



Source Criteria	Addressed in	Additional Guidance
	SOP:	
International Coun	cil on Harmonisati	on Good Clinical Practice Guidelines
3.1.1	101	
3.1.2	301	REBs are advised to have supporting material documenting
	402	compliance (e.g. application forms and documentation outlining the
	403	requirement material, in accordance with this element).
	404	
	701	
3.1.3	801 801	
3.1.4	402	
	403 405	
3.1.5	101	
3.1.3	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	REBs are advised to have supporting materials documenting
3.2.2	All	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 S	tatement: 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	
3.5	701 403	
3.5	701	
3.6	701	Outside of the scope of the SOPs
3.7	403	·
	701	
3.8	403	
	701	
3.9	403	
2.10	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	deliberations
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	
6.13	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		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	Reviewed; no changes needed.
11.7	301 403	Reviewed; no changes needed.
11.8	404 407	Reviewed; no changes needed.
	701	
11.9	404	Reviewed; no changes needed.
11.10.	403	TCPS2 Article 11.10 pertains to clinical trial registries. SOPs 105A, 105B and 105C pertain to Conflict of Interest and are silent on clinical trial registration. 403 is good as is.
11.11		TCPS2 Article 11.11 pertains to researcher responsibility to update the clinical trials registry entry in a timely manner. Both 105B and 403 are silent on this. I did not find reference to clinical trial registration in another SOP. No Article 11.12 in the 2022 version.
12.1	102 701	Article 12.1 does not speak to waiver of consent conditions, only that consent is required, whereas 701 describes waiver of consent.
12.2		Article 12.2 describes the additional information researchers must provide to participants (on top of Article 3.2 requirements) when seeking consent for use of human biological materials. SOP 701 does not specifically address this. I did not see it in another SOP.
12.3A and 12.3B	701	Reviewed, no changes needed.
12.4	701	Article 12.4 describes researchers' need to have an REB-approved plan for contacting participants for <i>additional</i> biological materials (or other reasons). SOP does not specifically speak to this very specific scenario, but does contain a detailed Recruitment section.
12.5		Outside of the scope of the SOPs (describes researcher/organizational responsibility).
12.6	403	Reviewed; no changes needed.
United States Code	e of Federal Regulat	ions
45 CFR 46.107(a) 21 CFR 56.107(a)	201	Reviewed; no changes required.
21 CFR 56.107(b)	201	Reviewed; no changes required.
45 CFR 46.107(b) 21 CFR 56.107(c)	201	Reviewed; no changes required.
45 CFR 46.107(c) 21 CFR 56.107(d)	201	These sections describe the Community (non-affiliated) member. 45CFR46 and 21CFR56 do not match up exactly with each other.
45 CFR 46.107(d)	105A	These sections describe REB member conflict of interest. 45CFR45
21 CFR 56.107(e) 45 CFR 46.107(e)	201	and 21CFR56 do not match up exactly with each other. Reviewed; no changes required.
21 CFR 56.107(f) 45 CFR 46.108(a)(2)/	202	No section 103(b)(3) in the revised 45CFR46.
21 CFR 56.115(a)(5)		
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Source Criteria	Addressed in	Additional Guidance
	SOP:	
45 CFR 46.108(a)(3)/	403	45CFR45.108 (a) and 103(b) do not correspond to each other.
	404	
21 CFR 56.115(a)(6)/	405	21CFR56.115(a)(6) correspond to SOP 302.
21 CFR 56.108(a)	601	
		21CFR56.108(a) corresponds to SOP 101.
45 CFR 46.108(a)(4)/	404	There is no longer a subsection 5 in 45CFR46.103(b).
	407	45CFR46.108a is compared above.
21 CFR 56.115(a)(6)/	903	21CFR56.108 is compared above.
21 CFR 56.108(b)		
45 CFR 46.108(b)		Note: the Glossary of Terms corresponds to 45CFR46.102 and
21 CFR 56.108(c)	302	21CFR56.102.
	401	
		Original page 5 ended with 'Glossary of Terms'. This copy ran over
		into page 6 because of added notes.
45 CFR 46.109(a)	402	
21 CFR 56.109(a)	402	
45 CFR 46.109(b)	701	REBs are advised to have supporting materials documenting
21 CFR 56.109(b)	701	compliance (e.g. an Informed Consent requirements checklist or
21 (11 30.103(8)		template consent addressing these criteria).
45 CFR 46.109(c)	701	template consent addressing these enterial.
21 CFR 56.109(c)	701	
45 CFR 46.109(d)	402	
21 CFR 56.109(e)	601	
45 CFR 46.109(e)	405	
21 CFR 56.109(f)	403	
45 CFR 46.110(b)	401	
21 CFR 56.110(b)	401	
45 CFR 46.110(c)	401	
21 CFR 56.110(c)	302	
45 CFR 46.110(d)	302	Outside of the scope of the SOPs (describes Regulatory Authority
21 CFR 56.110(d)		responsibility).
45 CFR 46.111(a)(1)	403	responsibility).
21 CFR 56.111(a)(1)	100	
45 CFR 46.111(a)(2)	403	
21 CFR 56.111(a)(2)		
45 CFR 46.111(a)(3)	403	
21 CFR 56.111(a)(3)		
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)		
45 CFR 46.111(a)(7)	403	
21 CFR 56.111(a)(7)		
45 CFR 46.111(b)	403	
21 CFR 56.111(b)		
45 CFR 46.112		Outside of the scope of the SOPs (describes organizational
21 CFR 56.112		responsibility).





45 CFR 46.113	Source Criteria	Addressed in SOP:	Additional Guidance
21 CFR 56.114	45 CFR 46 113		
45 CFR 46.114		407	
21 CFR 56.115(a)(1) 303 303 303 303 304 305			Outside of the scope of the SOPs (describes organizational
45 CFR 46.115(a)(1) 303 21 CFR 56.115(a)(2) 302 303 30			· · · · · · · · · · · · · · · · · · ·
21 CFR 56.115(a)(1) 45 CFR 46.115(a)(2) 302 21 CFR 56.115(a)(2) 303 303 21 CFR 56.115(a)(3) 303 21 CFR 56.115(a)(3) 303 21 CFR 56.115(a)(4) 303 303 21 CFR 56.115(a)(4) 303		303	responsibility).
45 CFR 46.115(a)(2) 302 21 CFR 56.115(a)(2) 303 303 45 CFR 46.115(a)(3) 303 45 CFR 46.115(a)(3) 303 45 CFR 46.115(a)(4) 303 45 CFR 46.115(a)(5) 202 21 CFR 56.115(a)(6) 403 45 CFR 46.115(a)(6) 404 405 407 601 903 45 CFR 46.115(a)(7) 701 21 CFR 56.115(a)(8) 812 CFR 56.115(a)(8) 821 CFR 56.115(a)(6) 902 45 CFR 46.115(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) 82 CFR 46.116(c) 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 82 CFR 46.116(c) 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 82 CFR 46.116(c) 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). 701 REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).		303	
21 CFR 56.115(a)(2) 303		302	
45 CFR 46.115(a)(3) 303 21 CFR 56.115(a)(4) 405 407 601 903 405 407 601 903 405 CFR 46.115(a)(4) 405 CFR 46.115(a)(5) 407 601 903 405 CFR 46.115(a)(7) 45 CFR 46.115(a)(8) 902 45 CFR 46.115(a) 902 46 CFR 46.115(a) 902 47 CFR 56.115(a) 902 48 CFR 46.116(a) 902 47 CFR 56.115(a) 902 48 CFR 46.116(a) 902 47 CFR 56.115(a) 902 48 CFR 46.116(a) 902 48 CFR 46.116(b) 902 49 CFR 50.25(b) 902 902 902 902 902 902 902 902 902 902			
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45 CFR 46.115(a)(4) 40	` ', '	303	
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45 CFR 46.115(a)(5) 202 303 303 45 CFR 46.115(a)(6) 404 405 407 601 903 45 CFR 46.115(a)(7) 701 21 CFR 56.115(a)(8) 407 45 CFR 46.115(b) 408 407 408 408 409			
21 CFR 56.115(a)(5) 303 403 404 405 407 601 903 405 407 601 903 405 407 407 405 407		202	
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45 CFR 46 Subpart B, 101 In SOP 701, S. 5.10.3, add the reference to 21 CFR 50 Subpart D	, ,		In SOP 701 S 5 10 3 add the reference to 21 CEP EO Subpart D
C, D 403	•		in 301 701, 3. 3.10.3, and the reference to 21 CFR 30 Subpart D
21 CFR 50 Subpart D 701			





Source Criteria	Addressed in	Additional Guidance
	SOP:	
21 CFR 56.109(d)	701	21 CFR 56.109(d) states: "In cases where the documentation requirement is waived under paragraph(c)(1) of this section, the IRB may require the investigator to provide subjects with a written statement regarding the research."
21 CFR 56.109(h)	403 701	The second secon
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	