

Developing a Special Request Biospecimen Disposal SOP

A core goal of the NCCCP is to reduce cancer healthcare disparities. An early step in the process is to understand the diverse populations that are cared for, beginning with the study of biospecimens collected for cancer research. Personal, religious, and cultural beliefs can affect an individual's decisions regarding biospecimen disposal or return; therefore, it is important to have policies for the handling of biospecimens that are congruent with the religious and cultural beliefs of the populations served.

Disposal SOP Development and Implementation

The NCCCP Biospecimens Subcommittee developed the NCCCP Special Request Biospecimen Disposal SOP in an attempt to responsibly handle requests related to biospecimens collected from individuals of different cultural backgrounds and ethnicities. The model was based on the protocol at Billings Clinic and the College of American Pathologists (CAP) Guidelines. The generic SOP template was designed to be respectful of the communities served by the NCCCP with the intent of ensuring a mutual understanding of processes for biospecimen handling between pathology custodians and patients who have cultural and/or religious beliefs about human tissue. The subcommittee created the template to help NCCCP sites: 1) encourage and assure patients who might otherwise limit their participation and 2) foster patients' trust that their wishes will be honored.

Development of the disposal SOP template involved many participants from various NCCCP sites, particularly in the research and biospecimen fields.

Stakeholders in the Disparities, Clinical Trials, and Biospecimens Subcommittees were engaged, and site-specific ethics and legal staff were critical to defining issues relevant to such a protocol and ensuring that it could be effectively implemented at NCCCP sites. Tissue procurement staff was also engaged in the process, which allowed for a thorough discussion of the options available to accommodate various religious and cultural beliefs. In addition, pathologists and others involved in tissue processing were consulted to ensure that tissue could be safely returned after processing without causing any increase in

risk of cancer (because of the formalin) or becoming biohazardous if someone then chose to dispose of the tissue in an unapproved manner.

The Special Request Biospecimen Disposal Protocol SOP template includes:

1. A Biospecimen Disposal Standard Operating Model Procedure for Special Requests Outside the Scope of Routine Biospecimen Disposal Policy (page 40).
2. A Model Biospecimen Special Disposal Request Form (page 41).
3. A Model Biospecimen Special Disposal Release Form (page 41).

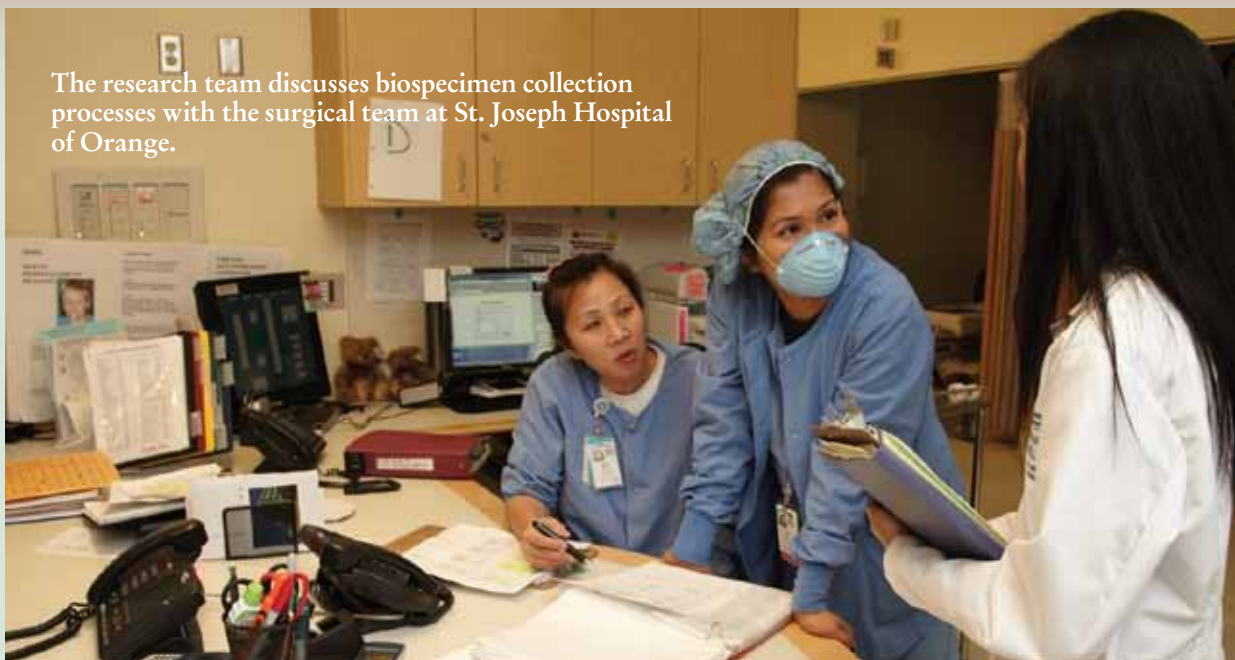
During the protocol development and implementation process, the NCCCP pilot sites shared best practices and



Biospecimen tissue collection during a surgical procedure at St. Joseph Hospital of Orange.

created a process that was “friendly” to the community hospital setting. While special requests for biospecimen disposal may not arise often in some areas of the country, NCCCP sites needed to be prepared to address the issue. The Biospecimens Subcommittee circulated the SOP to NCCCP sites to gather comments and suggestions from those that serve diverse cultures, as well as to ensure buy-in for future site adoption. Very early involvement of the pathologists and medical and surgical sub-specialists involved with tissue procurement was helpful to successful implementation of the SOP.

The research team discusses biospecimen collection processes with the surgical team at St. Joseph Hospital of Orange.



Lessons Learned

NCCCP sites reported the following challenges to the Special Request Biospecimen Disposal SOP:

- Competing priorities that prevented project completion
- State and local laws that required release of biospecimens through a mortuary
- Low frequency of special requests.

By the end of the NCCCP pilot's third year, only a few sites had implemented the protocol—largely because of competing priorities within their institutions and NCCCP net-

work responsibilities. The continued adoption and implementation of the NCCCP Special Request Biospecimen Disposal SOP is a work in progress. The 2007 pilot sites, and the new sites added to the network in 2010, are increasing the use of policies that incorporate cultural considerations related to the donation of biospecimens.

When developing a similar biospecimen disposal SOP, NCCCP sites suggest that community cancer centers be very mindful of the different cultures they serve. Protocols need to be culturally appropriate and sensitive to the needs of *all* patients. 📖

Case Example—NCCCP Site Billings Clinic

Billings Clinic Laboratory Services at Billings Clinic in Montana has had a biospecimens disposal policy in place since the 1990s. Given the community's significant American Indian population—approximately 6 percent of the regional population—the policy was designed with cultural awareness in mind. Seven reservations are in the Billings Clinic Cancer Center service area. Cancer rates for local American Indians are significantly higher than those for the non-Native American Indians and the survival rates are lower for most cancer types.

Part of the American Indian spiritual belief is to be buried as a whole, creating the need for special

disposal requests for tissue or body part collections. Obstacles may be encountered, for example, if there is not notification of the patient's special request before or at the time of surgery, or the laboratory is not aware of the patient's request and the specimen may be disposed of. Communication between the patient, the surgery team, and the pathology department is vital; all three play a critical role in policy adherence. Another unique challenge is that the special request for biospecimen disposal is a paper-based process and, under Montana law, funeral homes are not always directly involved and there is the potential for a communication breakdown.

The Billings Clinic disposal

policy was designed for quality patient care and service to ensure respect for the wishes of all patients served at the Clinic. Billings Clinic recognized the importance of developing a policy that was culturally appropriate for the facility's American Indian population. Overall, implementing a disposal policy at Billings Clinic improved cultural awareness for hospital and cancer program staff. Patients, surgeons, surgery staff, pathologists, and pathology staff were all instrumental in the successful implementation of this policy. The Billings Clinic disposal policy served as the starting template for NCCCP sites during the creation of the Special Request Biospecimen Disposal SOP. 📖

Biospecimen Disposal Standard Operating Model Protocol for Special Requests Outside the Scope of Routine Biospecimen Disposal Policy

DRAFT Version 1.3 11.2.09

Purpose:

This model protocol defines a model for the release, at the patient's, or patient's legal representative's request, of any patient biospecimen** that is not subject to local, state, or federal regulations, e.g., bullets, pacemakers, implants, especially in regard to religious, cultural, or other requests. The biospecimen(s) will be released after the pathology evaluation has been completed.

Some of these biospecimens may be bio-hazardous and potentially infectious necessitating decontamination when appropriate and explanation of potential risks to the recipient.

The facility may wish to include a procedure for re-acquiring the biospecimen if future studies are desirable, e.g., paraffin block. See the College of American Pathologists viewpoint concerning the issue of pathologist legal risk when no diagnostic tissue remains in a paraffin block that is submitted to another laboratory at the patient's request, but is then requested for additional studies by the patient or their physician.

All, portions, or none of this model procedure may be incorporated into the pathology department's policies and procedures at the discretion of the pathology medical director and facility risk management department. This model procedure should not supersede current federal, state, local, or facility regulations.

** Biospecimen is defined as any fluid, cells, tissue, substance, or material removed from the patient for pathology evaluation (clinical and anatomic pathology biospecimens) as well as remnant biospecimen (the biospecimen that is not used during the complete pathology evaluation) and derivative products such as: paraffin blocks, stained and unstained tissue on glass slides, nucleic acids or other derived chemical substances, and digital images.

Procedure:

1. The patient or patient's legal representative must submit a signed request to the pathology department for the release of the specified biospecimen(s). The request form can be filled out before or after collection of the biospecimen and returned to the pathology department with the biospecimen requisition if completed before collection or separately if completed after collection. The Biospecimen Special Disposal Request Form is available from the pathology department (see model form, page 41).

NOTE: As current policy, pathology departments may not release potentially infectious or bio-hazardous biospecimens (e.g., gallbladder stones, gangrenous limb amputations, blood/body fluids, tissue in formalin) to patients, but may release them to legal counsel or mortuaries with appropriate warning

and documentation, or to patients after appropriate decontamination (e.g., gallstones that have been rinsed in water and alcohol). Patient viewing and/or provision of photographs of the biospecimen(s) is also used in some pathology departments, thus avoiding release of the biospecimen(s). The potential legal risk for the pathologist if a person becomes infected or injured from a received biospecimen needs to be determined for each facility based on local, state, and federal regulations and precedents.

2. Notification to save the biospecimen is made in writing on the biospecimen requisition form by the collecting or submitting provider if before collection, e.g., physician, nurse, physician assistant, or by the patient or patient's legal representative if after collection and before routine disposal per pathology department policy. The pathology department will hold the requested biospecimen(s) for the patient or patient's legal representative until the appropriate release form has been completed. The patient or patient's legal representative will be notified by phone and by certified letter when the requested biospecimen(s) has completed the final pathology evaluation. A copy of the certified letter and its receipt will be attached to the request form along with a copy of the original biospecimen requisition, all being filed in a confidential and physically secure area. The information and process must be compliant with HIPAA regulations.

3. The biospecimen(s) will be packaged to prevent leakage in case of breakage of a liquid or "in formalin" biospecimen and the package clearly labeled BIO-HAZARDOUS. The patient or patient's representative will complete the release form (Attachment #3): date of pick up, patient's printed name and signature, full contact information of the person picking up the biospecimen such as the current address and phone number, and a witness' printed name and signature that the specimen was received by the stated patient or patient's legal representative (identification must be reviewed) and that biospecimen custodianship has been transferred from the institution to the patient or patient's legal representative.

Frequently Asked Questions:

Brief synopsis of pertinent policy points:

Model Biospecimen Special Disposal Request Form

Ver 1.0 9/28/09

Patient's name (printed): _____
Date of biospecimen collection: _____
Biospecimen pathology acquisition number: _____
Biospecimen type to be released: (e.g., blood, tissue, paraffin block, glass slides) _____

I, (the patient or legal representative), request the release of the above identified biospecimen to me or my legal representative:

Name (printed): _____
Current address (printed): _____

Current telephone number (include area code): _____

I, (the patient or legal representative), understand that the biospecimen I am requesting *may be bio-hazardous and potentially infectious*.

I hereby waive and release (facility name) and its employees and agents from any and all liabilities related to the transfer, handling, and disposition of this biospecimen once it has been released to me or my legal representative.

Printed name of patient or legal representative _____ Date _____

Signature of patient or legal representative _____ Date _____

If signed by a legal representative, what is your relationship to the patient? _____

RETAIN A COPY IN THE PATIENT'S FILE AND WITH THE BIOSPECIMEN RESULT REPORT
IN THE PATHOLOGY DEPARTMENT.

NCCCP/BS Disposal Project/Model Biospecimen Release Form Ver 1.0 9.28.09

Model Biospecimen Special Disposal Release Form

Ver 1.0 9/28/09

Patient's name (printed): _____
Date of release: _____
Biospecimen pathology acquisition number: _____
Biospecimen type to be released: (e.g., blood, tissue, paraffin block, glass slides) _____

(Facility name) will release the above identified biospecimen to the following patient or legal representative:

Name (printed): _____
Current address (printed): _____

Current telephone number (include area code): _____

I, (the patient or legal representative), understand that this biospecimen I am receiving *may be bio-hazardous and potentially infectious*. I understand that (facility name) is willing to dispose of the biospecimen, but at my request, has agreed to release the biospecimen to me or my legal representative.

I hereby waive and release (facility name) and its employees and agents from any and all liabilities related to the transfer, handling, and disposition of this biospecimen once it has been released to me or my legal representative.

Printed name of patient or legal representative _____ Date _____

Signature of patient or legal representative _____ Date _____

If signed by a legal representative, what is your relationship to the patient? _____

(Name of facility) Representative/Witness (printed and signature) _____ Date _____

RETAIN A COPY IN THE PATIENT'S FILE AND WITH THE BIOSPECIMEN RESULT REPORT
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NCCCP/BS Disposal Project/Model Biospecimen Release Form Ver 1.0 9.28.09