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| QMCR Regulatory Binder Template | | 2021 |
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**The Regulatory Binder is a place for regulatory, operational and organizational documents relating to your clinical trial. It should be comprehensive, so that someone not involved in the trial could review this binder and understand how the trial was set up, progressed, and closed out.**

**TEMPLATES FOR MOST REFERENCED DOCUMENTS CAN BE FOUND ON THE UNIVERSITY OF ALBERTA’S QMCR WEBSITE UNDER TOOLS AND TEMPLATES.**

**You can choose to locate information/documents in separate binders, on a secure electronic location or in the patient binder, however, it is recommended to include a Note-to-File stating where the information in that section can be/is located.**

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**Table of Contents**

**(Include sections relevant to your clinical trial eg: for a device trial, you would not require the Drug Temperature log, if your trial does not need a DSMB then you may remove that section. You may add sections at the end if desired )**

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## CURRENT APPROVED PROTOCOL

In this section, include a hard-copy of the current approved protocol. Typically, Health Canada (HC) provides approval first (in the form of an NOL), and the same protocol is submitted to the local Research Ethics Board (REB) for approval. Both HC and REB usually include the date of the protocol as part of the approval letter and this is used to track the version of the protocol that has been approved.

Protocol Helpful Tips:

* **A dated protocol version should identify the protocol (eg. 25MAR2019 (in the footer) )**
* Do not alter (in any way) the approved versions from REB or HC so that the identical version can be approved by both parties
* Any alterations should be accompanied by a change in the protocol date
* **ALL** alterations require REB approval, and may require HC approval as well.

Ask QMCR for guidance

* Previous approved protocols should be included in the Regulatory Binder in the Past Approved Version of Protocols section

## CURRENT APPROVED INFORMED CONSENT FORM

In this section, include a hard-copy of the current approved Informed Consent Form (ICF). The ICF includes both the Information Sheets as well as the Consent form. Typically, Health Canada (HC) provides approval first (in the form of an NOL), and the same ICF is submitted to the local Research Ethics Board (REB) for approval. Both HC and REB typically include the date of the ICF as part of the approval letter and this is used to track the version of the consent that has been approved.

Of note, depending on your study, there may be multiple consent forms. This could be deferred consents, assent forms (children), regained capacity consents, pregnancy consent forms. Include all applicable current ICFS in this section.

ICF Helpful Tips:

* **A dated version should identify the ICF as well as the REB Pro number in the footer**
  + **eg. 25MAR2019 Pro000XXXXX**
* The same date should be used for the Information Sheets and Signature page
* The ICF date is not necessarily associated with the protocol date (they may be different)
* It is recommended to avoid including names of study personnel and to only include the Principal Investigator on the ICF
  + This does not affect who may be included in future publications
  + Study personnel listed on the ICF are expected to be included on the Signature Delegation Log and have active study tasks/responsibilities
  + Study roles can be included instead of given and surnames (Research Coordinator 780-XXX-XXX)
* Do not alter (in any way) the approved ICF versions from REB or HC so that the identical version can be approved by both parties
* Any ICF alterations should be accompanied by a change in the ICF date
* **ALL** alterations to the ICF require REB approval, and may require HC approval as well. Ask QMCR for guidance
* Previous approved ICFs, by the local REB, should be included in the Regulatory Binder in the Past Approved Version of ICF section
* Health Canada may not necessarily provide approval for all consent documents. This would be the case if there was a local change to the ICF in which the local REB issues approval and the ICF is then sent to Health Canada as a notification

## INVESTIGATOR BROCHURE

In this section, include a hard-copy of the Investigator Brochure (IB – not a marketed product) or Product Monograph (PM – marketed product). This document may be provided by the sponsor, but is a compilation of the clinical and nonclinical data on the investigation product(s) relevant to the study. For a study comparing two marketed drugs (Advil vs Tylenol), both PMs should be included. For both IBs and PMs, a version date should be included.

IB / PM Helpful Tips:

* During the course of the study, if an updated version of the IB has been made available, please include in this section
* There is usually a signature page on the IB. A wet signature from the PI should be included on the IB signature page and filed in the Regulatory Binder
* Much more information is available in ICH-GCP-E6 section 7 Investigators Brochure.
* PM – Marketed products can often be found here: <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>

## QUALIFIED INVESTIGATOR UNDERTAKING

OR

## INVESTIGATOR AGREEMENT

For Biologics, Pharmaceuticals and Natural Health Products:

In this section, include a hard-copy of the completed Qualified Investigators Undertaking (QIU) form. This form outlines the person responsible for the conduct of the clinical trial at your specific site. This document is kept on file and is not required to be sent to REB or HC.

QIU Helpful Tips:

* Qualified Investigator (QI) is the person who HC recognizes as the person medically responsible for the trial. This may be a different person than the named local Principal Investigator (PI)
* It is recommended that the date of QI signature be prior to when the study began enrolment.
* For multi-centered trials, the main site should have a copy on file for each of the participating sites. Original stays at the site
* Special QIU form for Natural Health Product Directorate trials

For Device Trials:

In this section, include a hard-copy of the completed Investigator’s Agreement in accordance with subsection 81 (k) of the Medical Devices Regulations.

Investigator Agreement Helpful Tips:

* The signatory is a physician who conducts the study at the site and is the person medically responsible for the trial
* It is recommended that the date of signatory be prior to the start of the study

## HEALTH CANADA NO OBJECTION LETTER (NOL) or INVESTIGATIONAL TESTING AUTHORIZATION (ITA)

HC communicates approvals via a No Objection Letter (NOL) for biologics, pharmaceutical, radiopharmaceuticals and natural health products or via an Investigational Testing Authorization (ITA) letter for device trials. In this section, include a hard-copy of the NOL which outlines the documents HC has reviewed and approved (listing version dates).

NOL Helpful Tips:

* The NOL letter date is the date for which the approved documents are able to be utilized in the study.
* For multicenter trials, the main site may be responsible for this and will provide this document for your Regulatory Binder
* Other relevant HC communications can be included in this section as well (if the communication helps to explain, clarify or outline changes in how the study is run, it is considered relevant)
* Certain changes to the protocol may necessitate a CTA-A (Clinical Trial Application – Amendment) submission and a new NOL will be issued. Determining what changes will require an amendment is somewhat subjective – contact QMCR for assistance

## CLINICAL TRIAL SITE INFORMATION (CTSI)

The CTSI outlines the relevant site-specific information for a clinical study. Once all information has been obtained, this form should be completed and submitted to HC. **Device trials do not require a CTSI form.**

Amendments require a new CTSI form to be created and submitted.

The start date of the trial should be the date of your Study Initiation Visit (conducted by QMCR) or after. For protocol amendments, the date of implementation should be after the date of the local REB approval for the amendment.

CTSI Helpful Tips:

* Proof of submission (email print off to HC address and visible CTSI attached document) strongly recommended to be included in the Regulatory Binder
* Each site should have its own CTSI
* CR number would be available on HC letters and formal communications
* For a study where patients are treated at two different locations, two CTSIs should be completed and submitted.
* The REB approval date should match the REB approval letter
* Sponsor information on the first page should be current and correct
  + Governors of University of Alberta
  + Vice-President of Research (VPR) information is current
* Health Canada 3011 form contains most of the required information to complete the CTSI

## HREB (Human Research Ethics Board) APPROVALS

## (INITIAL AND RE-APPROVALS)

REB communicates approvals via Approval letters in the ARISE software platform. In this section, include a hard-copy of Approval letters which outlines the documents the REB has reviewed and approved (listing version dates). The letter date is the date for which the approved documents are able to be utilized in the study. Annual Approvals should also be included

REB Approval Letters Helpful Tips:

* For multicenter studies: protocols, ICFs, and documents provided to patients (including advertisements) need local REB approval
* Any document directed or provided to patients (eg: fasting information, recruitment posters, patient questionnaires, patient reimbursement cards)
* All changes to the protocol, IB, and ICF must be approved by the REB (this includes administrative changes, such as name or phone number information on an ICF)

## HREB DOCUMENTS

## (REBA OR LETTER OF ATTESTATION, LIST OF REB PANEL MEMBERS)

REB must provide documents demonstrating its adherence to regulatory requirements, including an Attestation form (certifying the REB complies with REB membership requirements and abides by Good Clinical Practice), and the REB membership list.

REB Approval Letters Helpful Tips:

* University of Alberta Attestation form can be found here:
  + <https://cloudfront.ualberta.ca/-/media/research/reo/human-ethics-files/forms-files/health-canada-reb-attestation-form-march-2019.pdf>
* University of Alberta Membership List (Health Panel):
  + <https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/research-ethics-boards/reb-3/membership-list-reb3>
* Membership lists are often updated yearly and membership lists should be included for all years that the study is active.

## HREB CORRESPONDENCE

The REB and the study team often have important communications surrounding the operations of a study trial. This section provides space (if needed) to document these communications.

REB Correspondence Helpful Tips:

* Include relevant communications between study team and REB board.
* Note to Files may also indicate that this information can be found on the ARISE platform

## OPERATIONAL APPROVAL / AHS ADMINISTRATIVE APPROVAL

Operational and AHS Approvals are internal documents required by AHS to use their property/space including posting study recruitment material. This is not a Health Canada regulated requirement, but is an important component of the local operations.

Operational / AHS Administrative Approval Helpful Tips:

* Contact NACTRC for Operational and AHS administrative approvals relevant to the AHS areas used during the course of the study.
* This includes clinic space, CIU beds and laboratory services (if you require labs other than standard of care labs)

## DATA SAFETY MONITORING BOARD (DSMB)

Some trials require a DSMB and this requirement is independently determined based on study trial risk. A DSMB is an independent data monitoring committee that assesses the progress of a clinical trial, the safety data and the critical efficacy endpoints. The board must include at least one member with expertise in the clinical area being studied. The DSMB can inform the sponsor and recommend continuation, modifications or termination of a trial.

DSMB Helpful Tips:

* Periodic progress reports should be submitted to REB via ARISE and QMCR
* A DSMB member signature page is recommended, as is DSMB meeting minutes throughout the study
* Conflict of Interest disclosures should be collected for all DSMB members
* Contact QMCR if your study requires a DSMB

## STAFF CV’S AND MEDICAL LICENSES

All study team members delegated tasks require a demonstration of their qualifications for these study tasks. These qualifications are typically demonstrated with a CV and if applicable, a medical/nursing/pharmacy license current to the year(s) active on the study.

CV and Medical License Helpful Tips:

* CVs should be signed and dated by the study team member. This demonstrates the information documented on the CV was up to date, along with the signature of the team member
* Medical Licenses should be included for the duration of the members involvement with the study (eg. A trial started in July 2015 and went until 2018. If J. Smith is an MD on the trial beginning in Feb 2016, his 2015 medical licensure is not required, but his 2016-2018 licensure would be needed on file)
* If a study coordinator is also a licensed nurse, but is not responsible for any study tasks that would require a nursing license (blood draws, physical assessments etc), a nursing license is not required.
* Only required for those who are listed on the Signature Delegation Log

## STUDY PERSONNEL TRAINING

All study team members delegated tasks require a demonstration of their study specific training. Often study teams hold a meeting where the study team is trained together. The meeting agenda or the power point slides can be printed and signed by those in attendance. Emails to the study team with documents can also be included, as with the responses from the study team when they have reviewed the material.

In addition, all study team members are required to demonstrate ICH-GCP training (ICH E6 R2 GCP). This applies to all devices, pharmaceuticals, biologics, radiopharmaceuticals and natural health products. This certification should be renewed every 2 years.

Health Canada Division 5 training is also required for trials in which a pharmaceutical, biologic, radiopharmaceutical and natural health product are used as part of the study. This certification only needs to be completed once, there is not an ongoing renewal required.

Navigate here to complete both ICH-GCP and Division 5 training: <https://www.ualberta.ca/vice-president-finance/audit-and-analysis/quality-management-in-clinical-research/training>

Study Personnel Training Helpful Tips:

* A Documentation of Training Log is a helpful tool to document the training of all study team members.
* The training materials themselves should also be included in the Regulatory Binder (e.g. slides, SOPs, protocol, IB etc). They may be included in this section, or referenced to their location in other sections of the binder.
* Throughout the study or when amendments are approved, study team training of the changes should be documented.
* When new members join the study team, the dates when study specific material was reviewed should be documented.
* Only required for those who are on the Signature Delegation Log

## DELEGATION OF RESPONSIBILITY LOG

This log records all study related delegated study tasks to study personnel.

Only those study team members delegated tasks are required to provide their CV, medical licenses (if applicable), study training, ICH-GCP and Division 5 (if applicable) training.

A Principal Investigator holds all responsibility of a trial. He/She can delegate specific responsibilities to qualified members of the study team. Both the study team member and the PI sign the row to indicate this transfer/acceptance of responsibility. Start dates for each study team member should be included, and end dates should only be documented when the study team member has left the study team (not pre-emptively).

Delegation of Responsibility Log Helpful Tips:

* PIs initial and date only the right hand column. The signature line at the bottom is only to be completed at the end of the study.
* If subsequent pages are needed, include a footer “Page \_\_ of \_\_”
* Training date column should correspond with the Documentation of Training Log.
* If someone is a co-Investigator on the protocol but does not have any study tasks (even in the case of a backup etc), then they should not be included on the Study Delegation Log (and therefore their CV, medical license and documentation of ICH-GCP and Division 5 training are not required). A Note to File describing their lack of involvement in study tasks could be included in this section.

## ADVERSE EVENT LOG

An Adverse Event (AE) is “any untoward medical occurrence in a clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment. This can be any unfavourable and unintended sign, symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.” A subject in a diet study who breaks an ankle between follow-up visits would need to be documented in the Adverse Event Log for that subject. Collect information of the Adverse Event including start/stop dates, the severity, causality, if it is related to the study intervention, action taken and the end result.

Adverse Event Log Helpful Tips:

* PIs must sign off on all AEs (if a PI is not medically qualified, the Qualified Investigator (QI) on record, would assume this role. The determination of the seriousness and relationship to the investigational product/device are to be determined by the PI (QI).
* Timely review of AEs should be maintained. This is proof of adequate medical oversight for all enrolled participants in the study.
* Abnormal laboratory findings are also considered AEs, unless indicated that they are “Not Clinically Significant (NCS)” by a qualified medical study team member on the printed laboratory findings.
* It is recommended that all subjects have their own AE Log and that if not AEs were noted for the subject, then that is indicated on the Log (Templated Log has a checkbox that asks if the participant has had any AE during the study).
* Includes any time after the ICF is signed until subject has completed study
* Include the start and end dates for the Adverse Event

## REPORTING SERIOUS ADVERSE EFFECTS (TO HC AND HREB)

A Serious Adverse Event (SAE) is “any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect”. REBs and Health Canada have specific timelines and routes to inform them of any Serious Adverse Events (SAEs).

Serious Adverse Event Reporting Helpful Tips:

* Expected Serious Adverse Events (events that have been identified in regulatory documents, such as the Investigator Brochure, within expected frequency numbers) do not need to be reported
* Having blank forms for both REB and HC in the Regulatory Binder is recommended
* Review Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH-E2A) for more specific requirements
* University of Alberta Research Ethics Office SAE Form (only unexpected adverse events): <https://cloudfront.ualberta.ca/-/media/research/reo/human-ethics-files/forms-files/local_sae_report.pdf>
* Health Canada reporting: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
* Local SAEs must be reported to the REB if the event is serious, unexpected, and considered to be related or possibly related to the study within 7 days of their discovery by the site

## PHARMACY

This section can be used to document processes, conversations and agreements made between the study team and the pharmacy (if applicable). This section can include receiving documents (invoices or packing slips), storage and shipping investigational product to sub-sites (if applicable).

For study drug that is stored at the research pharmacy, please see their SOP’s for additional information and add to the study binder.

## INVESTIGATIONAL DRUG / DEVICE ACCOUNTABILITY

This section includes accountability/inventory for all drug/device received into the study and those allocated to subjects. It also includes Subject compliance if applicable. Templated logs are available for drug, device and subject compliance tracking.

Investigational Product Accountability Helpful Tips:

* A log that tracks drugs/devices through the course of the study is recommended (from receiving to destruction/used or returned).
* This should correspond to subject worksheets which may also document subject compliance and lot numbers.
* Account for IP immediately once site receives, dispenses, collects any returned IP, or destroys IP.
* Some IP (e.g. controlled substances) may require a witness for destruction and a list of staff with access to IP storage.

## DRUG TEMPERATURE MONITORING

All drug/devices must be stored in accordance to their requirements as stipulated by the manufacturer. To document that the storage conditions comply with the temperature range and that the drug or device remains stable, a temperature log should be completed daily (workdays are sufficient, if stable temperatures are reasonably expected). This includes drugs or devices stored at room temperature.

Drug / Device Temperature Monitoring Helpful Hints

* Use a calibrated min/max thermometer
* Keep the current page of the Temperature Log in the storage location
* Any previous completed Drug Temperature Logs are to be included in the Regulatory Binder
* Study team members should be initialling the temperatures and the date on which it was taken

## LABORATORY CERTIFICATION

If your study requires any samples to be processed that are not part of standard of care, the laboratory used to process the samples needs to demonstrate they are currently certified. AHS affiliated laboratories have their certifications on their websites or the Hospital’s website.

## LABORATORY DIRECTOR’S CV

If your study requires any samples to be processed that are not part of standard of care, the laboratory used to process the samples needs to demonstrate they are currently certified. AHS affiliated laboratories have their Director’s CV on their websites. This is another check to be assured that the laboratory is certified.

## LABORATORY NORMALS

If your study requires any samples to be processed that are not part of standard of care, the laboratory used is required to produce the reference ranges/laboratory normals on which they compare their results to. AHS affiliated laboratories have their reference ranges/laboratory normals on their websites.

Laboratory Normals Helpful Hints

* Include reference ranges/laboratory normals for the population of your study (pediatric reference ranges for pediatric studies)
* Normal ranges can be updated through the lifetime of the study. Ensure that any updated reference ranges are filed and that the outdated ranges are retained in the study files
* Normal reference intervals can be found on the NACTRC website

## SCREENING AND ENROLLMENT LOG

This Log captures all individuals approached to participate in the study. It demonstrates who meets eligibility criteria and if the individual signed consent and was enrolled in the study. If a participant does not meet eligibility or declines participation, this is to be documented on the Screening and Enrollment log. This serves as a control for subject selection bias.

Screening and Enrollment Log Helpful Tips

* If subsequent pages are needed, include a footer “Page \_\_ of \_\_”
* Use a different subject numbering for screening subjects and enrolled subjects

## MASTER IDENTIFICATION LOG

This Log captures all individuals enrolled in the study. It captures sensitive contact information and is used in the event that a study subject needs to be contacted on an urgent basis.

Master Identification Log Helpful Tips

* Include the study participant number/ID on the log
* If subsequent pages are needed, include a footer “Page \_\_ of \_\_”
* Medical Numbers (e.g. ULI) are recorded only if permitted via ethics or part of other study data collection
* This log can be combined or captured in other ways or in the screening and enrollment log, as long as the master identification information is collected
* This log is never to be transmitted from the site

## SCREEN FAILURES/LOST TO FOLLOW-UP

An optional log that can track attempts to follow-up with subjects. This can be helpful for studies with multiple visits with strict visit windows.

Screen Failures / Lost to Follow Up Helpful Tips

* Reasons for withdrawal still need to documented, but this can be included in the subjects Progress notes.
* If your study doesn’t include any follow-up visits

## ORIGINAL SIGNED CONSENT FORMS

All signed original consent forms can be included in this section.

Original Signed Consent Forms Helpful Tips

* Original Signed Consent Forms can be temporarily kept in their subject binder until enrolment is complete and then collated and filed in one location at the end of the study. In the interim, a Note to File can be included stating that they are in the subject binder.
* An SOP on how your study completes the Informed Consent Process is strongly recommended. This can be reviewed as part of study personnel training. The SOP could be placed in this section as a reference.

## STANDARD OPERATING PROCEDURES

Any Standard Operating Procedures (SOPs) that apply to the study or are study specific should be included in this section. As part of study personnel training, they can be signed and dated when a study member has reviewed the SOP. It is strongly recommended that the following SOPs be included in each study:

* Investigational Product Management
* Adverse Event Reporting
* Record Retention
* Informed Consent Process

SOP Helpful Tips

* QMCR can be contacted for templated N2 SOPs for the above recommended SOPs

## CASE REPORT FORM

Blank copies of the worksheets or Case Report Forms (CRFs) that will be used to collect data for the study can be located here. The first time a piece of study data is recorded is considered “source”. If using worksheets, then these worksheets would be considered source and must be retained in the respective subject binder.

Case Report Form Helpful Tips

* Only collect that data that will support the study’s primary or secondary objectives
* Consider the order of the data collected when building the CRF, to make the data collection process smoother and more efficient
* Entries and corrections to CRFs should be completed by a study team member delegated to that task
* Corrections should use a single line to cross out the incorrect data, include the new corrected information and include an initial and that date of the correction.
* QMCR can assist in the eCRF development on the REDCap platform. Contact us early to work with your study team to develop your eCRF.

## PROTOCOL VIOLATIONS/DEVIATIONS

A protocol deviation is any event that occurs outside of the explicit details of the protocol. For example, if the protocol states that follow-up visit occurs 3-4 days after the initial visit, then a follow-up occurring on day 5 after the initial visit would be a protocol deviation. Deviations can be minor (mislabeling a tube) or major (unblinding event, randomized an illegible subject). The deviation should be described and, if a major deviation, see the REB website for details on which protocol deviations need to be reported to the REB. The PI should be aware of all protocol deviations and sign and date in a contemporaneous manner.

Protocol Deviation Helpful Tips

* Design your protocol with visit windows (Example: Follow-up visits occurs 4 days after the initial visit +/- 3 days)
* This log can be subject specific or cumulative for the entire study – whichever works best for your study team
* Protocol deviations are a normal occurrence in trials – not having any is quite rare
* The University of Alberta’s REB board has listed the deviations they should be made aware of here: <https://www.ualberta.ca/research/support/ethics-office/human-research-ethics/research-ethics-boards/reb-4/reporting-requirements>

## SUBJECT VISIT TRACKING LOG

An optional log, helpful for studies with many subjects with multiple visits or studies with long enrollment (over Christmas holidays or summer vacations) or high subject interaction.

## NOTES TO FILE

A Note to File is a tool used to outline the progress of a study. It helps to explain issues and outline the solution(s) that occur throughout the life of a trial. Templates are available, but can simply be a signed and dated memo added to the Regulatory Binder. These can be site specific but can also be distributed to sub-sites if applicable.

## MONITORING

Study initiation reports should be filed here.

All follow up letters/report from monitoring visits should be retained in this section. It is recommended that the investigator sign off on a copy of the follow up letter and have that copy filed (proof of receipt and knowledge of issues notes and activities that occurred during a periodic monitoring visit) in this section.

A Site Visit log can also be included in this section as proof that a monitor (outside of study personnel) provided oversight for the conduct of the study.

Any significant communication between study team members and the on-site monitoring team is recommended to be filed here.

## STUDY CLOSEOUT

When the study is complete, Health Canada and the REB should be notified. A templated letter is available. The Monitoring report of the close-out can also be included in this section.

## PAST APPROVED VERSIONS OF PROTOCOLS

Previous approved versions of the protocol are to be included in this section. A line through the front page of the document with the words “OUTDATED” can be helpful.

## PAST APPROVED ICF’S

Previous approved versions of the Informed Consent forms are to be included in this section. A line through the front page of the document with the words “OUTDATED” can be helpful.

## OTHER