

Document History:

Title: Pathology Specimen Release Policy **Site(s):** Shared Health Diagnostic Services
All SH Pathology Laboratories

Document #:	170-10-12	Version #:	04
Section:	Pathology	Subsection:	General

Approved by: <i>(approval on file)</i>	Lisa Manning	Date:	24-MAY-2023
		Effective Date:	29-JUN-2023

Details of Recent Revision

- Added 3.2
- Revised 3.3 and 6.1.2

DISCLAIMER: Please be advised that printed versions of any policy, or policies posted on external web pages, may not be the most current version of the policy. Although we make every effort to ensure that all information is accurate and complete, policies are regularly under review and in the process of being amended and we cannot guarantee the accuracy of printed policies or policies on external web pages. At any given time, the most current version of any Shared Health Inc. policy will be deemed to apply. Users should verify that any policy is the most current policy before acting on it.

1.0 PURPOSE

- 1.1 Tissue is sent to Pathology for diagnostic testing.
- 1.2 Pathology specimens are potentially infectious and have also been fixed in formalin which is a known carcinogen, therefore care must be taken when releasing these specimens to the public.
- 1.3 The purpose of this policy is to establish an environmentally safe and standardized process for releasing specimens/samples sent to pathology to a patient or substitute decision maker when requested. In the event a patient or substitute decision maker requests a specimen be released from a Shared Health Manitoba (SHSH) pathology laboratory, the Pathology Specimen Release Policy must be followed.

2.0 DEFINITIONS

- 2.1 Substitute decision maker: a third party identified to participate in decision-making on behalf of a patient who lacks decision making capacity. The task of a substitute decision maker is to faithfully represent the known preferences or, if the preferences are not known, the best interests of the incapable patient. For a minor who does not have decision making capacity, this means a legal guardian, such as Child & Family Services or a parent. Where issues respecting parental custody exist, a copy of the court order should be requested.
- 2.2 Intermediary – may include staff members from social work, spiritual care, patient services, and funeral homes.
- 2.3 Persons permitted to exercise the rights of an individual. Any of the above can make the request on the patient's behalf.

3.0 POLICY

- 3.1 Pathology specimens (for burial or any other) will not be released from the laboratory until the laboratory has received a signed Authorization to Release Pathology Specimen Form (F170-10-12 A) or one of the following facility forms:
 - 2.1.1 Consent for Release of Remains of Perinatal Loss Form (HSC NS00520)
 - 2.1.2 SBH form (SBH admitting has their own release form)

NOTE: WL, will use the attached form if a different form is not submitted and may work through the ward (RMC-single room maternity care). They will accept Miscarriage Options Forms/Request for Perinatal Loss Forms from outside facilities as long as the paperwork is signed and a funeral home has been assigned.
- 3.2 It is the lab's preference not to give slides/blocks to patients but rather to maintain direct pathology to pathology communication from lab to lab/facility to avoid any risk for damage/loss of materials.
- 3.3 A patient's or substitute decision maker's request to release a pathology specimen directly to a licensed funeral home or licensed organization for burial can be released as soon as the case has been signed out by a pathologist.
- 3.4 If a patient or substitute decision maker requests that a pathology specimen be directly released to the patient or substitute decision maker (outside of perinatal loss, release to a funeral home or explanted medical devices), lab staff should request assistance from SH Privacy Officer (204-926-7858) or SH Privacy Coordinator (204-926-1402). See example of exception request-Appendix 2.
- 3.5 If request to release tissue is from a perinatal loss and the facility's Spiritual Care or Maternity ward staff are acting as an intermediary, SH will follow the intermediary policy.
- 3.6 Explanted medical devices and /or implants required for litigation will be released only to the appropriate RHA. The RHA will be responsible for sending the explanted medical device and/or implant as per their policy. (WHRA policy on explanted devices is 110.220.060). NOTE: SBH Admitting Department has their own specimen release form that may be used.
- 3.7 Physician requests to return to manufacturer will be dictated by the pathologist and a note will be added to the case stating it was returned to the physician and the date it was returned.
- 3.8 Specimens will be kept for a minimum of 6 weeks post sign out (SH170-10-04 Records and Materials Retention Policy Pathology). Exception: POC's-if not signed out, the site must get the pathologist to sign off on the specimen release. If the authorized party does not pick up the

specimen within 6 weeks the specimen will be respectfully discarded as per SH policy 170-10-26 (Specimen Discard)

3.8.1 Exception: POC specimens requested for return for burial will be handled as per committal of ashes process at each site if not picked up within 3 months.

3.9 SH will give the patient a copy of the signed consent form. A signed copy of the release form will be attached to the specimen upon pick up.

3.10 Any specimen release will be noted as such in the LIS.

4.0 **PROCEDURE TO FILL OUT THE FORM**

4.1 The person requesting the specimen (the patient, intermediary, substitute decision maker, physician) must complete the "Authorization to Release Pathology Specimen form (Appendix 1).

4.2 The form is submitted to the laboratory.

5.0 **PROCEDURE TO RELEASE THE SPECIMEN**

5.1 TO Intermediary:

5.1.1 The intermediary contacts the site and coordinates picking up the specimen from the laboratory.

5.1.2 The intermediary signs the form and/or log sheet (site specific) and indicates the date and time the specimen was picked up.

5.1.3 The lab staff signs the form or log sheet (site specific) to verify the release. (Exception: SBH/ patient registration uses their own release form)

5.1.4 The lab staff determines whether risks need to be explained to intermediary.

5.1.5 The lab provides a print out of the risks. The specimen will also be labeled with a warning sticker.

5.1.6 The lab staff records the release in the LIS for full tracking purposes.

5.1.7 The completed form/log sheet is filed at the laboratory according to site-specific procedures and is retained for two years.

5.2 TO Patient and/or substitute Decision Maker:

5.2.1 Lab staff/SH Client Services contacts patient/Substitute Decision maker to make arrangements for specimen release.

5.2.2 SH Client Services will enter tissue requests into Intelex system.

5.2.3 Patient/Substitute decision maker present to pathology lab as arranged.

5.2.4 Pathology supervisor / Charge technologist reviews the authorization form and verifies patient's ID (PHIN or photo ID)

5.2.5 Pathology supervisor/charge technologists explains the potential hazards to the patient and if required provides impermeable gloves

5.3 The patient signs the form and/or log sheet (site specific) and indicates the date and time the specimen was picked up.

5.4 The lab staff signs the form or log sheet (site specific) to verify the release. (Exception: SBH/ patient registration uses their own release form for cases for burial)

5.5 The lab staff determines whether risks need to be explained to intermediary.

5.6 The lab provides a print out of the risks. The specimen will also be labeled with a warning sticker.

5.7 The lab staff records the release in the LIS for full tracking purposes. The completed form is filed at the laboratory according to site-specific procedures and is retained for two years.

5.8 If client services has been involved and a file has been created, contact them once the specimen has been released. If there is a signed form, contact can be via fax of the signed form to client services (confidential fax line is 204-940-2519). If there is only a log sheet sign off, send notification via email when release is complete.

6.0 INSTRUCTIONS TO PERSONS PICKING UP SPECIMEN/SAFETY

- 6.1 Explain the safety risks involved with the specimen:
 - 6.1.1 10% neutral buffered formalin (the liquid preservative) is a carcinogen and is poisonous.
 - 6.1.2 The formalin has been poured off or the tissue and the tissue washed (if not too small to lose) well with water but it is difficult to remove all preservative.
 - 6.1.3 The tissue or the preservative should NEVER be ingested.
 - 6.1.4 If the specimen was opened and handled in the lab, it is considered 'contaminated' (may have come in contact with other specimens)
- 6.2 Explain the proper handling when dealing with the specimen:
 - 6.2.1 The specimen should be handled while wearing impermeable gloves (water and chemical resistant) such as a nitrile glove.
 - 6.2.2 The specimen if opened should be handled in a well-ventilated area.
 - 6.2.3 The specimen should be kept refrigerated.

7.0 SPECIAL CIRCUMSTANCES

- 7.1 Specimens will not be released if they are Creutzfeldt-Jakob Disease (CJD) suspected or known positive. If a specimen is being released directly to a patient, the lab staff can check with the privacy officer if there are any potential infectious concerns.

8.0 LIS PROCESS

- 8.1 PA will add a retrieval flag.
- 8.2 Choose appropriate tracking station (Hold for Return for Burial/Sent for Return for Burial).
- 8.3 Additional information (funeral home information) can be added to the comments.

APPENDIX 1

Authorization to Release Pathology Specimens

I, _____ hereby authorize this Shared Health Manitoba
Patient Name

Pathology Laboratory _____ to release _____
Specific Location Pathology Specimen

A: Release from Lab to Patient/Intermediary

To me; or to: _____ who is a (choose one):
Family Member Physician

Reason for this request: _____

Telephone number of patient or family member: _____ Patient's DOB: _____

I have had explained to me the material risks of accepting this specimen and understand that all specimens I am receiving are potentially infectious and may contain 10% neutral buffered formalin (a known cancer causing agent, toxic and poisonous) or another preservative. It is recommended that the specimen(s) be kept refrigerated and that impermeable gloves be worn while handling the specimen(s) and that the specimens are handled in a well-ventilated area.

DO NOT DISPOSE OF SPECIMEN OR THE PRESERVATIVE DOWN THE DRAIN OR IN YOUR HOUSEHOLD GARBAGE. The specimen can be returned to a Shared Health Manitoba Pathology site for disposal (Monday-Friday 0800-15:30 hours).

I agree to hold the Shared Health Manitoba Pathology Lab harmless for any subsequent problems arising from accepting this specimen(s) and absolve the facility of any such liability and I am aware of the risks.

Risks explained: YES NO

Dated this _____ day of _____ 20____. Signature: _____

B: Release from Lab to Other

Funeral Home Hospital Ward WHRA/Legal department Other

Signature of authorized funeral home/personnel _____

Date _____

To be filled in at Lab: Release accepted: YES NO

Released by: _____ (Tech) From: _____ Date: _____

Released by: _____ (Pathologist if prior to 6 week sign out retention)

APPENDIX 2**SAMPLE of Exception Request****Request to Release Explanted Prosthetic Aortic Valve**

I, Dr. Sample, request the release of explanted prosthetic aortic valve on surgical pathology – 15/S045840 (PHIN 111065618). The explanted prosthetic aortic valve was received at SH- SBH Pathology on August 19, 2015 and the surgical pathology report was signed out on August 21, 2015 (gross description only).

The explanted prosthetic aortic valve will be used for educational purposes and stored at the valve museum as this is an old fashion Starr-Edward type ball and closed cage valve. The explanted prosthetic aortic valve shall not be reused, nor shall it be given to any patient.

I confirm that the medical device was not explanted due to a recall or premature failure and there were no implications to the patient and no potential for legal ramifications.

Requesting Physician: _____

Specimen Released: _____

Date of Release _____

Released by: _____

APPENDIX 3**FORMALIN HAZARD INFORMATION SHEET**

THIS PATHOLOGY SPECIMEN HAS BEEN PRESERVED WITH 10% NEUTRAL BUFFERED FORMALIN AND REQUIRES PROPER HANDLING.

SAFETY RISKS:

- FORMALIN IS A CARCINOGEN AND IS POISONOUS
- ALL PATHOLOGY SPECIMENS HANDLED IN THE LAB ARE CONSIDERED "CONTAMINATED" (MAY HAVE COME INTO CONTACT WITH OTHER PATHOLOGY SPECIMENS)
- THE SPECIMEN SHOULD BE KEPT REFRIGERATED
- THE SPECIMEN SHOULD ONLY BE HANDLED WHILE WEARING SAFETY GLASSES
- THE SPECIMEN SHOULD ONLY BE HANDLED WHILE WEARING IMPERMEABLE GLOVES (WATER AND CHEMICAL RESISTANT)
- THE SPECIMEN SHOULD ONLY BE HANDLED IN A WELL VENTILATED AREA
- THE TISSUE OR THE PRESERVATIVE SHOULD NEVER BE INGESTED

DO NOT DISPOSE OF SPECIMEN OR THE PRESERVATIVE DOWN THE DRAIN OR IN YOUR HOUSEHOLD GARBAGE. THE SPECIMEN CAN BE RETURNED TO A SHARED HEALTH MANITOBA PATHOLOGY SITE FOR DISPOSAL (MONDAY – FRIDAY 0800 -1530 HRS).

IF EXPOSED: CALL POISON CENTER OR DOCTOR/PHYSICIAN

APPENDIX 4**Warning Sticker Template**

WARNING:
Biohazard/Carcinogen:
10% Neutral Buffered Formalin

DO NOT DISPOSE OF SPECIMEN OR
THE PRESERVATIVE DOWN THE DRAIN
OR IN YOUR HOUSEHOLD GARBAGE.

This specimen can be returned to a
Shared Health Manitoba Pathology site
for disposal
(Monday–Friday 0800-1530 hrs)

IF EXPOSED: Call Poison Centre or Physician