Assessment and Reporting (line 127) (line 130)	Annex 1, section 2.7 Annex 1, section 3.13.2	Refer to Principle 1.2 Delete reference
<b>SPONSOR</b>		
3.2 Protocol and Trial Design (line 161 and 169) (line 177)	Annex 1, Appendix B Annex 1, section 2.3.2	Refer to Principle 8.3 Refer to Principle 5.1
3.3 Communication with the IRB/IEC (line 192)	Annex 1, section 1.1	Refer to Principles 3.1 and 8.3
3.5 Data Considerations (line 250)	Annex 1, section 4.3.3	Refer to Principles 1.6 and 9.3-9.6
3.6 Investigational Product Management (line 257)	Annex 1, section 3.15.3	Delete reference
3.8 Sponsor Oversight (line 295)	Annex 1, section 3.9 Annex 1, section 3.10 Annex 1, section 3.11 Annex 1, Appendix C	Refer to Principle 10