| SOP Number-Title | Question | Multiple Choice | Justification  Iiis this |
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| SOP 002\_Research  Team Roles and  Responsibilities | 1. In preparation for  a clinical study, the Qualified Investigator (QI)/Investigator or their delegates should: | a) determine at the beginning of the study, how  best to avoid a heavy workload and hire relief personnel  b) rely on the staff involved in the study to schedule their training in protocol content and application  c) maintain a list of appropriate qualified  personnel to whom the QI/Investigator has delegated significant study related duties  d) ensure the coordinator supervises all persons assisting with the trial to ensure they are adequately informed about the protocol and their roles and responsibilities | Correct Answer: c)  Rationale:  ICH GCP states the following:  The investigator and their delegates should have adequate qualifications and training to conduct trial- related duties (ICH GCP Section 4.1.1 and 4.1.5). The investigator should have available an adequate number of qualified staff to conduct the trial properly and safely (ICH GCP Section 4.2.3). The investigator should ensure all persons assisting with the trial are adequately informed about the protocol, and their trial-related duties and functions (ICH GCP Section 4.2.4). The Qualified Investigator (QI)/Investigator should maintain a list of appropriate qualified personnel to whom the QI/Investigator has delegated significant study related duties (ICH GCP Section 4.1.5) . . |
| SOP 002\_Research  Team Roles and  Responsibilities | 2. The Qualified Investigator (QI)/Investigator can: | a) delegate tasks to other qualified clinical research personnel to reduce their ultimate responsibility for the overall conduct of a clinical trial  b) delegate tasks to other qualified clinical research personnel but the QI/Investigator still assumes ultimate responsibility for compliance with all applicable regulations and guidelines  c) assign tasks/duties to qualified clinical research personnel without documentation, so long as the staff are trained on their role and responsibility delegated to them  d) delegate tasks to other qualified clinical research personnel so that the QI/Investigator no  longer carries the ultimate responsibility for the overall conduct of the clinical trial. | Correct Answer: b)  Rationale:  ICH GCP defines the Investigator as a person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team. and may be called the principal investigator. (Section 1.34). . |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 003\_Research  Team Training | 1. It is important for all clinical research personnel to be trained on (where applicable): | a) Health Canada Food and Drug Regulations and US Food and Drug Administration Regulations b) Good Clinical Practice Guidelines and Tri- Council Policy Statement  c) Privacy Legislation and Study Protocol and SOPs  d) guidelines for Intellectual Property  e) a, b  f) a, b, c  g) a, b, c, d | Correct Answer: f)  Rationale:  All clinical study staff is responsible for participating in all required training, and for understanding and utilizing the training, as dictated by study protocol requirements. |
| SOP 003\_Research  Team Training | 2. The documentation of qualifications and training of all clinical research personnel  is: | a) not necessary provided the QI/Investigator is confident that the training was effective and can be spoken to upon audit  b) to be retained either individually for every  participant or in a Master Training File for the whole group  c) the responsibility of the Sponsor and should be retained in the sponsor head office  d) b, c | Correct Answer: b)  Rationale:  All regulatory and GCP training should be documented and retained in the individual’s training records (may be held as part of a Master Training File). Clinical Research Personnel should be prepared to demonstrate all the training received. |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 004\_Clinical Research Protocol Feasibility and Site Selection | 1. Name key aspects that are involved in determining protocol feasibility | a) determine technical and ethical feasibility of the protocol  b) time and availability of research team  c) access to target population  d) ensure adequate space for storage of investigational product  e) ensure REB has correct composition  f) a, b, and c  g) a, b, c and e h) a, b, c and d | Correct Answer: h)  Rationale:  These are all elements referenced in Section 4 of ICH GCP. |
| SOP 004\_Clinical Research Protocol Feasibility and Site Selection | 2. Why is it important to define a budget and contract between the Sponsor and Investigator? | a) to ensure reimbursement of direct and indirect costs associated with the use of the research facility is defined  b) to define a few responsibilities of the investigator involved in the conduct of clinical research under contract with the sponsor or sponsor/investigator  c) to ensure the investigator has access to funds to go to conferences  d) none of the above | Correct Answer: a)  Rationale:  The site must be aware of the financial implications of any research in which it is participating. It is the site’s responsibility to specify its own guidelines regarding contracts, and the reimbursement of direct and indirect costs associated with the use of their facilities. |
| SOP 004\_Clinical Research Protocol Feasibility and Site Selection | 3. During a site selection visit a sponsor will look out for: | a) estimated recruitment potential for participant population  b) qualifications of key site personnel  c) CV for QI and a copy of their medical license  d) evidence of previous clinical trial experience e) Financial agreements  f) a, b, c , e  g) a, b, c, d  h) a, b, e | Correct Answer: g)  Rationale:  The answer to this question is supported by the elements referenced in Section 4 of ICH GCP. In particular a)4.2.1; b)4.2.3; c) and d)4.1.1 |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 005\_Study  Initiation/Activation | 1. Three items for review at the initiation meeting may include: | a) study protocol, CRF’s, knowledge of investigational products  b) Sponsor SOPs, Sponsor Monitor CV, Investigator CV  c) contract template, tour of facilities, budget negotiation principles  d) none of the above | Correct Answer: a)  Rationale: Clinical Monitor or other Sponsor or Sponsor-  Investigator representative conducts an initiation visit, as a final assessment of the site’s readiness to start the clinical trial. There are several items for review at the initiation meeting including but not limited to study protocol, CRF’s and knowledge of the investigational product. |
| SOP 005\_Study  Initiation/Activation | 2. The steps included in the Site Initiation/Activation process include: | a) review of protocol and study-related materials before the initiation visit  b) ensure the QI/Investigator and all research team members with delegated duties are present during the visit  c) review of items including but not limited to  protocol, guidelines, regulations, site SOPs, CRFs etc.  d) retained copy of sponsor generated site initiation report in the essential documents file e) a, b  f) a, b, c  g) a, c, d | Correct Answer: f)  Rationale:  Clinical Monitor or other Sponsor or Sponsor- Investigator representative conducts an initiation visit, as a final assessment of the site’s readiness to start the clinical trial. It is important to ensure that the steps involved in preparing for and following a site initiation visit are followed. |
| SOP 006\_Informed  Consent Forms | 1. When developing the informed  consent form (ICF) you  need to ensure that: | a) all of the required essential elements are included  b) only major adverse events are included  c) you leave out all serious side effects so as not to scare the participant/authorized third party  d) it is written in such a way that the participant/authorized third party cannot refuse to participate | Correct Answer: a)  Rationale:  ALL essential elements must be included, not just some. Side effects may not be left out, and all consent must be voluntary, not based on how the consent form is written. |
| SOP 006\_Informed  Consent Forms | 2. Once you have completed  development of the ICF, before implementing it, the site needs to obtain approval from: | a) the REB/IEC  b) the Sponsor  c) Health Canada  d) a) and b) | Correct Answer: d)  Rationale:  (Section 5.7.1) Outlines who approves the ICF. They include the Sponsor, Sponsor- Investigator, QI/Investigator, (as applicable) and the REB/IEC. |
| SOP 007\_Research Ethics Board: Submissions and Ongoing Communications | 1. Which of the following study documents, must be submitted to the REB for review and approval? | a) Study Coordinator CV  b) Institutional Lab License c) Protocol  d) Source Document template | Correct Answer: c)  Rationale:  Before initiating a research study, the investigator/institution should have written and dated approval/favorable opinion from the REB for the protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), and any other written information to be provided to participants. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 007\_Research Ethics Board: Submissions and Ongoing Communications | 2. How often must study progress reports be submitted to the REB? | a) on an annual basis (at minimum)  b) every 3 years  c) every 5 years  d) every 10 years | Correct Answer: a)  Rationale:  The investigator should submit written summaries of the research study status to the REB annually, or more frequently, if requested by the REB. The investigator should promptly provide written reports to the sponsor, REB and, where applicable, the institution  on any changes significantly affecting the conduct of the research study, and/or increasing the risk to participants. |
| SOP 008\_Informed  Consent Process | 1. Who can obtain  informed consent? | a) the clinical trials nurse  b) the Principal Investigator c) the sub or co-investigator  d) any appropriately trained clinical research personnel | Correct Answer: d)  Rationale:  Any or all parts of this procedure may be delegated to appropriately trained clinical research personnel but remain the ultimate responsibility of Sponsor/Sponsor- Investigator and QI/Investigator. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 008\_Informed  Consent Process | 2. Is it possible to consent a participant/authorized third party who does not read or understand English or French? | a) if a participant/authorized third party is unable to read, an impartial witness must be present during the entire informed consent discussion  b) if the participant/authorized third party does not speak the language  used in the informed consent form (ICF) they should not sign it  c) the informed consent discussion must take place in the participant’s/authorized third party’s first/preferred language, using a qualified interpreter/translator  d) a) and c) | Correct Answer: d)  Rationale:  If a participant/authorized third party is unable to read, an impartial witness must be present during the entire informed consent discussion. If the participant/authorized third party does not speak English or French (where applicable), the informed consent discussion must take place in the participant’s/authorized third party’s first/preferred language, using a qualified interpreter/translator. |
| SOP 008\_Informed  Consent Process | 3. What do you document to ensure the ICF process is followed? | a) reference ICH GCP section 4.8 in the source documentation  b) the participant’s family members present and  their understanding of the material reviewed c) the participant/authorized third party having been given ample opportunity to read the ICF, ask questions and decide whether or not to participate in the research study  d) the time required for the Investigator to be  able to obtain consent in order to complete the screening work-up | Correct Answer: c)  Rationale:  No investigator may involve a participant in research unless the investigator has obtained informed consent as per applicable regulation(s) and as approved by the REB/IEC. Appropriate documentation must be maintained. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 009\_Subject  Recruitment and  Screening | 1. What methods  can be applied by site staff to support recruitment efforts? | a) advertisements, approved by the REB/IEC  b) collecting participant phone numbers from clinic staff  c) having student volunteers randomly approach participants in clinic waiting rooms  d) sending emails to participants who are due to visit the hospital | Correct Answer: a)  Rationale:  Subject recruitment procedures for example, include advertisements ). Advertisements may take the form of flyers, posters, internet advertisements. They must be approved by the REB/IEC before they are provided to participants. |
| SOP 009\_Subject  Recruitment and  Screening | 2. What documentation must be retained associated with subject recruitment activities? | a) date of the recruitment materials received from the sponsor  b) subject enrollment log, listing enrolled  participants phone numbers only  c) subject identification code list, which permits the identification of all participants who have taken part in the study (who were given a study number), in case follow-up of a participant  is necessary  d) recruitment materials such as advertisements  e) c) and d) f) b) and d) | Correct Answer: e)  Rationale:  The following documents  should be available before and during a clinical study to evidence the most current approved information is used:  ICH GCP:  8.3.3 dated approval of REB/IEC for subject recruitment, including any updates.  8.3.20 subject screening log  8.3.21 subject identification code list  8.3.22 subject enrollment log |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 10\_Management of Investigational Products | 1. Who has the ultimate responsibility for an investigational product? | a) participant  b) pharmacist c) investigator  d) clinical research coordinator | Correct Answer: c)  Rationale:  Outlines the responsibilities: The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that investigational products are managed according to all of the applicable regulatory, International Conference  on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements. Any or all parts of this procedure may be delegated to appropriately trained clinical research personnel but remain the ultimate responsibility of the Sponsor-Investigator or Qualified Investigator (QI)/Investigator. |
| SOP 10\_Management of Investigational Products | 2. Who is responsible for the manufacturing, labeling, packaging and shipping of investigational product? | a) Health Canada  b) Qualified Investigator  c) Sponsor or Sponsor Investigator d) Pharmacist | Correct Answer: c)  Rationale:  Outlines who is responsible for manufacturing, labeling, packaging and shipping of investigational product. The manufacturing, labeling, packaging and shipping of investigational product (including active comparator(s) and placebo, if applicable) is the responsibility of the Sponsor or Sponsor-Investigator. |
| SOP 011\_Management of Biological Specimens | 1. What information relating to the management of biological specimens can be found in the protocol or laboratory manual? | a) laboratory contact information (for central laboratories)  b) Study Coordinator contact information c) where to buy the shipping boxes  d) when to contact the REB | Correct Answer: a)  Rationale:  The contents of a research study protocol should include name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research study. |
| SOP 011\_Management of Biological Specimens | 2. Where should biological specimen storage records and destruction records  be filed? | a) at the laboratory  b) with the essential study documentation c) at the pharmacy  d) they don’t need to be filed | Correct Answer: b)  Rationale: Biological specimen storage records and destruction records should be added to the files at the end of the trial to demonstrate the compliance of the investigator, with the standards of Good Clinical Practice and with all applicable regulatory requirements. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 012\_ Adverse Event/ Drug Reaction Documentation, Assessment and Reporting | 1. Which serious adverse events are reported to Health Canada? | a) unexpected b) expected  c) life-threatening and fatal  d) a) and c) | Correct Answer: d)  Rationale:  Guidance for Clinical Trial Sponsors; Continuous  Assessment (12.3) Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, Amendment C.05.014 and ICH EA2 Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (3A) |
| SOP 012\_ Adverse Event/ Drug Reaction Documentation, Assessment and Reporting | 2. What is the time- line for reporting fatal and life threatening SAE’s to Health Canada? | a) within 48 hours  b) within 7 days of becoming aware of the  SAE  c) within 15 days d) within 30 days | Correct Answer: b)  Rationale:  Guidance for Clinical Trial Sponsors; Continuous Assessment (12.3) Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, Amendment C.05.014 and ICH EA2 Clinical Safety Data Management: Definitions And Standards for Expedited Reporting (3B) |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 013\_Study  Monitoring and  Communication | 1. When preparing  for a monitoring visit the clinical research personnel should: | a) ensure that documentation is up-to-date,  the applicable CRFs are completed and the regulatory binder/file including essential documents is up-to-date  b) not worry if CRFs are not completed,  patients in the clinic come first  c) clear a corner of their desk to share with the Monitor  d) notify to PI so he can be in attendance to  oversee the Monitor | Correct Answer: a)  Rationale:  The Sponsor or Sponsor-Investigator will assign a Monitor to conduct periodic investigator site visits to directly assess compliance with the protocol and applicable regulations and guidelines. Clinical Research Personnel are responsible for ensuring they are prepared for each monitoring visit. |
| SOP 013\_Study  Monitoring and  Communication | 2. Which document does NOT need to be provided during a monitoring visit? | a) current list of study personnel and delegation of tasks  b) signed photo ID for signature verification c) signed informed consent forms and evidence consent was obtained prior to participant’s participation in the trial  d) source documents | Correct Answer: b)  Rationale:  When facilitating a monitoring visit, the clinical research personnel should be prepared to provide several documents in order to verify that the responsible staff has been properly appropriately delegated their duties and that the data collected is true and accurate. |
| SOP 014\_Clinical Data  Management | 1. For studies regulated by Health Canada (Biologics, Natural Health Products, Drugs and Medical Devices), how long must all paper and/or electronic source  documents be stored for? | a) 5 years b) 15 years c) 25 years  d) until the biologic, product or medical device  is approved for sale by Health Canada | Correct Answer: b)  Rationale:  This is a regulatory requirement and is set forth in (Section C.05.012 (4)) Health Canada, Food and Drug Regulations, Part C, Division 5, Drugs for Clinical Trials Involving Human Subjects, (Schedule 1024), June 20, 2001. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 014\_Clinical Data  Management | 2. Who must sign and date the case report form after the final data entry is made? | a) Monitor  b) sponsor project lead c) research assistant  d) qualified investigator or delegate | Correct Answer: d)  Rationale:  Qualified Investigator or delegate: Sign and date the  CRF where indicated, after the final entry. |
| SOP 015\_Investigator Study Files and Essential Documents | 1. Who is responsible for the maintenance of the study files at the study site? | a) the clinical trials nurse  b) the clinical research associate/sponsor c) the sub investigator  d) the qualified investigator who may delegate to appropriately trained clinical research personnel | Correct Answer: d)  Rationale:  The Sponsor-Investigator or Qualified Investigator (QI)/Investigator is responsible for ensuring that study file creation and maintenance meet all of the applicable regulatory, International Conference on Harmonisation (ICH) Good Clinical Practice (GCP), sponsor, and local requirements. Any or all parts of this procedure may be delegated to appropriately trained study team members, but remain the ultimate  responsibility of the Sponsor-Investigator or Qualified Investigator (QI)/Investigator. Tasks delegated from Qualified Investigator to others should be documented, signed and dated by the Qualified Investigator and the person to whom the functions were delegated. The extent of delegation should be clearly stated and evidence of satisfactory training of personnel involved in these processes should be documented. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 015\_Investigator Study Files and Essential Documents | 2. What happens to the study files after the study completion? | a) participant records are stored for 5 years  b) records are destroyed in compliance with institutional policy  c) study files are stored in compliance with institutional policy, relevant privacy legislation, and regulatory requirements  d) all study files are sent to the sponsor | Correct Answer: c)  Rationale: Store participant records in compliance with institutional policy, relevant privacy legislation, and regulatory requirements. Store completed study documents in a secure location for the required period of time. Ensure they are secure from fire, water, theft, vandalism, tampering and loss, but are easily  accessible for review and audit. Maintain and  inventory the study file contents and note the intended storage location. Monitor study and electronic document storage regularly to ensure quality of the storage. |
| SOP 016\_Study Close- Out | 1. The termination site visit typically includes the following activities: | a) planning to store participant records for 5 years b) ensuring records are destroyed in compliance with institutional policy  c) ensuring study files are stored in compliance  with institutional policy; relevant privacy legislation, and regulatory requirements  d) providing payment to the coordinator and investigators for their efforts | Correct Answer: c)  Rationale:  The preparation and procedures for the Study Closure Visit are more or less the same to that of a monitoring visit. Refer to Section 5.0 of the Health Canada, Guidance for Industry, Good Clinical Practice: Consolidated Guideline, ICH Topic E6, 1997: |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 016\_Study Close- Out | 2. Actions and important communications associated with study close-out include: | a) informing the participant’s family that the clinical study has ended  b) informing some research participants  c) there is no need to inform anyone. They will notice that the study is closed  d) inform all members of the clinical research team and all relevant departments (e.g., pharmacy, laboratory, diagnostic imaging) of the study close-out | Correct Answer: d)  Rationale:  The preparation and procedures for the Study Closure Visit are more or less the same to that of a monitoring visit. Refer to Section 5.0 of the Health Canada, Guidance for Industry, Good Clinical Practice:  Consolidated Guideline, ICH Topic E6, 1997: |
| SOP 017\_Audits and  Inspections | 1. An official examination by regulatory authorities of documents, facilities and any other resources deemed to be related to the clinical study  is known as: | a) a regulatory verification visit (RVV)  b) a sponsor directed audit c) an inspection  d) a site visit | Correct Answer: c)  Rationale:  Definition Inspection: an official examination by regulatory authorities of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical study, and that may be located at the site of the study, at the Sponsor or Sponsor-Investigator's or contract research organization (CRO) facilities, or at other establishments deemed appropriate by the regulatory authorities. |
| SOP 017\_Audits and  Inspections | 2. When preparing for a regulatory inspection, the clinical research personnel should: | a) verify the purpose and stages of the audit/inspection  b) deal directly with the regulatory authority  and do not inform the sponsor  c) not worry about missing records  d) not have to prepare the logistical aspects of the visit i.e., access to a copier, telephone etc.  e) a) and b)  f) a) and d) | Correct Answer: a)  Rationale:  An inspection is an official review of documents, facilities, records and any other resources that are deemed by the authority (ies) to be related to the clinical trial. It is imperative to understand the inspection process and expectations of the inspector(s). |
| SOP 018\_Clinical Trial  Application | 1. Why file a CTA? | a) a CTA must be filed to Health Canada for  clinical trials in Phases I through III of development  b) a CTA must be filed if the study is a multicenter study that involves US sites and falls under FDA regulations  c) a CTA is filed only for studies that are using  an investigational new drug | Correct Answer: a)  Rationale:  A CTA must be filed for clinical trials in Phases I through III of development (including comparative bioavailability trials). Approval must be received prior to study activation. This includes studies in which a marketed drug is used outside of conditions specified in the Notice of Compliance (NOC) or Drug Identification Number (DIN) application, i.e., if the indication(s) and clinical use, target population(s), dosage regimen(s), route(s) of administration, or dosage form(s) differ from those described in the Product Monograph. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 018\_Clinical Trial  Application | 2. When can you commence the clinical trial? | a) when the feasibility assessment is completed  b) when conditional ethics approval is obtained  c) when the No Objection Letter (NOL) is received  d) when the study drug arrives at the site | Correct Answer: c)  Rationale:  Approval must be received prior to study activation. Wait for No Objection Letter (NOL), indicating a satisfactory review and approval, before commencing trial activities. Submit a copy of NOL to REB, if required. |
| SOP  019\_Confidentiality and  Privacy | 1. Who may have direct access to participant’s confidential personal  information? | a) participant  b) study coordinator c) sponsor  d) anyone authorized in the informed consent  form | Correct Answer: d)  Rationale:  ICH GCP makes reference to confidentiality in Section 2.11: The consent form must describe to the participant who will have access to their information and for what purposes (e.g., Health Canada, US Food and Drug  Administration (FDA), Research Ethics Board (REB), research sponsors and personnel monitoring/auditing the research on their behalf) |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP  019\_Confidentiality and  Privacy | 2. Confidential and participant identifying information (enrollment lists, consent forms, etc…) are: | a) stored at the site in a secure location  b) retained by the sponsor at study close-out  c) stored with the research case report forms  binder  d) stored in a secure location by the Research  Ethics Board Chairperson | Correct Answer: a)  Rationale:  ICH GCP Section 8 outlines where documents should be stored and copies maintained. |
| SOP 023\_Clinical Trial Application (CTA) (Natural Health Products) | 1. After submitting a CTA, approval must be received. | a) within 15 days  b) prior to study activation c) no approval is needed  d) prior to REB approval | Correct Answer: b)  Rationale:  After submitting a CTA, approval must be received prior to study activation. This includes studies in which a marketed natural health products is used outside of conditions specified in the Product License/Monograph/Labelling Standard or Natural Product Number (NPN) application, i.e., if the indication/s and clinical use, target population/s, dosage regimen/s, route/s of administration, or dosage form/s differ from those described in the Product Monograph.  Wait for Notice of Authorization (NOA), indicating a satisfactory review and approval, before commencing trial activities |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 023\_Clinical Trial Application (CTA) (Natural Health Products) | 2. Reasons for  amendments to the CTA, requiring a CTA-Amendment submission include | a) changed or additional natural health product  safety assessment  b) changed address Principle Investigator  c) dosing regimen, inclusion/exclusion criteria d) grammatical errors in protocol  e) change in Case Report forms f) b, d, e  g) a, c | Correct Answer: g)  Rationale:  Reasons for amendments include, but are not limited to, changes to the list outlined in this section. |
| SOP 024\_ Investigational Testing Authorization (ITA) for Medical Devices (non- IVDD) and Manufacturer/Sponsor Obligations | 1. An ITA for a study for a medical device is required for | a) Class I medical device  b) Class II, III or IV medical device not licensed in Canada, manufactured by/for one physician + used only for their participants  c) Class II, III, IV, medical device licensed in  Canada + not used under license indication.  + manufactured by another physician or company + used to support/expand Canadian license  d) Class II, III, IV medical device licensed in Canada + device used under license indication + study in Canada | Correct Answer: c)  Rationale:  There are different requirements depending on Class, where the device is manufactured, and where it is licensed. The combination of these factors will dictate when an ITA is required. |
| SOP 024\_ Investigational Testing Authorization (ITA) for Medical Devices (non- IVDD) and Manufacturer/Sponsor Obligations | 2. When a conditional investigational  testing authorization, pending REB approval has been received, the actual testing of the device  may begin when | a) Immediately  b) Once REB approval has been obtained c) Upon execution of the contract  d) Once REB approval has been obtained and submitted to the Medical Devices Bureau | Correct Answer: d)  Rationale:  Class III and IV applications: A conditional investigational testing authorization may be granted, pending the receipt of a Research Ethics Board approval. However, the investigational testing cannot begin until this approval has been obtained.  and submitted to the Medical Device Bureau. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 025\_ Equipment Calibration and Maintenance | 1. Information in the equipment maintenance records should include | a) Name, model/serial/identification numbers b) occasional calibration records  c) service repair records  d) price of the equipment e) a, c  f) a, b, d | Correct Answer: e)  Rationale:  The information in the equipment maintenance records should include but is not limited to the items listed in this section (as applicable). |
| SOP 025\_ Equipment Calibration and Maintenance | 2. Staff training related to equipment calibration should include | a) Identify all staff/vendors involved in QA QC of equipment, including responsibilities for reporting.  b) Labeling all equipment with the study protocol number  c) Include this information in the SOPs or related documents (e.g., study delegation log).  d) Ensure that responsible staff/vendors are  qualified by education and training in relation to the equipment requiring assessment/repair.  e) a, b,  f) a, c, d | Correct Answer: f)  Rationale:  Staff training related to equipment calibration should include all the items listed in this section. |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 100\_CRF Design | 1. When creating a draft of the Case Report Forms you should NOT take into account the  following: | a) the study protocol  b) applicable regulatory requirements c) data collection  d) CRA preference | Correct Answer d)  Rationale:  Outlines the details of what to take into consideration when developing CRFs. These  documents help to ensure all the appropriate data is captured in accordance with the applicable rules and determining the most appropriate method of collection. |
| SOP 100\_CRF Design | 2. Which of the following is the most important aspect to consider when developing case report forms? | a) monitoring preference of the CRA  b) consistency with the protocol statistical  plan  c) investigator preference  d) cost | Correct Answer: b)  Rationale:  Consistency with the protocol statistical plan ensures that the data captured on the CRF provide the information needed to complete the statistical analysis for the study. |
| SOP 101\_Study  Analysis and Reporting | 1. The following activities are necessary for study analysis and reporting, EXCEPT: | a) informing all study sites of closure and serious adverse event (SAE) reconciliation  b) database quality control, database cleaning,  freeze, lock  c) finalization and sign-off of the statistical analysis implementation of the statistical analysis plan  d) the launch date to market for the drug under investigation reporting study outcome and results to regulators, and Research Ethics Board (REB)/Independent Ethics Committee (IEC)  e) review of the results and clinical report writing, archiving of the trial master file TMF) | Correct Answer: d)  Rationale:  Study analysis and reporting includes all activities, from the last participant visit to the finalization of the study report. , |
| SOP 101\_Study  Analysis and Reporting | 2. The statistical outputs for a specific study including  tables, figures, and  listings are prepared according to which study document? | a) data management plan b) statistical analysis plan  c) nature or Science publication guidelines d) clinicaltrials.gov guidelines | Correct Answer: b)  Rationale:  Prepare/present study data as tables, figures, listings, and statistical output, as outlined in the statistical analysis plan for the study. |
| SOP 102\_Protocol  Development | 1. Which of the following is not part of a protocol? | a) hypothesis and design b) budget  c) eligibility criteria  d) primary and secondary study outcomes  e) study procedures | Correct Answer: b)  Rationale:  Outlines the items that go into a protocol. Budgets are not part of that list. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 102\_Protocol  Development | 2. Protocols must be approved by the following before they can be initiated: | a) REB  b) Health Canada (as applicable)  c) a Lawyer  d) a) and b) | Correct Answer: d)  Rationale:  Outlines which parties must approve the protocol before it can be implemented. This doesn’t include a lawyer. |
| SOP 103\_Data  Management Plan | 1. The Data Management Plan (DMP) is a study specific document that explains the process which data are to be handled and serves as: | a) the statistical analysis plan  b) a set of instructions for data management c) a communication tool to discuss with participants  d) the case report form | Correct Answer: b)  Rationale:  The Data Management Plan (DMP) is a document that is developed to help govern a specific research study, in terms of data management, and is a plan to help achieve regulatory standards and uniformity in data management practices. |
| SOP 103\_Data  Management Plan | 2. Sections that may be included in the  draft Data Management Plan (DMP)are: | a) proof of approval from the Research Ethics Board (REB), case report forms (CRF),  protocol summary, and serious adverse event  (SAE) data reconciliation  b) timelines, data validation, data entry, and source notes from clinicians or nurses  c) adverse event (AE) reports, lab data handling, quality control (QC), dictionary and coding management | Correct Answer: c)  Rationale:  Data Management Plans (DMPs) do not need to be approved by the REB although certain aspects of the DMP may be approved by the REB as a part of the regular approval process such as proof of data security. Source notes from clinicians or nurses are never included in the DMP. Source notes are stored in the database, if they are electronic source notes, or  are stored in the study participant’s research file if they are paper. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 103\_Data  Management Plan | 3. Before a new study starts: | a) the data manager should write a new Data Management Plan specific to the study and base it on protocol, scope of work, contract agreement, analysis plans, and the data flow. b) the data manager must ensure the Data Management Plan is approved, and made available to the research team and all other staff involved in the research study such as those at the lab or pharmacy  c) Data Management Plans should include a list of all functional roles within the data management process and the personnel who fulfill those roles.  d) the Data Management Plan does not need to be identified on every page by characters such as the protocol identifier and/or title that clearly associate the Data Management Plan with its respective study  e) a); b) and c)  f) a); c) and d) | Correct Answer: e)  Rationale:  All of these processes are key aspects of building a DMP and are complete before the tasks it describes are undertaken. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 104\_Database Set- up | 1. Database set-up is an extremely important aspect of study start-up.  Which of the  following does not apply to database set-up? | a) the database set-up can include annotation of the CRFs and eCRF  b) the database set-up will be defined  according to the study protocol  c) database set-up can only be defined for research studies that are entirely electronic  d) database set-up will be defined according to  the CRF and the study protocol | Correct Answer: c)  Rationale:  A database can be set-up to accommodate studies that are entirely electronic and also those that incorporate paper case report forms (CRF). Where paper CRFs are incorporated, both the CRF and the protocol are used to define the database. |
| SOP 104\_Database Set- up | 2. The purpose of the Database Set-up SOP is to: | a) describe the tasks necessary to generate, test, implement and approve a database set-up for a study to ensure accurate, reliable, complete and secure electronic data  b) ensure monitoring visits can be performed as part of the study protocol  c) differentiate between studies that are using a paper based data capture methodology and electronic data capture  d) provide justification for additional study  funding | Correct Answer: a)  Rationale:  This Standard Operating Procedure (SOP) describes the tasks necessary to generate, test, implement and approve a database set-up for a study to ensure accurate, reliable, complete and secure electronic data. |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 105\_Database Maintenance and Management | 1. With respect to the interim release of data, it is important to maintain a record of the released datasets to include: | a) the data fields in the dataset as well as the date and time the data set was created  b) the person to whom the data set was released and a copy of the master subject identification list in the event the dataset was released incorrectly  c) the recoding of the treatment assignment so that the sponsor or sponsor-investigator can make a change to protocol before approval from the REB | Correct Answer: a)  Rationale:  In a situation where data has accidentally been released, the appropriate notifications and reports are taken care of by the investigator and/or the sponsor  or sponsor-investigator as appropriate. These situations are never handled directly by the data management or information technology (IT) team. Further, changes made to a protocol must be approved by the REB before they can be implemented at the site. |
| SOP 105\_Database Maintenance and Management | 2. A database that is located on a networked shared drive must have: | a) limited access to it by only allowing research team members and interdepartmental staff to access it  b) secured and limited access to the database  using network accounts or database access accounts  c) controlled access by setting up a username and password that can be shared amongst the research team  d) open access to anyone who wants to see  the data | Correct Answer: b)  Rationale:  Only those who actually need access to it have authorization to access it. This does not include all research team members and/or interdepartmental staff. Allowing access to staff that do not need access is a breach of privacy. The participant’s participation in the study is kept confidential according to the informed consent. |
| SOP 106\_File Transfer | 1. The statement that best describes the purpose of the File Transfer SOP is: | a) to ensure the Principal investigator has access to data at all times  b) allows for unencrypted data to be shared  c) describes the steps required during the transfer of external files to and from the study database to preserve the integrity of transmitted data and the study database  d) provides a procedure to enter data captured on CRFs including laboratory results and participant reported outcome measures | Correct Answer: c)  Rationale:  This Standard Operating Procedure (SOP) describes the steps required during the transfer of external files to and from the study database to preserve the integrity of transmitted data and the study database. |
| SOP 106\_File Transfer | 2. How is data security achieved when files need to be transferred? | a) files are encrypted using local encryption methods and software and may also be transferred as password protected compressed archives  b) files may be transferred when encrypted and then sent indirectly to the destination  c) encryption is only required when transferring or receiving data to/from outside Canada  d) PROTECT is the only approved encryption  software | Correct Answer: a)  Rationale:  Data Security, Files should never be sent indirectly. File transfer must always ensure data integrity and security |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 107\_Database  Lock and Archiving | 1. Database lock includes all of the following except: | a) ensure the Sponsor, Sponsor-Investigator or QI/Investigator (if applicable) is notified that the database will be locked and obtain approvals as necessary  b) ensure all data have been quality checked appropriately  c) ensure CRF annotation is complete  d) ensure all appropriate data validation and review procedures are complete  e) remove all user write-access to the database  and lock the database  f) unblind the study database if necessary | Correct Answer: c)  Rationale:  CRF annotation is completed during study start-up, not during database lock. |
| SOP 107\_Database  Lock and Archiving | 2. The database can be unlocked if: | a) the error affects a table or listing in the statistical analysis plan  b) the error changes or has major impact on a narrative (summary of findings)  c) the error involves no change to a primary safety or efficacy parameter(s)  d) a) and b) | Correct Answer: d)  Rationale:  The database is unlocked for investigations,  documentation, and analyzed for impact any time a post database lock error is discovered. |

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| SOP Number-Title | Question | Multiple Choice | Justification |
| SOP 108\_System Setup, Maintenance and Security | 1. When is it necessary to develop, maintain and document a system backup and recovery plan? | a) only when the research study has been approved by Health Canada and/or the FDA b) only when my research study is big enough to warrant the use of a large capacity system  c) only if the IT department tells us it is site policy  d) when electronic data management, of any level, is a part of the research study | Correct Answer: d)  Rationale:  A system backup and recovery plan is developed, tested and approved by research study team members who are trained to do so. It is always done before study conduct to verify accuracy of the process and allow for changes to be made. Backup and recovery process must be tested periodically for most common failure scenarios. |
| SOP 108\_System Setup, Maintenance and Security | 2. Security patches, anti-virus/anti-spy- ware software, and firewalls are all examples of: | a) physical security b) virtual security  c) logical security d)computer games | Correct Answer: b)  Rationale:  These are all types of intangible security measures put into place for data management systems used in research studies, ensuring data security. |

| SOP Number-Title | Question | Multiple Choice | Justification |
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| SOP 109\_System Backup and Recovery Planning | 1. Software related information concerning the data management system (DMS), such as the operating system, encryption software,backup software,  vendor name and website, relevant contact information, release/version numbers, and details on any special patches should be: | a) kept in a storage locker  b) clearly identifiable and documented  c) destroyed when new documentation is distributed  d) only kept until the end of the study enrollment period | Correct Answer: b)  Rationale:  All software information related to the DMS is always kept, even after new documentation is distributed, and is easily identifiable and located similar to the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) “Essential” documents. |
| SOP 109\_System Backup and Recovery Planning | 2. Ensuring that the backup medium is behind locked doors, preventing unauthorized access, is an example of  what type of  security? | a) physical security b) virtual security  c) logical security | Correct Answer: a)  Rationale:  A locked door is a tangible measure of security. |
| SOP 109\_System Backup and Recovery Planning | 3. Two important aspects of the system recover process are: | a) periodic testing and identifying the maximum downtime before acting on the recovery plan  b) distributing the recovery plan to all data management personnel and rapidly trying random solutions | Correct Answer: a)  Rationale:  The recovery plan should be secured but kept close at hand by identifiable systems personnel and the recovery process follows a pre-established systematic plan to get up and running. |