

| Source Criteria                                                                 | Addressed in SOP:                      | Additional Guidance                                                                                                                                                                 |
|---------------------------------------------------------------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>International Council on Harmonisation Good Clinical Practice Guidelines</b> |                                        |                                                                                                                                                                                     |
| 3.1.1                                                                           | 101                                    |                                                                                                                                                                                     |
| 3.1.2                                                                           | 301<br>402<br>403<br>404<br>701<br>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<br>403<br>405                      |                                                                                                                                                                                     |
| 3.1.5                                                                           | 101<br>701                             |                                                                                                                                                                                     |
| 3.1.6                                                                           | 403<br>701                             |                                                                                                                                                                                     |
| 3.1.7                                                                           | 403<br>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<br>201<br>202                     |                                                                                                                                                                                     |
| 3.2.2                                                                           | 302<br>All                             | REBs are advised to have supporting materials documenting compliance (e.g. documenting compliance with written SOPs)                                                                |
| 3.2.3                                                                           | Glossary of Terms<br>302               |                                                                                                                                                                                     |
| 3.2.4                                                                           | 302                                    |                                                                                                                                                                                     |
| 3.2.5                                                                           | 201<br>302                             |                                                                                                                                                                                     |
| 3.2.6                                                                           | 201                                    |                                                                                                                                                                                     |
| 3.3.1                                                                           | 101<br>201                             |                                                                                                                                                                                     |
| 3.3.2                                                                           | 302                                    |                                                                                                                                                                                     |
| 3.3.3                                                                           | 402<br>403<br>405                      |                                                                                                                                                                                     |
| 3.3.4                                                                           | 402<br>403<br>405                      |                                                                                                                                                                                     |
| 3.3.5                                                                           | 401                                    |                                                                                                                                                                                     |
| 3.3.6                                                                           | 102                                    |                                                                                                                                                                                     |
| 3.3.7                                                                           | 404                                    |                                                                                                                                                                                     |
| 3.3.8                                                                           | 404                                    |                                                                                                                                                                                     |

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|-------------------------------------------------------------------------------------|--------------------------|----------------------------------|
| 3.3.9                                                                               | 402<br>407<br>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<br>403<br>404<br>405 |                                  |
| 2.10                                                                                | 403                      |                                  |
| 2.11                                                                                | 403                      |                                  |
| 3.1                                                                                 | 403<br>701               |                                  |
| 3.2                                                                                 | 403<br>701               |                                  |
| 3.3                                                                                 | 701                      |                                  |
| 3.4                                                                                 | 403<br>701               |                                  |
| 3.5                                                                                 | 403<br>701               |                                  |
| 3.6                                                                                 |                          | Outside of the scope of the SOPs |
| 3.7                                                                                 | 403<br>701               |                                  |
| 3.8                                                                                 | 403<br>701               |                                  |
| 3.9                                                                                 | 403<br>702               |                                  |
| 3.10.                                                                               | 403<br>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<br>403<br>701               |                                                                                                                                                                                                                                                                                       |
| 5.3             | 107<br>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<br>701                      |                                                                                                                                                                                                                                                                                       |
| 5.6             | 701                             |                                                                                                                                                                                                                                                                                       |
| 5.7             | 102<br>301<br>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.<br>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<br>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<br>201<br>202<br>203        |                                                                                                                                                                                                                                                                                       |
| 6.8             | 203                             |                                                                                                                                                                                                                                                                                       |
| 6.9             | Glossary of Terms<br>201<br>302 |                                                                                                                                                                                                                                                                                       |
| 6.10.           | 302                             |                                                                                                                                                                                                                                                                                       |
| 6.11            | 102                             |                                                                                                                                                                                                                                                                                       |

| Source Criteria | Addressed in SOP:        | Additional Guidance                                                                                                                                                                                              |
|-----------------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6.12            | 401<br>403<br>404<br>405 |                                                                                                                                                                                                                  |
| 6.13            | 105A<br>601              |                                                                                                                                                                                                                  |
| 6.14            | 405                      |                                                                                                                                                                                                                  |
| 6.15            | 404<br>801               |                                                                                                                                                                                                                  |
| 6.16            | 404<br>801               |                                                                                                                                                                                                                  |
| 6.17            | 302<br>303<br>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<br>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<br>701               |                                                                                                                                                                                                                  |
| 10.4            | 107<br>403<br>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<br>701                      |                                                                                        |
| 11.7                                                                                 | 301<br>403                      |                                                                                        |
| 11.8                                                                                 | 404<br>407<br>701               |                                                                                        |
| 11.9                                                                                 | 404                             |                                                                                        |
| 11.10.                                                                               | 105A-C<br>403                   |                                                                                        |
| 11.11                                                                                | 105B<br>403                     |                                                                                        |
| 11.12                                                                                | 403                             |                                                                                        |
| 12.1                                                                                 | 102<br>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                             |                                                                                        |
| <b>United States Code of Federal Regulations</b>                                     |                                 |                                                                                        |
| 45 CFR 46.107(a)<br>21 CFR 56.107(a)                                                 | 201                             |                                                                                        |
| 45 CFR 46.107(b)<br>21 CFR 56.107(b)                                                 | 201                             |                                                                                        |
| 45 CFR 46.107(c)<br>21 CFR 56.107(c)                                                 | 201                             |                                                                                        |
| 45 CFR 46.107(d)<br>21 CFR 56.107(d)                                                 | 201                             |                                                                                        |
| 45 CFR 46.107(e)<br>21 CFR 56.107(e)                                                 | 105A                            |                                                                                        |
| 45 CFR 46.107(f)<br>21 CFR 56.107(f)                                                 | 201                             |                                                                                        |
| 45 CFR 46.108(a)/<br>45 CFR 46.103(b)(3)<br>21 CFR 56.115(a)(5)                      | 202                             |                                                                                        |
| 45 CFR 46.108(a)/<br>45 CFR 46.103(b)(4)<br>21 CFR 56.115(a)(6)/<br>21 CFR 56.108(a) | 403<br>404<br>405<br>601        |                                                                                        |
| 45 CFR 46.108(a)/<br>45 CFR 46.103(b)(5)<br>21 CFR 56.115(a)(6)/<br>21 CFR 56.108(b) | 404<br>407<br>903               |                                                                                        |
| 45 CFR 46.108(b)<br>21 CFR 56.108(c)                                                 | Glossary of Terms<br>302<br>401 |                                                                                        |

| Source Criteria                            | Addressed in SOP: | Additional Guidance                                                                                                                                                   |
|--------------------------------------------|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 45 CFR 46.109(a)<br>21 CFR 56.109(a)       | 402               |                                                                                                                                                                       |
| 45 CFR 46.109(b)<br>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)<br>21 CFR 56.109(c)       | 701               |                                                                                                                                                                       |
| 45 CFR 46.109(d)<br>21 CFR 56.109(e)       | 402<br>601        |                                                                                                                                                                       |
| 45 CFR 46.109(e)<br>21 CFR 56.109(f)       | 405               |                                                                                                                                                                       |
| 45 CFR 46.110(b)<br>21 CFR 56.110(b)       | 401               |                                                                                                                                                                       |
| 45 CFR 46.110(c)<br>21 CFR 56.110(c)       | 401<br>302        |                                                                                                                                                                       |
| 45 CFR 46.110(d)<br>21 CFR 56.110(d)       |                   | Outside of the scope of the SOPs (describes Regulatory Authority responsibility).                                                                                     |
| 45 CFR 46.111(a)(1)<br>21 CFR 56.111(a)(1) | 403               |                                                                                                                                                                       |
| 45 CFR 46.111(a)(2)<br>21 CFR 56.111(a)(2) | 403               |                                                                                                                                                                       |
| 45 CFR 46.111(a)(3)<br>21 CFR 56.111(a)(3) | 403               |                                                                                                                                                                       |
| 45 CFR 46.111(a)(4)<br>21 CFR 56.111(a)(4) | 403<br>701        |                                                                                                                                                                       |
| 45 CFR 46.111(a)(5)<br>21 CFR 56.111(a)(5) | 403<br>701        |                                                                                                                                                                       |
| 45 CFR 46.111(a)(6)<br>21 CFR 56.111(a)(6) | 403               |                                                                                                                                                                       |
| 45 CFR 46.111(a)(7)<br>21 CFR 56.111(a)(7) | 403               |                                                                                                                                                                       |
| 45 CFR 46.111(b)<br>21 CFR 56.111(b)       | 403               |                                                                                                                                                                       |
| 45 CFR 46.112<br>21 CFR 56.112             |                   | Outside of the scope of the SOPs (describes organizational responsibility).                                                                                           |
| 45 CFR 46.113<br>21 CFR 56.113             | 407               |                                                                                                                                                                       |
| 45 CFR 46.114<br>21 CFR 56.114             |                   | Outside of the scope of the SOPs (describes organizational responsibility).                                                                                           |
| 45 CFR 46.115(a)(1)<br>21 CFR 56.115(a)(1) | 303               |                                                                                                                                                                       |
| 45 CFR 46.115(a)(2)<br>21 CFR 56.115(a)(2) | 302<br>303        |                                                                                                                                                                       |
| 45 CFR 46.115(a)(3)<br>21 CFR 56.115(a)(3) | 303               |                                                                                                                                                                       |
| 45 CFR 46.115(a)(4)<br>21 CFR 56.115(a)(4) | 303               |                                                                                                                                                                       |
| 45 CFR 46.115(a)(5)<br>21 CFR 56.115(a)(5) | 202<br>303        |                                                                                                                                                                       |

| Source Criteria                                     | Addressed in SOP:                      | Additional Guidance                                                                                                                                                   |
|-----------------------------------------------------|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 45 CFR 46.115(a)(6)<br>21 CFR 56.115(a)(6)          | 403<br>404<br>405<br>407<br>601<br>903 |                                                                                                                                                                       |
| 45 CFR 46.115(a)(7)<br>21 CFR 56.115(a)(7)          | 701                                    |                                                                                                                                                                       |
| 45 CFR 46.115(b)<br>21 CFR 56.115(b)                | 303<br>902                             |                                                                                                                                                                       |
| 45 CFR 46.116(a)<br>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)<br>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)<br>21 CFR 50.27(a)                 | 701                                    |                                                                                                                                                                       |
| 45 CFR 46.117(b)<br>21 CFR 50.27(b)                 | 701                                    |                                                                                                                                                                       |
| 45 CFR 46.117(c)                                    | 701                                    |                                                                                                                                                                       |
| 45 CFR 46 Subpart B,<br>C, D<br>21 CFR 50 Subpart D | 101<br>403<br>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<br>(e)                          |                                        | Outside the scope of these SOPs.                                                                                                                                      |
| 21 CFR 50.20                                        | 701                                    |                                                                                                                                                                       |
| 21 CFR 56.23(a)                                     | 701                                    |                                                                                                                                                                       |