

Getting Involved in Clinical Trials

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Session Overview

- The Pathologist's obligation to the medical record
- The Pathologist's obligation to the patient
- Review of selected study protocols
- When to use a Materials Transfer Agreement

The Medical Record

- The Pathology report comprises the medical record in pathology and release is subject to HIPAA.
- Tissues and slides constitute the materials on which the report is based and release is subject to institutional policy and regulatory/accreditation requirements.
- Patient consent is required for release of reports and tissue/slides, but only release of reports is compelled by patient consent.

Custodial Requirements - Material Storage

Case example: University of Washington
WA State Department of Health: blocks and slides on site for 10 years
CAP accreditation requirements: blocks and slides on site for 10 years (ANP.12500)
UWMC institutional/departmental policy: blocks and slides on site indefinitely (no time limit)

Who Owns the Tissue?

- The Pathologist is the legal custodian of patient materials and the patient medical record in pathology.
- The patient's ownership rights to tissue are not well defined and may depend on local, state or institutional policy or governance.
- Access to residual tissue is subject to IRB approval, but may not require patient consent if anonymized.

Residual Tissue Defined

- Materials not preserved in paraffin blocks, stored fluid or frozen tissue samples 14 days after final report is generated are considered 'residual.'
- (based on CAP Anatomic Pathology checklist ANP.11550)
- No 'residual' tissues can be released under any circumstance until 14 days after final report is issued.
 - Except...hardware, medical devices, placentas....

Requirements for Release to Clinical Trials

- Institutional review board approval
- Patient consent
- Approval by the Pathologist as 'custodian of the wax'

What Materials are Required by Clinical Trials?

Examples from active research protocols

- SWOG 0515: diffuse large B cell lymphoma
- RTOG 0525: glioblastoma
- NSABP B39: breast carcinoma
- RTOG 0234: squamous cell carcinoma

What Should the Pathologist Do?

- Examine both the protocol and IRB approval documents before considering release.
- Evaluate the existing pathology materials to determine if release risks the integrity of those materials.
- Choose the release option least likely to compromise the material on file.
- Negotiate with local clinical trials coordinators for alternatives.
- Request appropriate reimbursement for time and lab work.

When is a Materials Transfer Agreement Required?

- Simple answer: when a patient intends to enroll in a trial offered at another institution, *or*
- When research is going to be performed at another institution, whether part of a clinical trial or not.
- MTA may also require IRB approval at the receiving institution
- Release of materials for clinical testing does not require an MTA



Summary - "Pearls of Pathology"

- The Pathologist should be familiar with the requirements of the clinical trial:
 - Demand a copy of the trial protocol
 - Demand documentation of IRB approval
 - Expect reimbursement for costs incurred
- The Pathologist, as custodian, is responsible for determining what materials are available and how release of requested slides or tissue may compromise the integrity of that material

Summary - "Pearls of Pathology"

- The Pathologist must be familiar with local, state and regulatory/accreditation requirements for patient sample storage
- The Pathologist must be willing to negotiate with the trials co-ordinator or refuse release if the requested materials compromise the integrity of patient care
- The pathologist must ensure that a Materials Transfer Agreement is executed when appropriate.
