Source Criteria	Addressed in SOP:	Additional Guidance
International Council on Harmonisation Good Clinical Practice Guidelines		
3.1.1	101	
3.1.2	301 402 403 404 701 801	REBs are advised to have supporting material documenting compliance (e.g. application forms and documentation outlining the requirement material, in accordance with this element).
3.1.3	801	
3.1.4	402 403 405	
3.1.5	101 701	
3.1.6	403 701	
3.1.7	403 701	
3.1.8	403	
3.1.9	701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
3.2.1	105A 201 202	
3.2.2	302 All	REBs are advised to have supporting materials documenting compliance (e.g. documenting compliance with written SOPs)
3.2.3	Glossary of Terms 302	
3.2.4	302	
3.2.5	201 302	
3.2.6	201	
3.3.1	101 201	
3.3.2	302	
3.3.3	402 403 405	
3.3.4	402 403 405	

3.3.5	401	
3.3.6	102	
3.3.7	404	
3.3.8	404	

Source Criteria	Addressed in SOP:	Additional Guidance
3.3.9	402 407 601	
3.4	303	
Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2)		
1.1	101	
2.1	102	
2.2	102	
2.3	102	
2.4	102	
2.5	102	
2.6	102	
2.7	403	
2.8	405	
2.9	401 403 404 405	
2.10	403	
2.11	403	
3.1	403 701	
3.2	403 701	
3.3	701	
3.4	403 701	
3.5	403 701	
3.6		Outside of the scope of the SOPs
3.7	403 701	
3.8	403 701	
3.9	403 702	

3.10.	403 703	
3.11	701	
3.12	403, 701	
4.1	403	
4.2	403	
4.3	403	
4.4	403	

Source Criteria	Addressed in SOP:	Additional Guidance
4.5	403	
4.6	403	This SOP does not repeat the specific list outlined in TCPS2. These criteria have been grouped under a broader heading. REBs are expected to consider all applicable aspects as part of their deliberations.
4.7	403	
4.8	403	
5.1		Outside of the scope of the SOPs (describes researcher/organizational responsibility). REB aspects are addressed in SOPs as outlined in this table.
5.2	107 403 701	
5.3	107 403	
5.4		Outside of the scope of the SOPs (describes researcher/organizational responsibility). REB aspects are addressed in SOPs as outlined in this table.
5.5	403 701	
5.6	701	
5.7	102 301 403	This SOP does not repeat the specific list outlined in TCPS2. These criteria have been grouped under a broader heading. REBs are expected to consider all applicable aspects as part of their deliberations.
6.1	101	
6.2	101	Aspects of this element are the responsibility of the institution and are outside the scope of this set of SOPs. REBs are advised to have supporting material documenting compliance (e.g. describing the reporting requirements to the highest body within an institution, etc.).
6.3	101 404	
6.4	201	REBs are advised to have supporting materials documenting compliance (e.g. REB membership list addressing these requ irements).
6.5	201	

6.6	202	
6.7	103 201 202 203	
6.8	203	
6.9	Glossary of Terms 201 302	
6.10.	302	
6.11	102	

Source Criteria	Addressed in SOP:	Additional Guidance
6.12	401 403 404 405	
6.13	105A 601	
6.14	405	
6.15	404 801	
6.16	404 801	
6.17	302 303 402	
6.18	402	
6.19	402	
6.20.	402	
6.21	501	
6.22	501	
6.23	501	
6.24		Outside of the scope of the SOPs (describes organizational responsibility).
7.1	105A-C	
7.2	105B-C	
7.3	105A	
7.4	105B 801	
8.1-8.4		Outside of the scope of the SOPs (describes organizational responsibility).
9.1-9.22	403	This SOP does not repeat the specific criteria outlined in TCPS2. These criteria have been grouped under a broader heading. REBs are expected to consider all applicable aspects as part of their deliberations.
10.1	102	

10.2	301	
10.3	403 701	
10.4	107 403 701	
10.5	301	
11.1	403	
11.2	403	
11.3	403	
11.4	403	
11.5	403	

Source Criteria	Addressed in SOP:	Additional Guidance
11.6	403 701	
11.7	301 403	
11.8	404 407 701	
11.9	404	
11.10.	105A-C 403	
11.11	105B 403	
11.12	403	
12.1	102 701	
12.2	701	
12.3	701	
12.4	701	
12.5		Outside of the scope of the SOPs (describes researcher/organizational responsibility).
12.6	403	
United States Code of Federal Regulations		
45 CFR 46.107(a) 21 CFR 56.107(a)	201	
45 CFR 46.107(b) 21 CFR 56.107(b)	201	
45 CFR 46.107(c) 21 CFR 56.107(c)	201	

45 CFR 46.107(d) 21 CFR 56.107(d)	201	
45 CFR 46.107(e) 21 CFR 56.107(e)	105A	
45 CFR 46.107(f) 21 CFR 56.107(f)	201	
45 CFR 46.108(a)/ 45 CFR 46.103(b)(3) 21 CFR 56.115(a)(5)	202	
45 CFR 46.108(a)/ 45 CFR 46.103(b)(4) 21 CFR 56.115(a)(6)/ 21 CFR 56.108(a)	403 404 405 601	
45 CFR 46.108(a)/ 45 CFR 46.103(b)(5) 21 CFR 56.115(a)(6)/ 21 CFR 56.108(b)	404 407 903	
45 CFR 46.108(b) 21 CFR 56.108(c)	Glossary of Terms 302 401	

Source Criteria	Addressed in SOP:	Additional Guidance
45 CFR 46.109(a) 21 CFR 56.109(a)	402	
45 CFR 46.109(b) 21 CFR 56.109(b)	701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
45 CFR 46.109(c) 21 CFR 56.109(c)	701	
45 CFR 46.109(d) 21 CFR 56.109(e)	402 601	
45 CFR 46.109(e) 21 CFR 56.109(f)	405	
45 CFR 46.110(b) 21 CFR 56.110(b)	401	
45 CFR 46.110(c) 21 CFR 56.110(c)	401 302	
45 CFR 46.110(d) 21 CFR 56.110(d)		Outside of the scope of the SOPs (describes Regulatory Authority responsibility).
45 CFR 46.111(a)(1) 21 CFR 56.111(a)(1)	403	
45 CFR 46.111(a)(2) 21 CFR 56.111(a)(2)	403	
45 CFR 46.111(a)(3) 21 CFR 56.111(a)(3)	403	
45 CFR 46.111(a)(4) 21 CFR 56.111(a)(4)	403 701	

45 CFR 46.111(a)(5) 21 CFR 56.111(a)(5)	403 701	
45 CFR 46.111(a)(6) 21 CFR 56.111(a)(6)	403	
45 CFR 46.111(a)(7) 21 CFR 56.111(a)(7)	403	
45 CFR 46.111(b) 21 CFR 56.111(b)	403	
45 CFR 46.112 21 CFR 56.112		Outside of the scope of the SOPs (describes organizational responsibility).
45 CFR 46.113 21 CFR 56.113	407	
45 CFR 46.114 21 CFR 56.114		Outside of the scope of the SOPs (describes organizational responsibility).
45 CFR 46.115(a)(1) 21 CFR 56.115(a)(1)	303	
45 CFR 46.115(a)(2) 21 CFR 56.115(a)(2)	302 303	
45 CFR 46.115(a)(3) 21 CFR 56.115(a)(3)	303	
45 CFR 46.115(a)(4) 21 CFR 56.115(a)(4)	303	
45 CFR 46.115(a)(5) 21 CFR 56.115(a)(5)	202 303	
Source Criteria	**Addressed in SOP:**	**Additional Guidance**
45 CFR 46.115(a)(6) 21 CFR 56.115(a)(6)	403 404 405 407 601 903	
45 CFR 46.115(a)(7) 21 CFR 56.115(a)(7)	701	
45 CFR 46.115(b) 21 CFR 56.115(b)	303 902	
45 CFR 46.116(a) 21 CFR 50.25(a)	701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
45 CFR 46.116(b) 21 CFR 50.25(b)	701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
45 CFR 46.116(c)	701	
45 CFR 46.116(d)	701	
45 CFR 46.117(a) 21 CFR 50.27(a)	701	
45 CFR 46.117(b) 21 CFR 50.27(b)	701	

45 CFR 46.117(c)	701	
45 CFR 46 Subpart B, C, D 21 CFR 50 Subpart D	101 403 701	
21 CFR 56.109(d)	701	
21 CFR 56.109(h)	403	
21 CFR 50.25(c)	701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
21 CFR 50.25(d) and (e)		Outside the scope of these SOPs.
21 CFR 50.20	701	
21 CFR 56.23(a)	701	