

Source Criteria	Addressed in SOP:	Additional Guidance
CGSB		
4.2.2.1	101	Aspects of this element are operational, and are institution/REB specific. Institutions/REBs are advised to have supporting materials documenting compliance.
4.2.2.2	105C 203	Aspects of this element are the responsibility of the institution and are outside the scope of this set of SOPs. Institutions/REBs are advised to have supporting materials documenting compliance.
4.2.2.3		Permission outside the scope of the SOPs.
4.2.2.4	202	Aspects of this element are the responsibility of the institution and are outside the scope of this set of SOPs. Institutions/REBs are advised to have supporting materials (e.g., terms of reference, performance evaluation procedures) documenting compliance.
4.2.2.5	105A-C 101 402 403	
4.2.2.6	105A-C	
4.2.3.1	801	
4.2.3.2	402 407	
4.2.3.3	101	
4.2.3.4	404 407 903	
4.2.4.1		Requirement outside of the scope of the SOP (organizational requirement to provide necessary resources).
4.2.4.2	103 203	
4.3.1.1	201	
4.3.2.1	201	
4.3.2.2	201	
4.3.2.3	201	
4.3.2.4	201	
4.3.2.5		Aspects may be REB-specific. The exact size and composition of the REB is determined by the amount and range of research they review. Institutions/REBs are advised to have supporting materials (e.g., REB membership list reflecting the requirements) documenting compliance.
4.3.2.6	201	
4.3.2.7	103	
4.3.2.8	105A 103	

Source Criteria	Addressed in SOP:	Additional Guidance
4.3.2.9	105A	
4.3.3.1	201	Aspects of this element are suggested, and additionally include institutional requirements. Institutions/REBs are advised to have supporting materials documenting compliance with the mandatory component (established knowledge criteria), and are encouraged to comply with the suggested components.
4.3.3.2	203	
4.3.3.3	203	Aspects are outside of the scope of the SOP (organizational requirement to provide necessary resources).
4.3.3.4	203	
4.3.4.1	103	Aspects are outside of the scope of the SOP (organizational requirement to provide necessary resources).
4.3.4.2	104 204	Institutions/REBs are advised to have supporting materials (e.g., job descriptions) documenting compliance. SOP 204 may not be applicable to all REBs (e.g., if the REB does not appoint REB administrative staff to serve on the REB).
4.3.4.3	104	SOP 204 may not be applicable to all REBs (e.g., if the REB does not appoint REB administrative staff to serve on the REB).
4.3.4.4	204	SOP 204 may not be applicable to all REBs (e.g., if the REB does not appoint REB administrative staff to serve on the REB).
4.3.4.5	204	SOP 204 may not be applicable to all REBs (e.g., if the REB does not appoint REB administrative staff to serve on the REB)
4.3.4.6	204	SOP 204 may not be applicable to all REBs (e.g., if the REB does not appoint REB administrative staff to serve on the REB)
4.3.4.7	105A	
4.4.1.1	All	
4.4.1.2	402	
4.4.2.1	501	
4.4.2.2	501	
4.4.2.3	501	
4.4.2.4	501	
4.4.3.1	301 402 601	REBs are advised to have supporting materials (e.g. template application forms, published deadlines, REB letter templates) documenting compliance with this element.
4.4.3.2	301 105	REBs are advised to have supporting materials (e.g. template application forms and attachment requirements) documenting compliance with this element.
4.4.3.3	403	
4.4.3.4	301	
4.4.4.1.1	401 403 404 405	
4.4.4.2.1	403	

Source Criteria	Addressed in SOP:	Additional Guidance
4.4.4.2.2	403 501	The SOP does not repeat the list outlined in the CGSB document. Some criteria have been grouped under a broader heading. REBs are expected to consider all applicable aspects as part of their deliberations.
4.4.4.2.3	403	
4.4.4.2.4	403 501	
4.4.4.2.5	403	
4.4.4.2.6	403	
4.4.4.2.7	403	
4.4.4.2.8	403 701	
4.4.4.2.9	403 701	REBs are advised to have supporting materials documenting compliance (e.g. an Informed Consent requirements checklist or template consent addressing these criteria).
4.4.4.2.10	403 701	
4.4.4.2.11	403	
4.4.4.2.12	403	
4.4.4.2.13	403 701	
4.4.4.2.14	403	
4.4.4.2.15	403 701	
4.4.4.2.16	403 701	These SOPs do not repeat the specific list outlined in the CGSB document. Some criteria have been grouped under a broader heading. REBs are expected to consider all applicable aspects as part of their deliberations.
4.4.4.3.1	401 402	
4.4.4.3.2	401	
4.4.4.4.1	302	REBs are advised to have supporting materials documenting compliance (e.g. a published schedule of meeting dates with submission deadlines).
4.4.4.4.2	301 302	
4.4.4.4.3	302	
4.4.4.4.4	Glossary of Terms 201 302	
4.4.4.4.5	302 402	
4.4.4.4.6	201 302	
4.4.4.4.7	302 402	
4.4.4.4.8	201 302	

Source Criteria	Addressed in SOP:	Additional Guidance
4.4.4.4.9	105A 302 402	
4.4.4.4.10	402	
4.4.4.4.11	401 402	
4.4.4.4.12	201 302	
4.4.4.5.1	401	
4.4.4.5.2	401	
4.4.4.5.3	401	
4.4.4.5.4	302 401	
4.4.5.1	601	
4.4.5.2	402 601	REBs are advised to have supporting material documenting compliance (e.g. REB template and/or letters containing information specified in this element)
4.4.5.3	402 601	REBs are advised to have supporting material documenting compliance (e.g. REB template and/or letters containing information specified in this element)
4.4.5.4	402 601	REBs are advised to have supporting material documenting compliance (e.g. REB template and/or letters containing information specified in this element)
4.4.5.5	402 601	REBs are advised to have supporting material documenting compliance (e.g. REB template and/or letters containing information specified in this element)
4.4.5.6		The SOPs document the requirement for REBs to retain such documentation, and that it may be provided upon request. REBs are encouraged to comply with all suggested components.
4.4.5.7	601 407	
4.4.6.1	404	
4.4.6.2	404	
4.4.6.2	404	
4.4.6.4	401 404	
4.4.6.5	404	
4.4.6.6	404 406 903	
4.4.6.7	404	
4.4.6.8	403 701 903	
4.4.6.9	101 301 701	
4.4.7.1	402	

Source Criteria	Addressed in SOP:	Additional Guidance
	405	
4.4.7.2	405	
4.4.7.3	405	REBs are advised to have supporting material documenting compliance (e.g. continuing review submission documentation requirements).
4.4.7.4	401 405	
4.4.7.5	401 405	
4.4.8.1	402 601	
4.4.8.2	402 601	
4.4.8.3	402 601	
4.4.9.1	406	
4.5.1.1	303	
4.5.2.1(a-p)	All	
4.5.3.1	303	
4.5.3.2	303	
4.5.3.3	302	
4.5.4	303	
International Conference 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	

Source Criteria	Addressed in SOP:	Additional Guidance
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	
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	
3.1	403 701	
3.2	403 701	

Source Criteria	Addressed in SOP:	Additional Guidance
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	
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	
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	

Source Criteria	Addressed in SOP:	Additional Guidance
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	
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	
7.1	105A-C	
7.2	105B-C	
7.3	105A	
7.4	105B 801	

Source Criteria	Addressed in SOP:	Additional Guidance
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	
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)	201	

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21 CFR 56.107(c)		
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	
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	

Source Criteria	Addressed in SOP:	Additional Guidance
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	
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

Source Criteria	Addressed in SOP:	Additional Guidance
		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	