Table of Concordance

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	

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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	

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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 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	

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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	

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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	404 407 701	Reviewed; no changes needed.
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 ***additional*** 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 of Federal Regulations		
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) 21 CFR 56.107(e)	105A	These sections describe REB member conflict of interest. 45CFR45 and 21CFR56 do not match up exactly with each other.
45 CFR 46.107(e) 21 CFR 56.107(f)	201	Reviewed; no changes required.
45 CFR 46.108(a)(2)/ 21 CFR 56.115(a)(5)	202	No section 103(b)(3) in the revised 45CFR46.
		(blank row inserted to keep the contents of the next row on the same page)

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Source Criteria	Addressed in SOP:	Additional Guidance
45 CFR 46.108(a)(3)/ 21 CFR 56.115(a)(6)/ 21 CFR 56.108(a)	403 404 405 601	45CFR45.108 (a) and 103(b) do not correspond to each other. 21CFR56.115(a)(6) correspond to SOP 302. 21CFR56.108(a) corresponds to SOP 101.
45 CFR 46.108(a)(4)/ 21 CFR 56.115(a)(6)/ 21 CFR 56.108(b)	404 407 903	There is no longer a subsection 5 in 45CFR46.103(b). 45CFR46.108a is compared above. 21CFR56.108 is compared above.
45 CFR 46.108(b) 21 CFR 56.108(c)	302 401	Note: the Glossary of Terms corresponds to 45CFR46.102 and 21CFR56.102.
		Original page 5 ended with 'Glossary of Terms'. This copy ran over into page 6 because of added notes.
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).

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Source Criteria	Addressed in SOP:	Additional Guidance
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	
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(a)(8)		IRB documentation to include: "The rationale for an expiated reviewer's determination …that research … is more than minimal"
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	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria). The Cancer Committee template ICF addresses these criteria.
45 CFR 46.116(d)	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(e)	701	
45 CFR 46.116(f)	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	In SOP 701, S. 5.10.3, add the reference to 21 CFR 50 Subpart D

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Source Criteria	Addressed in SOP:	Additional Guidance
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	
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	