

| Source Criteria | Addressed in SOP number | Additional Guidance |
|---|-------------------------|--|
| Canadian General Standards Board | | |
| 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 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 | |
| 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. |

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| 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 documenting compliance. |
| 4.2.2.5 | 101, 105A-C, 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 | 103, 105A | |
| 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). |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|-----------------|-------------------------|---|
| 4.3.4.3 | 104, 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). |
| 4.3.4.4 | 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 | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|-----------------|-----------------------------------|---|
| 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 | 201, 302, Glossary of Terms | |
| 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 | |
| 4.4.4.4.9 | 302, 402, 105A | |
| 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) |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|--|------------------------------|---|
| 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 | 407, 601 | |
| 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, 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 | |
| 4.4.8.3 | 402 | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|--|-------------------------|---|
| 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 | |
| 3.2.4 | 302 | |
| 3.2.5 | 201, 302 | |
| 3.2.6 | 201 | |
| 3.3.1 | 101, 102 | |
| 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 | |
| 3.3 | 701 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|-----------------|-------------------------|--|
| 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 | |
| 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, 104 | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|-----------------|-----------------------------|--|
| 6.7 | 103, 201, 202, 203 | |
| 6.8 | 203 | |
| 6.9 | 201, 302, Glossary of Terms | |
| 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 | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|--|-------------------------|--|
| 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 | |
| 5 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|--|-----------------------------------|---|
| 45 CFR 46.108(b), 21 CFR 56.108(c) | 302, 401, Glossary of Terms | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|--|------------------------------------|---|
| 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) | 302303 | |
| 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 | |

| Source Criteria | Addressed in SOP number | Additional Guidance |
|---|-------------------------|---|
| 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) &(e) | | Outside the scope of these SOPs. |
| 21 CFR 50.20 | 701 | |
| 21 CFR 56.23(a) | 701 | |