| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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. |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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 |
| 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) |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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) |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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) |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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) |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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) |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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) |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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) |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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) |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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 |
| 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 |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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) |

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| SOP Number-Title | Question | Multiple Choice |
| 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 |
| 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 |

| SOP Number-Title | Question | Multiple Choice |
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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 |
| 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 |
| 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 |