



Note	Source Criteria	Addressed in	Additional Guidance
International Council on Harmonisation Good Clinical Practice Guidelines			Additional Caldange
3.1.1 101 3.1.2 301 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 3.1.6 403 701 701 3.1.8 403 3.1.9 701 3.2.1 105A 201 202 3.2.2 302 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 3.2.2 302 REBs are advised to have supporting materials documenting compliance (e.g. documenting compliance with written SOPs) 3.2.3 Glossary of Terms 302 3.2.4 302 302 3.2.5 201 3.3.1 101 201 3.3.2 3.3.2 302 3.3.3 402 403 403 403 403 403 403 403 403 3.3.4 402 403 403 403 403 403 403 403 403 <th>International Cour</th> <th></th> <th>on Good Clinical Practice Guidelines</th>	International Cour		on Good Clinical Practice Guidelines
402			
402	3.1.2	301	REBs are advised to have supporting material documenting
A03			
701 801		403	
801		404	
3.1.3 801 3.1.4 402			
3.1.4			
403 405			
A05	3.1.4		
3.1.5 101 701 3.1.6 403 701 3.1.7 403 701 3.1.8 403 3.1.9 701 3.2.1 105A 201 202 3.2.2 302 All compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 3.2.3 Glossary of Terms 302 3.2.4 302 Ompliance (e.g. documenting compliance with written SOPs) 3.2.5 201 302 302 3.2.6 201 302 302 3.3.1 101 201 302 3.3.2 302 302 302 3.3.3 402 403 405 405 405 405 405 405 405 405 405 405			
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701 403 701 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	216		
3.1.7 403	3.1.6		
701	3 1 7		
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 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 3.2.6 201 302 3.3.1 101 201 3.3.2 302 3.3.3 402 403 405 405 405 405 3.3.4 402 403 405 405 405 405 3.3.5 401 3.3.6 102 3.3.7 404	5.1.7		
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Compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 3.2.1			REBs are advised to have supporting materials documenting
template consent addressing these criteria). 3.2.1 105A 201 202 3.2.2 302 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 3.3.1 101 201 3.3.2 302 3.3.3 402 403 405 405 3.3.4 402 403 405 3.3.5 401 3.3.6 102 3.3.7 404	3.1.3	701	
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 3.3.3 402 403 405 405 403 405 3.3.4 402 403 405 405 3.3.5 401 404			
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 302 302 3.2.4 302 302 3.2.5 201 302 302 3.3.1 101 201 302 3.3.2 302 302 3.3.3 402 403 405 403 405 3.3.5 401 402 3.3.6 102 3.3.7	3.2.1	105A	,
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 3.3.1 101 201 201 201 3.3.2 302 3.3.3 402 403 405 405 3.3.4 402 403 405 405 3.3.5 401 3.3.6 102 3.3.7 404		201	
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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	3.2.2		
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3.2.4 302 302 302 302 302 302 303.1 101 201 303.2 303 303 303 303 303 303 303 303 303 30	3.2.3	Glossary of Terms	
3.2.5 201 302 3.2.6 201 3.3.1 101 201 3.3.2 302 3.3.3 402 403 405 3.3.5 401 3.3.5 401 3.3.6 102 3.3.7 404		302	
302 3.2.6 201 3.3.1 101 201 3.3.2 302 3.3.3 402 403 405 405 405 405 405 405 405 405 405 405	3.2.4	302	
302 3.2.6 201 3.3.1 101 201 3.3.2 302 3.3.3 402 403 405 405 405 405 405 405 405 405 405 405	3.2.5	201	
3.2.6 201 3.3.1 101 201 201 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	5.2.5		
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3.3.3 402 403 405 3.3.4 402 403 405 3.3.5 401 3.3.6 102 3.3.7 404			
403 405 3.3.4 402 403 405 3.3.5 401 3.3.6 102 3.3.7 404	3.3.2	302	
403 405 3.3.4 402 403 405 3.3.5 401 3.3.6 102 3.3.7 404	3.3.3	402	
3.3.4 402 403 405 3.3.5 401 3.3.6 102 3.3.7 404			
403 405 3.3.5 401 3.3.6 102 3.3.7 404			
405 3.3.5 401 3.3.6 102 3.3.7 404	3.3.4		
3.3.5 401 3.3.6 102 3.3.7 404			
3.3.6 102 3.3.7 404	2.25		
3.3.7 404			
	3.3.6	102	
2.2.9. 404	3.3.7	404	
3.3.0 404	3.3.8	404	





Source Criteria	Addressed in SOP:	Additional Guidance
3.3.9	402	
	407	
	601	
3.4	303	
Tri-Council Policy S	Statement: Ethical Co	onduct 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	
3.8	701 403	
3.0	701	
3.9	403	
	702	
3.10.	403	
3.11	703	
	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	demonstrations
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 requirements).
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	
6.13	405 105A	
0.13	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	301	Outside of the seems of the CODE (describes a green in this red
0.24		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	deliberations.
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	Additional Guidance
	SOP:	
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
12.5		researcher/organizational responsibility).
12.6	403	, , , , , , , , , , , , , , , , , , , ,
United States Code	of Federal Regulati	ons
45 CFR 46.107(a)	201	
21 CFR 56.107(a)	201	
45 CFR 46.107(b)	201	
21 CFR 56.107(b)	201	
45 CFR 46.107(c)	201	
21 CFR 56.107(c)	201	
45 CFR 46.107(d)	201	
21 CFR 56.107(d)		
45 CFR 46.107(e)	105A	
21 CFR 56.107(e)		
45 CFR 46.107(f)	201	
21 CFR 56.107(f)		
45 CFR 46.108(a)/	202	
45 CFR 46.103(b)(3)		
21 CFR 56.115(a)(5)		
45 CFR 46.108(a)/	403	
45 CFR 46.103(b)(4)	404	
21 CFR 56.115(a)(6)/	405	
21 CFR 56.108(a)	601	
45 CFR 46.108(a)/	404	
45 CFR 46.103(b)(5)	407	
21 CFR 56.115(a)(6)/	903	
21 CFR 56.108(b)		
45 CFR 46.108(b)	Glossary of Terms	
21 CFR 56.108(c)	302	
	401	





Source Criteria	Addressed in	Additional Guidance
	SOP:	
45 CFR 46.109(a)	402	
21 CFR 56.109(a)		
45 CFR 46.109(b)	701	REBs are advised to have supporting materials documenting
21 CFR 56.109(b)		compliance (e.g. an Informed Consent requirements checklist or
		template consent addressing these criteria).
45 CFR 46.109(c)	701	
21 CFR 56.109(c)		
45 CFR 46.109(d)	402	
21 CFR 56.109(e)	601	
45 CFR 46.109(e)	405	
21 CFR 56.109(f)		
45 CFR 46.110(b)	401	
21 CFR 56.110(b)		
45 CFR 46.110(c)	401	
21 CFR 56.110(c)	302	
45 CFR 46.110(d)		Outside of the scope of the SOPs (describes Regulatory Authority
21 CFR 56.110(d)		responsibility).
45 CFR 46.111(a)(1)	403	
21 CFR 56.111(a)(1)	1.00	
45 CFR 46.111(a)(2)	403	
21 CFR 56.111(a)(2)	103	
45 CFR 46.111(a)(3)	403	
21 CFR 56.111(a)(3)	103	
45 CFR 46.111(a)(4)	403	
21 CFR 56.111(a)(4)	701	
45 CFR 46.111(a)(5)	403	
21 CFR 56.111(a)(5)	701	
45 CFR 46.111(a)(6)	403	
21 CFR 56.111(a)(6)	103	
45 CFR 46.111(a)(7)	403	
21 CFR 56.111(a)(7)	103	
45 CFR 46.111(b)	403	
21 CFR 56.111(b)	103	
45 CFR 46.112		Outside of the scope of the SOPs (describes organizational
21 CFR 56.112		responsibility).
45 CFR 46.113	407	responsibility).
21 CFR 56.113	107	
45 CFR 46.114		Outside of the scope of the SOPs (describes organizational
21 CFR 56.114		responsibility).
45 CFR 46.115(a)(1)	303	responsibility).
21 CFR 56.115(a)(1)	303	
45 CFR 46.115(a)(2)	302	
21 CFR 56.115(a)(2)	303	
45 CFR 46.115(a)(3)	303	
21 CFR 56.115(a)(3)	303	
	202	
45 CFR 46.115(a)(4)	303	
21 CFR 56.115(a)(4)	202	
45 CFR 46.115(a)(5)		
21 CFR 56.115(a)(5)	303	





Source Criteria	Addressed in	Additional Guidance
	SOP:	
45 CFR 46.115(a)(6)	403	
21 CFR 56.115(a)(6)	404	
	405	
	407	
	601	
	903	
45 CFR 46.115(a)(7)	701	
21 CFR 56.115(a)(7)		
45 CFR 46.115(b)	303	
21 CFR 56.115(b)	902	
45 CFR 46.116(a)	701	REBs are advised to have supporting materials documenting
21 CFR 50.25(a)		compliance (e.g. an Informed Consent requirements checklist or
		template consent addressing these criteria).
45 CFR 46.116(b)	701	REBs are advised to have supporting materials documenting
21 CFR 50.25(b)		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)	701	
21 CFR 50.27(a)		
45 CFR 46.117(b)	701	
21 CFR 50.27(b)		
45 CFR 46.117(c)	701	
45 CFR 46 Subpart B,	101	
C, D	403	
21 CFR 50 Subpart D	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		Outside the scope of these SOPs.
(e)		
21 CFR 50.20	701	
21 CFR 56.23(a)	701	