Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
SOP001_01 SOP Administrative Management	1. When writing SOPs, it is important to:	a) Use language that allows individual staff to decide if they should follow the SOP or not b) Use the active voice and present verb tense, as much as possible c) Use individual names so site staff knows who is responsible for the actions outlined in the SOPs d) Leave a lot of room for interpretation	**Correct Answer: b)** Use the active voice and present verb tense, as much as possible. **Rationale: Section 5.1.7** Use of active language such as "must" or "will" decreases the chance of non-compliance and provides site staff with clear directions.	
SOP 002_01 Biospecimen Facility Maintenance and Security	1. In the event of a power outage for an extended period of time you should do the following with refrigerators and freezers	a) Ensure that all refrigeration units remain closed until the power is restored. b) Remove all contents from low temperature freezers and place into back up units of the same temperature, until the power is restored and the desired temperature level is reached. c) Remove all contents and transfer to Styrofoam containers and coolers. d) If the power outage is less than 10 hours, note the time the outage lasted and do nothing with the contents of the units.	**Correct Answer: b)** Remove all contents from low temp freezers and place into back up units of the same temperature, until the power is restored and the desired temperature level is reached. **Rationale: Section 5.8.1 and 5.8.2** If the outage is for a short period of time then a) would be sufficient, but an established guideline should be set where, if the it is longer than such time all contents must be removed and the above is done. Styrofoam will not maintain the ultra-low temperatures. Anything over 3 hours needs to be	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
			put in another area.	
	2. Equipment maintenance should include which of the following:	a) Regular cleaning, decontamination, calibration and repair, temperature testing and back up alarm testing on a scheduled basis. b) Visual inspection, occasional cleaning and repair, temperature charting once a month and alarm testing by building maintenance once a month. c) Equipment check only upon instrument failure, document the time it occurred and what the problem was and when the instrument was back in-service. d) Factory scheduled preventative maintenance programs are all that is required.	**Correct Answer: a)** Regular cleaning, decontamination, calibration and repair, temperature testing and back up alarm testing on a scheduled basis. **Rationale: Section 5.9.1** Regular scheduled maintenance and inspection on equipment is mandatory to ensure equipment is working properly. Alarms need to be in working order 24hrs/7 days a week and connected to a surveillance system in the event of a power failure to ensure someone will be notified.	
SOP 003_01 Biohazardous Waste management	1. Biohazardous Anatomical waste should be disposed of in the following manner;	a) Dispose all biohazardous waste in a CSA approved puncture resistant container, incinerate and dispose of in accordance with institutional, national, and provincial	**Correct Answer: d)** Place all human anatomical waste and materials used that have come into contact with such waste into a bag that is clearly labeled with the universal biohazard symbol,	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		guidelines. b) Place all waste in regular garbage and send to city landfills. c) Place all human anatomical waste and materials used that have come into contact with such waste into a bag that is clearly labeled with the universal biohazard symbol and send to city landfill. d. Place all human anatomical waste and materials used that have come into contact with such waste into a bag that is clearly labeled with the universal biohazard symbol, decontaminate by autoclaving, and arrange for proper disposal.	decontaminate by autoclaving, and arrange for proper disposal. **Rationale: Section 5.1.1** All biohazardous waste needs to be decontaminated PRIOR to disposal or removal by any disposal company to ensure that anyone coming in contact with such material will not be contaminated.	
	2. When dealing with sharps, the following disposal instructions should be followed:	a) Dispose of all sharps waste into a clearly labeled biohazard bag, incinerate and send to city landfill. b) Recap used sharps and dispose into a clearly labeled CSA approved puncture resistant container labeled with a biohazard symbol, incinerate	**Correct Answer: c)** Dispose of all used sharps into a clearly labeled CSA approved puncture resistant container labeled with a biohazard symbol, incinerate and dispose of using institutional, national, and provincial guidelines. **Rationale: Section 5.3.1**	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		and dispose of using institutional, national, and provincial guidelines. c) Dispose of all used sharps into a clearly labeled CSA approved puncture resistant container labeled with a biohazard symbol, incinerate and dispose of using institutional, national, and provincial guidelines. d) All sharps should be recapped and disposed of in sharp resistant containers.	To avoid injury sharps are NEVER to be recapped, for any reason under universal precautions policy.	
SOP 004_1 Inventory Verification	1. A properly designed inventory verification system should	a) Not be password/security controlled. b) Not be locked, allowing easy access to specimens for usage by all trained personnel. c) Have periodically scheduled inventory verification performed by cleaning staff. d) Have a minimal time limit set for the time specimens are handled or removed from proper storage conditions to ensure the integrity of the sample has not been compromised.	**Correct Answer: d)** Have a minimal time limit set for the time specimens are handled or removed from proper storage conditions to ensure the integrity of the sample has not been compromised. **Rationale : Section 5.1.1 and 5.2.8** Timely storage handling of samples is mandatory to maintain sample integrity and viability.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. If a specimen is found that is not on the inventory log, staff should:	a) Document and discard the sample as this an extra sample and there is no history. b) Document as much information as you can from the sample and assign it a storage location, log it into the inventory, and perform a formal investigation including a deviation report. c) Return the sample to a quarantined area and assume the person who put it there will retrieve it. d) Return sample to patient.	**Correct Answer: b)** Document as much information as you can from the sample and assign it a spot, log it into the inventory and then do a formal investigation including a deviation report. **Rationale: Section 5.2.14** All attempts should be made to identify samples in the inventory.	
SOP 101_01 Biorepository Team Roles and Responsibilities	1. The biorepository Director should	a) Book relief staff to take on all responsibilities when the Director is on vacation. b) Be qualified by education, training, and experience to assume responsibility for the proper conduct of the program, and meet all the qualifications specified by the applicable regulatory requirements. c) Not worry about providing evidence of qualifications requested by the REB/IEC	**Correct Answer: b)** Be qualified by education, training, and experience to assume responsibility for the proper conduct of the program, and meet all the qualifications specified by the applicable regulatory requirements. **Rationale:** Section 5.1.1) and 5.1.3 The Director and his/her delegates should have adequate qualifications and training to assume responsibility for the proper conduct of the program, and meet all the qualifications specified by the	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		and the regulatory authorities. d) Ensure the program is conducted in compliance with the REB/IEC and, if applicable, appropriate regulatory authorities, at the Director's discretion.	applicable regulatory requirements. . The biorepository Director is ultimately responsible the biorepository, team, and space requirements, conformity with the requirements regulatory authorities and of the REB/IEC, and team training. Although some of these tasks may be delegated to other qualified staff members, the Director assumes ultimate responsibility for the overall conduct of the biorepository program, and for compliance with all applicable regulations and guidelines.	
	2. The biorepository Director 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 biorepsoitory to schedule their training in biorepository-related knowledge and skills. c) Maintain a list of appropriate qualified personnel to whom the Director has delegated significant biorepository program-related duties. d) Not worry about REB and regulatory requirements	**Correct Answer: c)** Maintain a list of appropriate qualified personnel to whom the Director has delegated significant biorepository program-related duties. **Rationale: Section 5.1.2 and 5.3** The Director should document the delegation of tasks/duties	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
SOP 102_01 Biorepository Staff Training	1. A core module for training repository staff should include general ethical considerations that are relevant for a biorepository program such as:	a) Training in marketing the biospecimens to gain financial profits b) Training in contract negotiation with pharmaceutical sponsors c) Training in how to deal with difficult colleagues d) Training in Privacy Legislation	**Correct Answer: d)** Training in Privacy Legislation **Rationale: Section 5.1.2** With the introduction of new legislation to protect the privacy of individually identifiable personal information, all biorepository staff must understand the obligations imposed by the applicable privacy legislation, and the implications to their day-to-day practice. Data Collection in Canada must comply with the Personal Information Protection and Electronic Documents Act (PIPEDA), unless formally exempted by provincial privacy legislation that has been recognized as substantially similar to PIPEDA. It is therefore important for all biorepository personnel to be versed in privacy legislation requirements and institutional policies.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. SOP training: The purpose of having documented SOPs is to:	a) Provide written guidelines for the performance of biospecimen collection and , if applicable, all aspects of clinical trials b) Avoid quality and consistency in processes c) Ensure compliance with applicable teach how to interpret the regulations and guidelines to allow for individual preferences d) Use them as the sole method of training of new personnel.	**Correct Answer: a)** Provide written guidelines for the performance of biospecimen collection and , if applicable, all aspects of clinical trials **Rationale: Section 5.4** SOPs are instrumental in ensuring compliance, consistency and teaching staff how procedures are to be completed. Therefore the purpose of having documented SOPs is to provide written guidelines for the performance of biospecimen collection and, if applicable, all aspects of clinical trials, promote quality and consistency in processes, ensure compliance with applicable regulations and guidelines; and facilitate training of new personnel.	
SOP 103_01 Informed Consent Forms	1. When developing the informed consent form you need to ensure that:	a) Most of the required essential elements are included b) A description is included how the tissue sample, blood and data will be handled, stored, and released to researchers. c) You leave out a statement informing the participants what participation in the biorepository program will mean for them.so as not to	**Correct Answer: b)** A description is included how the tissue sample, blood and data will be handled, stored, and released to researchers. **Rationale: Section 5.3.1** Outlines what is required. All essential elements must be included, not just some. In forming the participant about what participation means should be included, and all	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		scare the participant d) It is written in such a way that the participant cannot refuse to participate	consent must be voluntary, not based on how the consent form is written.	
	2. After revising the informed consent form, before implementing it, you need to obtain approval from:	a) REB b) Biorepository Director c) Health Canada d) a) and b)	**Correct Answer: d)** a) and b) **Rationale: Section 5.7.1** outlines who approves changes to the consent form They include the Director and the REB/IEC. Health Canada does not approve consent forms) After revising a consent form you need to obtain approval from the biorepository Director and the REB/IEC before implementing any revised ICFs. The only exception is in emergency situations (immediate safety hazard to participants), or as covered under exceptions to informed consent process. (Section 5.7.2) Do not begin using the revised ICF until written approval is received from the REB/IEC.	
SOP 104_01 Informed Consent Process for	1. Who can obtain informed consent?	a) Biorepository staff b) The biorepository Director c) Any appropriately trained	**Correct Answer: d)** b) and c) **Rationale: Section 3.0**	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
Biorepositories		biorepository staff members to whom the Director has delegated the procedure d) b) and c)	Informed consent can only be obtained by appropriately trained staff, after formal delegation by the Director of this task to such staff., Any or all parts of this procedure may be delegated to appropriately trained study team members, but the Director is responsible for ensuring that the team under his/her supervision complies with the informed consent process described in this SOP.	
	2. Is it possible to consent a potential participant who does not read, or understand English or French?	a) If a participant is unable to read, an impartial witness must be present during the entire informed consent discussion b) If the subject does not speak the language used in the consent form they should not sign it c) The informed consent discussion should take place in the subject's first/preferred language, using a qualified interpreter d) a) and c)	**Correct Answer: d)** a) and c) **Rationale:** If a subject is unable to read, an impartial witness must be present during the entire informed consent discussion. If the subject does not speak English or French (where applicable), the informed consent discussion must take place in the subject's first/preferred language, using a qualified interpreter. (Section 5.4)	
SOP 105_01 Document Quality and Care for	1. Good documentation practices for data	a) Entering data in a sequential manner with an empty space between entries.	**Correct Answer: c)** Recording both collection and data entry dates for data obtained after a late visit.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
Biorepositiories	entry includes:	b) Inserting late data between existing entries or in the margin. c) Recording both collection and data entry dates for data obtained after a late visit. d) a) and b)	**Rationale: Section 5.2:** Do not insert late data between existing lines or in the margin. Record data following other entries, with the notation of late entry	
	2. The privacy and confidentiality of participants is best protected by:	a) Ensuring that only electronic devices are used for biorepository purposes. b) Retaining a signature sheet that identifies who has access and those who can enter or correct data. c) Identifying participant data by using unambiguous codes that includes. identifying information d) Only allowing data for REB/IEC-approved research to leave the institution. e) Destroying lists that link participants to study identifiers.	**Correct Answer: b)** Retaining a signature sheet that identifies who has access and those who can enter or correct data. **Rationale: Section 5.4:** Confidentiality 7 Direct Access to Clinical Data & Source Documents-5.4.3 In addition to privacy regulations, policies and procedures, the privacy and confidentiality of participants is protected by ensuring that a record, in the form of a signature sheet, is kept of any persons who can access, enter or correct source data.	
SOP 106_01 Database System Set-Up, Maintenance and Security	1. Who is responsible for assigning identification codes, establishing a Disaster Recovery	a) The biorepository Director b) IT System Administrator c) The Data Management Director d) Principal Investigator	**Correct Answer: b)** IT System Administrator **Rationale: Section 5.3.13** The IT system administrator is the	**Complete**

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	Plan, and updating delegation of tasks form?		person in charge of system management and has responsibility that includes assigning identification codes, establishing a disaster recovery plan and updating the delegation of tasks form.	
	2. Key elements of physical security measures includes:	a) Ensuring that computer systems used for housing databases are protected by firewalls b) Complying with regulatory requirements and privacy legislation c) Securing Data Management System components behind locked doors, and using magnetic cards or biometric recognition systems d) Creating a plan for web-based applications that includes database access privileges	**Correct Answer: c)** Securing Data Management System components behind locked doors, and using magnetic cards or biometric recognition systems **Rationale: Section 5.3.9** The physical security of premises where components such servers, workstations, and external drives are protected behind locked doors, and accessed using magnetic cards or biometric recognition systems.	**Complete**
SOP 107_01 File Transfers for Biorepositories	1. Data security is best maintained the following methods **EXCEPT**:	a) Encrypting files for transfer using local encryption methods and software. b) Files may also be transferred as password protected compressed archives or transferred directly using encrypted file transfer.	**Correct Answer: c)** **Rationale: Section 5.2** Data security is maintained by encrypting files for transfer using local encryption methods and software. Files may also be transferred as password protected compressed	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		c) Using regular, unencrypted email methods, and informing recipient files when files have been sent, to ensure timely opening of the email d) Ensure that the original data files that are to be received by the data centre and that are to be transferred into the database are write-protected and are included in the data archiving process	archives or transferred directly using encrypted file transfer. Ensure that the original data files that are to be received by the data centre and that are to be transferred into the database are write-protected and are included in the data archiving process an email message as a secondary option. Using regular, unencrypted email methods, and informing recipient files when files have been sent, to ensure timely opening of the email is not an adequate way to maintain data security	
	2. When sending data files, how do you ensure that the file was received?	a) Request verification or documentation from the receiving site that the file was received and verified b) Send a follow up email to the receiving site c) Ensure that the data file is accompanied by content and format documentation d) Record the number of observations and variables to verify the data	**Correct Answer: a)** Request verification or documentation from the receiving site that the file was received and verified **Rationale: Section 5.3.4** To ensure that the file was received and verified, request documentation from the receiving site or provide documentation to the transmitting site.	
SOP 108_01 Clinical Annotation for Biorepositiories	1. When collecting clinical data, it is important to:	a) Conform to requirements stipulated by applicable regulatory authorities.	**Correct Answer: a)** **Rationale : Section 5.2**	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		b) Collect data without obtaining informed consent c) Ensure collected data is shared with researchers. d) a) and b)	Collected clinical data must be in accordance with all applicable regulations and guidelines, and Research Ethics Boards (REB)/ Independent Ethics Committees (IEC).	
	2. Specimens with incomplete data can still be useful:	a) To facilitate data sharing and understanding b) To track treatment and participant outcomes c) For limited research applications d) To protect participants and comply with privacy regulations	**Correct Answer: c)** For limited research applications **Rationale: Section 5.3** Specimens with an incomplete data set will still be useful but for a more limited set of research applications.	
Complete	1.Tracking procedures for biorepository materials is essential to:	a) Allow for keeping complete inventory and generating a full audit trail of changes made to the database system b) Ensure there is enough freezer, refrigerator or storage space is assigned c) Update the inventory to allow for the rejection of samples d) Identify specimens using bar codes and identifiers	**Correct Answer: a)** Allow for keeping complete inventory and generating a full audit trail of changes made to the database system **Rationale: Section 5.2** A tracking and inventory system should ensure that it is capable of generating a full audit trail of changes made to the database or system.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. Labeling of human biological sample receptacles should	a) Include only computer printed barcodes b) Be printed using only enough information to identify the contents c) Be specific and include medical record numbers and patient identifiers as long as long as they are compliant with privacy legislation d) Not include additional information e) Allow for unique identifiers or tracking numbers to be associated with samples in the database	**Correct answer: e)** Allow for unique identifiers or tracking numbers to be associated with samples in the database **Rationale: Section 5.1** Ensure that the information is specific enough so that the encoded information can be associated with the sample in the database.	
SOP 110_01 Blood Collection for Biorepositories	1. Which of the following is correct?	a) Record the time and date of the blood draw immediately before drawing the blood. b) Record the date of the blood draw immediately after drawing blood, the time of the draw is not necessary to record. c) Record the time and date of the blood draw immediately after drawing the blood. d) Record the date of the blood draw immediately before drawing blood, the time of the	**Correct answer: c)** Record the time and date of the blood draw immediately after drawing the blood. **Rationale: Section5.3.6** The date and time is recorded immediately after drawing. The time and data of the draw may be valuable information to researchers who use the samples in the future. Labeling immediately after drawing the blood helps ensure the most accurate date and time information is on the vial.	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		blood draw is not necessary to record.		
	2. When transporting blood samples to pathology department ensure:	a) The tubes are placed on dry ice to keep cold during transportation. b) Place in a thermal pack of 30 degrees Celsius to keep samples warm. c) Transport the tubes at room temperature. d) The temperature during transportation is not important as blood is a stable substance.	**Correct answer: c)** Transport the tubes at room temperature. **Rationale: Section 5.4.4** Transport tubes at room temperature. Do not allow the samples to freeze or be exposed to an ambient temperature of greater than 25° C. Variations in temperature affect the blood samples and may result in lower or higher results for specific makers when analyzed.	**Complete**
SOP 111_01 Blood Processing and Storage for Biorepositories	1. Fractionate the collected whole blood (for plasma) by:	a) Centrifuging at 1500-2000 x g for 15 minutes at room temperature. b) Centrifuging at 150-200 x g for 15 minutes at room temperature. c) Centrifuging at 1500-2000 x g for 1.5 minutes at room temperature. d) Centrifuging at 150-200 x g	**Correct answer: a)** Centrifuging at 1500-2000 x g for 15 minutes at room temperature. **Rationale: Section 5.3.1** 1500 to 2000 x g for 15 minutes at room temperature is the optimum conditions for blood fractionation. Therefore, fractionate the whole blood (blood collected in tubes	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		for 1.5 minutes at room temperature.	containing an anticoagulant such as EDTA or Heparin) by centrifuging at 1500-2000 x g for 15 minutes at room temperature.	
	2. After the whole blood has been fractionated (for plasma) the blood is separated into the following three layers	a) Upper Layer: Buffy Coat Middle Layer: Plasma Bottom Layer: Red Blood Cells b) Upper Layer: Plasma Middle Layer: Buffy Coat Bottom Layer: Red Blood Cells c) Upper Layer: Red Blood Cells Middle Layer: Plasma Bottom Layer: Buffy Coat d) Upper Layer: Buffy Coat Middle Layer: Red Blood Cells Bottom Layer: Plasma	**Correct answer: b)** Upper Layer: Plasma Middle Layer: Buffy Coat Bottom Layer: Red Blood Cells **Rationale: Section 5.3.1** The upper layer is generally clear and pale yellow in colour. The second layer is a narrow grayish white interface band representing the "buffy coat" or leukocyte fraction. The third or bottom layer is dark red and consists of the erythrocytes or red blood cells.	
SOP 112_01 Nucleic Acid Extraction from Blood Specimens	1. What is the optimal temperature to store extracted RNA at:	a) -80 degree Celsius or lower. b) Room temperature c) -20 degree Celsius or lower. d) Core body temperature ranging from 36 to 38 degrees Celsius.	**Correct answer: a)** -80 degree Celsius or lower. **Rationale: Section 5.2.5** Store RNA samples at -80º C or lower. Warmer temperature storage can result in lower quality RNA over time.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. Which of the following general extraction considerations is **NOT** true:	a) Due to the sensitivity of nucleic acid amplification technologies, precautions should be taken to avoid cross contamination of samples. b) Avoid cross-contamination after each vortexing step, briefly centrifuge the tubes to remove droplets that may be on the lids of the tubes. c) Take care not to introduce RNase or DNase into the sample during or after the purification procedure. d) Using an aerosol-barrier is not recommended.	**Correct answer: d)** Using an aerosol-barrier is not recommended. **Rationale: Section 5.1.3** Always use aerosol-barrier tips. Aerosol-barrier tips prevent liquid contamination.	
SOP 113_01 Tissue Collection and Transportation to Pathology	1. What is the recommended maximum time between the biopsy/resection and time of freezing of a given sample?	a) 30 minutes b) 5 minutes c) 1 minute d) 60 minutes	**Correct answer: a)** 30 minutes **Rationale: Section 5.2.6** Ensure that no more than 30 minutes elapses between the time of biopsy/resection and time of freezing of a given sample. If, due to practical considerations, the elapsed time is greater, records must clearly document the actual time period. If samples are left out for longer than 30 minutes it can compromise the sample quality.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. Which of the following should **NEVER** be done?	a) Placing tissue intended for banking as a fresh frozen specimen in formalin. b) Collect only tumour tissue that is surplus to clinical needs and diagnosis for the biorepository. c) Encourage the Operating Room (OR) staff to notify the pathologist or designate about the time of ischemia (when blood vessels were clamped). d) Transport the tissue from the Operating Room to the Pathology Lab, using a rapid specimen transport protocol.	**Correct answer: a)** Placing tissue intended for banking as a fresh frozen specimen in formalin. **Rationale: Section 5.1.3** Never place tissue intended for banking as a fresh frozen specimen in formalin. Fresh Frozen specimens are not preserved in formalin. OCT is generally used.	
SOP 114_01 Tissue Harvesting for Biorepositories	1. What is the recommended maximum time that can elapse between the time of biopsy/resection and the time of freezing of a given	a) 5 minutes b) 60 minutes c) 30 minutes d) 12.5 minutes	**Correct answer: c)** 30 minutes **Rationale: Section 5.1.14** Timing is critical. Ideally, no more than 30 minutes must elapse between the time of biopsy/resection and time of freezing of a given sample. If, due	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	sample?		to practical considerations, the elapsed time is greater, records must clearly document the actual time period (in hours).	
	2. When there is an abundant amount of tumour the recommended harvest sample size is:	a) 2 to 3 mm^3 b) 10 to 11 mm^3 c) 1 to 2 mm^3 d) 3 to 4 mm^3	**Correct answer: d)** 2 to 3 mm^3 **Rationale: Section 5.1.12** If there is abundant tumour, attempt to harvest about 3-4 mm3 or more (depending on size and availability). Taking less than this amount may make the sample too small to conduct analysis on.	
SOP 115_01 Freezing Tissues for Biorepositories	1. How soon should tissue be optimally frozen after resection to preserve DNA, RNA and protein?	a) Within 60 minutes b) Within 30 minutes c) Within 2 hours d) Within 12 hours e) Within 24 hours	**Correct Answer: b)** Within 30 minutes **Rationale: Section 5.1.2** As soon as tissue is removed from its blood supply, it begins to degrade. Enzymes, protein and RNA are most sensitive, but DNA will also start to break down if not snap frozen shortly after resection.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. What medium is used to embed frozen tissue?	a) Optimal Cutting Temperature (OCT) b) formalin c) paraffin d) culture medium e) saline	**Correct Answer: a)** Optimal Cutting Temperature (OCT) **Rationale: Section 5.2.5** Optimal Cutting Temperature (OCT) medium is used as a support medium for frozen tissue sections cut at -20C. Frozen sections may be stained for rapid pathology examination without the need for fixation in formalin.	
SOP 116_01 Preservation of Tissue: Paraffin Embedding	1. How long should tissue be fixed in formalin before paraffin embedding?	a) 1-2 hours b) 2-12 hours c) 12-24 hours d) 24-48 hours e) At least 48 hours	**Correct Answer: d)** 24-48 hours **Rationale: Section5.2.9** Proper tissue fixation terminates any ongoing biochemical reactions and increases the stability of the treated tissues. Overfixation may interfere with immunohistochemical analysis.	
	2. At what temperature should FFPE blocks be stored?	a) Room temperature (20-25C) b) Refrigerator (4C) c) Freezer (-20C) d) Log temperature freezer (-80C) e) Liquid nitrogen freezer (-180C)	**Correct Answer: a)** At room temperature (20-25C) **Rationale: Section 5.3.10** Formalin fixed and paraffin embedded (FFPE) blocks are stable at room temperature indefinitely when temperature and humidity are controlled and exposure to light is minimized.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
SOP 117_01 Sectioning of Paraffin and OCT Embedded Tissue	1. How thick are tissues cut for histological sections?	a) 1-2 microns b) 2-5 microns c) 4-5 microns d) 10-20 microns e) 20-50 microns	**Correct Answer: c)** 4-5 microns **Rationale: Section 5.2.3** The average diameter of a cell is 10uM, so tissue sections are cut 4-5 uM for optimal histopathologic analysis. Thicker sections may be cut for other purposes such as nucleic acid extraction.	
	2. What device are frozen sections cut on?	a) Cryotome b) Cryomold c) Microtome d) Hemostat e) Microscope	**Correct Answer: a)** Cryotome **Rationale: Section 5.2.1** The cryotome is refrigerated so that the tissue remains frozen while being cut. It is known as a cryostat.	
SOP 118_01 Haematoxylin and Eosin Staining of Tissue Sections	1. What cellular components stain blue with hematoxylin?	a) Nuclei b) Cytoplasm c) Connective tissue d) a) and c) e) b) and c)	**Correct Answer: a)** **Rationale: Section 5.18** Hematoxylin stains basophilic structures such as the cell nucleus.	
	2. What cellular component stains red/pink with eosin?	a) Nuclei b) Cytoplasm c) Connective tissue d) a) and c) e) b) and c)	**Correct Answer: e)** **Rationale: Section 5.18** Eosin stains acidophilic structures such as the cytoplasm. Hematoxylin and eosin stain (H&E stain) is one of the	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
			principal stains in histology allowing the pathologist to differentiate various normal and diseased cell types as well as intracellular and extracellular components.	
SOP 119_01 Nucleic Acid Extraction from Tissue	1. At what temperature should extracted RNA be stored?	a) 37C b) Room temperature c) 4C d) -20C e) -80C or colder	**Correct Answer: e)** -80C or colder **Rationale: Section 5.2.22** RNA is particularly sensitive to degradation. RNA integrity is crucial for obtaining reliable and meaningful gene expression data.	
	2. At what temperature should extracted DNA be stored?	a) 37C b) Room temperature c) 4C d) -20C e) -80C or colder	**Correct Answer: c)** 4C **Rationale: Section 5.4.4** DNA is much more stable than RNA. DNA may be extracted from fixed or frozen tissue and stored indefinitely at 4C or colder.	
SOP 120_01 Assessing Quality of Tissue Specimens	1. As applicable to specimen type, the review of tissue should confirm and asses the following:	a) Tissue type and diagnosis, tumour type and grade, presence of tumour cells, percent cellularity of tumour and stroma, percent necrosis of signs of degradation, presence of inflammatory cells b) Specimen quality, harvesting times of specimen collection,	**Correct Answer: a)** Tissue type and diagnosis, tumour type and grade, presence of tumour cells, percent cellularity of tumour and stroma, percent necrosis of signs of degradation, presence of inflammatory cells **Rationale: Section 5.2.2**	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		harvesting and freezing c) Morphologic review, quality of collection and storage practices, scoring system d) Tissue type and diagnosis, scoring system, presence of tumour cells, percent cellularity of tumour and stroma, percent necrosis and signs of degradation, presences of inflammatory cells.	These are the parameters of assessment used to allow the pathologist to develop a "quality score" for a particular tissue or molecular sample.	
	2. Reviews for tissue should be done by:	a) The study PI b) A Technician c) A Study Nurse Coordinator d) A qualified Pathologist	**Correct Answer: d)** A qualified Pathologist **Rationale: Section 5.1** A defined "quality score" will be assigned to a sample that has undergone assessment at a designated quality control lab.	
SOP 121_01 Assessing Quality of Nucleic Acids	1. What percentage of your stored samples should you assess for DNA quality?	a) 0.1% b) 10% c) 1% d) 100%	**Correct Answer: c)** 1% **Rationale: Section 5.2.1** One percent of the blood and tumour tissue samples stored should have the DNA quality assessed.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. What is considered a high quality DNA score and a low quality score?	a) 12 high, below 5 low b) 10 high, below 7 low c) 15 high, below 5 low d) 5 high, below 1 low	**Correct Answer: b)** 10 high, below 7 low **Rationale: Section 5.2.6** A score of 10 is indicative of high quality DNA; a score below 7 is indicative of poor quality DNA.	
	3. Which RNA bands run on gel are indicative of intact RNA?	a) 28s and 18s b) 260s and 280s c) 20s and 10s d) 18s and 8s	**Correct Answer: a)** 28s and 18s **Rationale: Section 5.4.4** After running a small amount of the sample on a denatured agarose gel to visualize the ribosomal RNA bands (28s and 18s). Crisp 28s and 18s bands are indicative of intact RNA. A 2:1 ratio of 28s:18s species has been considered a benchmark for intact RNA.	
SOP 122_01 TMAs from Paraffin Embedded Tissue blocks	1. Who is responsible for designating representative tumour on the blocks or slides?	a) Pathologist b) Technologist c) PI d) Nurse coordinator	**Correct Answer: a)** Pathologist **Rationale: Section 5.2.1** The pathologist will examine the slides/tissue blocks and mark areas that are suitable to represent the tumour as per the basis the research study block is being designed for.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. What are the recommended storage parameters for non-paraffin dipped/protected slides?	a) Room temperature in slides case for no more than 3 months b) Refrigerated at 4°C c) Room temperature in slide case for no more than 2 months d) Frozen at -4° C for no more than 3 months	**Correct Answer: b**) Refrigerated at 4°C **Rationale: Section 5.4.3** Keep non-paraffin dipped/ protected slides at 4° C in a standard micro-slide box. This is sufficient for most antigens and prevents degradation of tissue.	
SOP 123_01 Specimen Retrieval from Biorepositories	1. What is the uniform effective cooling rate for a biospecimen?	a) 0.5°C per 20 min b) 1°C per min c) 1° C per 10 min d) 0.5°C per min	**Correct Answer: b)** 1°C per min **Rationale: Section 5.1.1** The rate of cooling controls the size of the ice crystals and how fast they are formed within the cells. This may affect cell recovery. The rate of 1° C per minute from ambient temperature is effective for a variety of cells.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. What is the ideal thaw condition from a frozen state for a frozen biospecimen?	a) 1°C per min b) Room Temperature c) 37° C water bath d) Move sample to wet ice for 10min and then room temperature	**Correct Answer: c)** 37° C water bath **Rationale: Section 5.1.4** Although slow cooling is best for cell viability, the opposite is true for thawing from frozen state. Agitation of the sample in a 37°C water bath is best for cells, but may be damaging to certain cells if the process is done too long.	
SOP 124_01 Material Request and Release from Biorepositories	1. What information is required on the Material Request and Release form from the researcher, when requesting biospecimens?	a) Applicant's name and contact, title of project, Sponsor information, Ethics review and approval, Curriculum Vitae of the applicant. b) Title of project, Methodology, funding, Types and quantity of samples required c) Applicant's name, Title and description, Funding, Study Calendar d) Title of project, Methodology, staff list, Ethics Review approval	**Correct Answer: b)** Title of project, Methodology, funding, Types and quantity of samples required **Rationale: Section 5.2.1** The material request form should help obtain the following information from the requesting researcher: • Applicant's name and research project • Title and description of research project • Duration and proposed start date • Methodology of research project • Funding Source • Types and quantity of samples	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
			required • Ethics review and approval for Research project • Curriculum Vitae of the applicant	
	2. What is the approximate how turnaround times in days for reviewing requests and review outcomes for biospecimens?	a) 60 days, and 5 days b) 20 days, and 2 days c) 30 days, and 3 days d) 40 days, and 2 days	**Correct Answer: c)** 30 days and 3 days **Rationale: Section 5.5** Turnaround times for reviewing requests should be 30 days or less from the date of receipt of the request. The Biorepository review committee review outcomes should be communicated to the researcher within 3 working days of the decision.	
SOP 125_01 Completing Materials Transfer Agreement	1. The biospecimen may be released to a third party upon approval of the	a) Donor b) Principle Investigator c) Hospital CEO d) REB/IEC	**Correct Answer: d)** REB/IEC **Rationale: Section 5.1.5** Biospecimen must not be provided to a third party without the approval of the REB/IEC and the signing of a MTA. The REB/IEC is responsible for ensuring the transfer of materials follows the appropriate rules and regulations.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
	2. Who should sign the Material Transfer Agreement?	a) Donor b) REB/IEC c) Researcher and an appropriate representative from the biorepository d) Appropriate representative from the biorepository	**Correct Answer: c)** Researcher and an appropriate representative from the biorepository **Rational: Section 5.1.3** Upon approval of release by the REB/IEC, the MTA must signed by the researcher, and the appropriate representative from the biorepository.	
SOP 201_01 Labelling and Tracking Biospecimens for Clinical Trials	1. Which of the following should you **NOT** do?	a) Include only information on the label that is compliant with applicable privacy legislation, such as protocol number, study ID, sample type, and time point. b) Include patient identifying information, such as medical record number on the label. c) Ensure that the information is specific enough so that the encoded information (e.g., unique identifier or accession number) can be associated with the biospecimen in the inventory system, and on the corresponding study requisition. d) Record the assigned unique identifier, such as the	**Correct Answer: b)** Include patient identifying information, such as medical record number on the label. **Rationale: Section 5.1.4** Do not include patient identifying information, such as medical record number on the label. Including this information may violate patient confidentiality. Only the information that is compliant with privacy legislation should be included on the label.	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		accession number or bar-code from each biospecimen at the time of collection or receipt.		
	2. Which of the following is **NOT** mandatory when labeling specimens?	a) Label all level of receptacles containing human biospecimens or products, from the smallest unit (cryovial, histological slide, or filter) to the large storage units, with a patient-specific label. b) Ensure that each label used adheres tightly to the receptacle under all projected storage conditions. c) Ensure that the printing on the labels is resistant to all common laboratory solvents and water d) Always include on the label the date and time of collection.	**Correct Answer: d)** Always include on the label the date and time of collection. **Rationale: Section 5.1.6** Optional: If there is sufficient space on the label, include additional information such as date of collection and time of collection. Include only static information. For some protocols it may be mandatory to record date and time, for others it may not be mandatory. Refer to specific protocol.	
SOP 202_01 Destruction of Human Specimen Material	1. Which of the following is **NOT** a step to be taken in the destruction of human specimen material?	a) Retrieve specimens from storage facility. b) Thaw all frozen samples. c) Remove all labels from specimen containers. d) Record specimen disposal in inventory system.	**Correct Answer: b)** Thaw all frozen samples. **Rationale: Section 5.1** There is no need to thaw frozen samples prior to disposing of them. Simply dispose of samples in	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
			appropriate biohazardous waste container as per institutional procedures.	
	2. With whom should you confirm the destruction of specific specimens?	a) Patient/donor b) Any qualified biobank colleague that has access to the samples and can confirm the destruction of the correct sample(s) c) The biobank's data collector(s) d) Qualified investigator	**Correct Answer: d)** Qualified investigator **Rationale: Section 5.1.2** This section of the SOP clearly states that prior to destruction of any samples, one must confirm destruction of specific samples with the qualified investigator.	
SOP 203_01 Blood Collection and Storage for Clinical Trials	1. Which of the following statements regarding preparation for drawing blood is **NOT** true:	a) Ensure that blood collection is performed by qualified personnel. b) Complete the required participant information on the blood specimen requisition c) Assemble blood collection tubes and supplies required d) Assess participant's physical and mental disposition, and determine if this is the appropriate time to draw blood. e) Blood should be draw at a time that is convenient for	**Correct Answer: e)** Blood should be drawn at a time that is convenient for the patient. **Rationale: Section 5.2.1-5.2.4** Blood draws for clinical trials need to be performed at the time points established by the trial and not at the convenience of the patient. Time points are specific due to the criteria of the trial and could influence outcomes if not followed correctly.	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		the patient.		
	2. Which of the following statements is **NOT** true regarding performing a venipuncture draw:	a) Confirm participant's identity b) Place participant in a sitting or supine position c) Hyperextend the participant's arm, and apply tourniquet to expose veins. Do not apply too tightly. If superficial veins are not readily apparent, force blood into the vein by massaging the arm from wrist to elbow, tap the site with index and second finger, apply a warm/damp cloth to the site, or lower extremity to allow veins to fill. d) Select suitable site for venipuncture. Avoid areas with excessive scars or hematomas. Note: Hand and wrist veins are acceptable; however, antecubital veins are optimal. e) Immediately after performing the venipuncture, recap the needle and discard in the nearest waste basket.	**Correct Answer: e)** Immediately after performing the venipuncture, recap the needle and discard in the nearest waste basket. **Rationale : Section 5.3.1-5.3.12** NEVER recap a needle for any reason. Recapping needles is the leading cause of unnecessary finger pokes of phlebotomist. Also never toss a used needle into the regular garbage. Needle need to be disposed of in a proper sharps container.	
SOP 204_01 Blood Processing	1. Which of the following general	a) Blood may be drawn from a study participant after the	**Correct Answer: c**) Serum must be processed after 90 minutes in order to	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
and Storage for Clinical Trials	practices regarding blood processing is false?	patient has been through the informed consent process and has consented to participate in the clinical trial b) Record the time of blood collection and time of blood processing. c) Serum must be processed after 90 minutes in order to allow time for coagulation. d) Plasma and buffy coat should be processed within 30 minutes.	allow **Rationale: Sections 2.0 and 5.1** As per section 2.0, blood for clinical trials may only be drawn after patient has consented to participate in the trial. As per section 5.1, time of blood collection and processing must be recorded and plasma and buffy coat should be processed within 30 minutes. Serum must be processed after one hour, not 90 minutes.	
	2. Which of the following is **NOT** a step in the separation of serum, as outlined by this SOP?	a) Incubate tubes containing whole blood and silica for one hour to allow coagulation to occur b) Collect whole blood in tubes coated in a clotting activator c) Discard supernatant that is leftover after clotting and centrifuging d) Serum should be placed in cryovials labeled with storage address	**Correct Answer: c)** Discard supernatant that is leftover after clotting and centrifuging **Rationale: Section 5.4, especially section 5.4.5** The supernatant, the fraction of the blood that has not clotted, is the serum. Do not discard! Aspirate the supernatant and transfer to labeled cryovials.	
SOP 205_01 Tissue Biopsy Collection and Processing for	1. Which of these considerations regarding tissue biopsy collection	a) Biopsy samples obtained for nucleic acid research do not need to be preserved within 30 minutes due to the ability	**Correct Answer: a)** Biopsy samples obtained for nucleic acid research do not need to be preserved within 30 minutes due to the ability of these	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
Clinical Trials	and processing is false?	of these molecules to survive long periods of time at room temperature b) If sample cannot be immediately preserved, keep moist with saline until preservation takes place c) Certain agents or treatments that inactivate degrading enzymes may be used on tissue samples to preserve nucleic acid integrity. d) Biopsy samples must be taken with a needle at least 18G in size.	molecules to survive long periods of time at room temperature **Rationale: Sections 5.2.8, 5.2.9** For optimal sample quality, biopsy samples should be preserved within 30 minutes of collection, regardless of the type of research being conducted.	
	2. Which of the following biopsy tissue preparations requires freezing in liquid nitrogen?	a) Optimal Cutting Temperature Compound b) RNAlater® c) Formalin fixation d) 70% ethanol	**Correct Answer: a)** Optimal Cutting Temperature Compound **Rationale: Sections 5.1.3, 5.3.4, 5.4.4, 5.5.5, 5.6.3.** Specimens used for extraction of nucleic acids and protein may be snap frozen in a cryovial with no other agents. Cryomolds containing OCT and a tissue sample must be submerged in liquid nitrogen to freeze and set OCT. Specimens stored in vials containing RNAlater® may be	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
			stored in a -80°C freezer *or* in liquid nitrogen.	
	3. Which statement regarding the process of specimen freezing in OCT compound is **INCORRECT?**	a) Place a few drops of the OCT compound in empty cryomold b) Submerge cryomold and OCT in liquid nitrogen to set first layer of OCT c) Release any air bubbles trapped around tissue submerged in OCT media d) Submerge cryomold containing biopsy specimen and all OCT media in liquid nitrogen.	**Correct Answer: b)** Submerge cryomold and OCT in liquid nitrogen to set first layer of OCT **Rationale: Sections 5.5, 5.5.1, 5.5.2, 5.5.4, 5.5.5** There is no need to submerge mold in liquid nitrogen a first time until biopsy specimen is in mold and covered in OCT media.	
SOP 206_01 Archival Tissue Request and Release for Clinical Trials	1. When requesting archival tissue, which of the following must be communicated with the originating institution?	a) Title and description of research project, names of all employees working on clinical trial, participant's name and date of birth b) Qualified/Principal Investigator name and contact information, surgical specimen required, destination and designated recipient of archival tissue, name of surgeon who excised tissue c) Tissue requirements for	**Correct Answer: d)** Title and description of research project, participant's name and date of birth, surgical specimen required, destination of tissue **Rationale: Section 5.1.1** All items listed in point d) are required when requesting archival tissue from originating institution. The names of all employees working on the clinical trial, name of surgeon who excised tissue, and clinical research coordinator's name and	

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		blocks or slides, surgical specimen required, clinical research coordinator's name and contact information d) Title and description of research project, participant's name and date of birth, surgical specimen required, destination of tissue	contact information are not required.	
	2. What is **NOT** required before a request for archival tissue is made?	a) Patient has given his/her informed consent and signed ICF b) Slides have been made from archival tissue c) Research Ethics Board approval d) Patient has undergone a previous surgical procedure (e.g, biopsy, surgery)	**Correct Answer: b)** Slides have been made from archival tissue **Rationale: Sections 2.0, 5.1.2** Patient consent and Research Ethics Board approval must be obtained prior to requesting archival tissue. In order for there to be archival tissue to be requested, the patient must have had a previous surgical procedure or there would not be a surgical specimen, nor a surgical specimen number to reference. Slides do not need to be made from archival tissue; many analyses required whole blocks.	
SOP 207_01 Specimen Retrieval	1. Which of the following is **NOT** a step in the retrieval of specimens?	a) Locate storage location of specimens to be retrieved and remove specimens from storage.	**Correct Answer: b)** Contact study's qualified/principal investigator to let him/her know samples are being retrieved	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		b) Contact study's qualified/principal investigator to let him/her know samples are being retrieved c) File deviation reports for samples that are missing or found in an incorrect location d) Compile completed study requisitions for all specimens to be retrieved	**Rationale: Sections 5.2.1, 5.2.2, 5.2.3** Steps a) and d) must be completed when retrieving specimens. Step c) needs to be completed when samples are discovered to be missing or found in incorrect storage location during retrieval. The study's qualified/principal investigator does not need to be notified when the samples are being retrieved.	
	2. Which of the following is true regarding specimen retrieval?	a) Each time a specimen is retrieved, the inventory system must be updated with the date the specimen was retrieved and its new location b) When retrieving several frozen cryovials, store them in a shallow bath of liquid nitrogen to allow the samples to be sorted. c) Samples are never to be stored on dry ice because of its designation as a dangerous good. d) Specimens being used for nucleic acid research can be exposed to slightly higher temperatures because of the	**Correct Answer: a)** Each time a specimen is retrieved, the inventory system must be updated with the date the specimen was retrieved and its new location **Rationale: Section 5.2.5** All specimens must be tracked so their location is known at all times. Therefore, the inventory system must be updated with the date the specimen was retrieved and its new location. Frozen cryovials should be stored on dry ice when sorting samples but caution should be practiced with this dangerous good. The amount of time specimens spend at higher temperatures should be	

Biospecimen SOP Version 1.0 Quiz Questions-with justification

SOP Number-Title	Question	Multiple Choice	Justification	COMMENTS
		ability of these molecules to tolerate extreme conditions.	reduced or eliminated, regardless of the nature of the research project being conducted.	