# Research Compliance and Quality Assurance Program (RCQA):
# Audit Checklist – Regulatory Files

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|---|---|
| **Protocol Title / Code:** | |
| **Sponsor:** | |
| **PI Name:** | |
| **Auditor Name:** | |
| **Audit Date(s):** | |

| **Regulatory File Organization + Other General Items** | | | | | |
|---|---|---|---|---|---|
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| Binder is organized in a logical fashion; easy to locate study documents; no loose pages. | ☐ | ☐ | ☐ | ☐ | |
| Binders are properly labeled. | ☐ | ☐ | ☐ | ☐ | |
| For documents filed centrally – memos are filed to clarify this. | ☐ | ☐ | ☐ | ☐ | |
| The study is registered on clinicaltrials.gov. * | ☐ | ☐ | ☐ | ☐ | |
| **REB Files / Correspondence** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| Initial REB application and approval filed, with all submitted and approved documents listed with correct version dates. | ☐ | ☐ | ☐ | ☐ | |
| REB applications and approvals for all amendments filed, with all submitted and approved documents listed with correct version dates. | ☐ | ☐ | ☐ | ☐ | |

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| No protocol (or amendment) implementation prior to REB approval(s). | ☐ | ☐ | ☐ | ☐ | |
| Annual REB review applications and approvals are within timeline and filed. | ☐ | ☐ | ☐ | ☐ | |
| Spot check information written in REB applications to ensure accuracy. | ☐ | ☐ | ☐ | ☐ | |
| Upon study closeout, final report submitted to REB (if required), and other REB requirements are met. | ☐ | ☐ | ☐ | ☐ | |
| REB membership lists filed for all full-board reviews. Updated membership lists are filed as required. | ☐ | ☐ | ☐ | ☐ | |
| For all full-board reviews, documentation that study team members (who also are REB members) recused themselves from voting and declared a COI. | ☐ | ☐ | ☐ | ☐ | |
| **Regulatory Files** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| All applicable CTA and CTA-As* and their corresponding NOLs are complete and filed. Note any delays. Evidence of submission is on file (e.g. Fed-Ex waybill). | ☐ | ☐ | ☐ | ☐ | |
| All applicable CTA-Ns* and corresponding acknowledgements completed and filed. | ☐ | ☐ | ☐ | ☐ | |

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| Note delays. Evidence of submission is on file (e.g. email). | | | | | |
| Health Canada QIU signed and dated prior to commencement of study, and filed. | ☐ | ☐ | ☐ | ☐ | |
| If study drug is under an IND with FDA, form 1572 is completed, signed and dated by PI prior to study commencement, and filed. Exception: PI requested to participate as a foreign clinical trial site and waiver is obtained). | ☐ | ☐ | ☐ | ☐ | |
| All COI declarations, including financial disclosures of all investigators and the institution, are signed and dated prior to study commencement, revised as required, and filed. | ☐ | ☐ | ☐ | ☐ | |
| CTSI filed and all information correct.* | ☐ | ☐ | ☐ | ☐ | |
| **Screening/Registration** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| Screening and enrollment log is filed, and there are no discrepancies with source documents. | ☐ | ☐ | ☐ | ☐ | |
| Study master list is filed and stored securely, as per requirement. | ☐ | ☐ | ☐ | ☐ | |
| Global and local accrual on par with expected recruitment target; if not, this is clarified.* | ☐ | ☐ | ☐ | ☐ | |

# Research Compliance and Quality Assurance Program (RCQA):
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| **Delegation/Training Documentation** | | | | | |
|---|---|---|---|---|---|
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| SIV agenda, attendance, and slides are filed. | ☐ | ☐ | ☐ | ☐ | |
| All study tasks are included on the delegation log. | ☐ | ☐ | ☐ | ☐ | |
| Tasks are appropriately delegated to each individual (i.e. matches the role and qualifications of the individual and the delegation criteria). | ☐ | ☐ | ☐ | ☐ | |
| All changes to delegations (except for end dates) are re-signed and dated by the PI. | ☐ | ☐ | ☐ | ☐ | |
| Date of training is no later than the delegated individual's effective/start date (i.e. the date of PI sign off). | ☐ | ☐ | ☐ | ☐ | |
| All documentation of training is completed and filed appropriately. This includes, but is not limited to: protocol training, GCP training, and HC Division 5 training. | ☐ | ☐ | ☐ | ☐ | |
| All other sponsor-required training (e.g. eCRF, IVRS) documentation filed for all applicable study staffs. | ☐ | ☐ | ☐ | ☐ | |
| End dates of study staff no longer participating in the study are been recorded on the delegation log. | ☐ | ☐ | ☐ | ☐ | |

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| Documentation of staff training on amendments and any other changes to the conduct of the study (as applicable). Note any delays. | ☐ | ☐ | ☐ | ☐ | |
| **Research Staff and Other Site-Specific Files** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| Medical licenses for all investigators filed and are up to date. | ☐ | ☐ | ☐ | ☐ | |
| CVs for all study team members are filed. | ☐ | ☐ | ☐ | ☐ | |
| All applicable labs have lab certification / accreditation and normal ranges filed. | ☐ | ☐ | ☐ | ☐ | |
| **Safety Documents (ie. SUSARs, SAEs, DSMBs)** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| SUSARs are distributed to all study investigators periodically, as per requirements. | ☐ | ☐ | ☐ | ☐ | |
| Each safety report is assessed for reporting requirements – e.g., meets the Health Canada (HC) reporting requirements; documentation is filed accordingly. * | ☐ | ☐ | ☐ | ☐ | |
| HC-reportable safety reports are reported to HC in a timely manner as ADRs and filed. * | ☐ | ☐ | ☐ | ☐ | |

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| All safety reports received from sponsor or drug manufacturer are filed and signed off by the PI, as per requirements. | ☐ | ☐ | ☐ | ☐ | |
| SUSARs do not require further action from the site. | ☐ | ☐ | ☐ | ☐ | |
| DSMB reports are filed and there is documentation of PI's acknowledgment and review. | ☐ | ☐ | ☐ | ☐ | |
| Local SAEs are assessed by PI against REB reporting criteria, and reported accordingly. | ☐ | ☐ | ☐ | ☐ | |
| All other reportable events have been reported to the REB, as per reporting criteria. | ☐ | ☐ | ☐ | ☐ | |
| **Monitoring + Deviation Tracking** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| According to site visit log, monitoring plan (if available) is followed. | ☐ | ☐ | ☐ | ☐ | |
| Privacy and confidentiality agreements by monitors / external auditors signed and filed. | ☐ | ☐ | ☐ | ☐ | |
| Monitoring reports from all monitoring visits are filed. Reports are reviewed and signed off by the PI, as per requirements. Spot check reports for any outstanding deviations, issues, or trends. | ☐ | ☐ | ☐ | ☐ | |
| Deviation log (or other forms of acceptable documentation) available and signed off by PI | ☐ | ☐ | ☐ | ☐ | |

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| within acceptable timeframe (with indication of PI's assessment of whether deviation is REB-reportable). | | | | | |
| CAPA in response to major deviations or deviation trends are documented and implemented. | ☐ | ☐ | ☐ | ☐ | |
| Deviations that are assessed by PI to be reportable to REB are reported within required timeframe. | ☐ | ☐ | ☐ | ☐ | |
| **Study Documents** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| All versions of protocol are filed and consistent with REB approvals. | ☐ | ☐ | ☐ | ☐ | |
| All versions of consent forms are filed and consistent with REB approvals. | ☐ | ☐ | ☐ | ☐ | |
| All versions of IB are filed and consistent with REB approvals/acknowledgement. | ☐ | ☐ | ☐ | ☐ | |
| All participant materials are filed (e.g. diaries, questionnaires, recruitment materials) and consistent with REB approvals. | ☐ | ☐ | ☐ | ☐ | |
| **Correspondence** | | | | | |
| **Verification of the following:** | ☑ | ☒ | **N/A** | **Not Reviewed** | **Comments** |
| SIV minutes fully documented and filed – issues outlined and resolved within timelines. | ☐ | ☐ | ☐ | ☐ | |

## Research Compliance and Quality Assurance Program (RCQA):
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| Correspondence regarding site/study activation filed. | ☐ | ☐ | ☐ | ☐ | |
| Correspondence to the study team regarding different stages of study filed: start-up, interim analysis, accrual on hold, accrual closed, study termination and close out, etc. | ☐ | ☐ | ☐ | ☐ | |
| Correspondence filed indicates that each amendment was provided to the study team as it is approved. | ☐ | ☐ | ☐ | ☐ | |
| If the study had teleconference(s)/meeting(s) – attendance and minutes are filed. | ☐ | ☐ | ☐ | ☐ | |
| Correspondence shows that consent forms have been approved by sponsor prior to submission to local REB. | ☐ | ☐ | ☐ | ☐ | |
| If study is closed out, letter from the sponsor stating that the study activities have been completed and the site is closed is filed. | ☐ | ☐ | ☐ | ☐ | |
| If study is closed out, following documentations are filed: confirming return of study-related materials such as laboratory supplies, investigational product/devices, equipment, CRFs, randomization codes, etc. | ☐ | ☐ | ☐ | ☐ | |

***** Applies to a sponsor or investigator-sponsor role.

**Additional Notes:**