ANMC Clinical Tissue Bank / Alaska Native Tumor Registry

James J. Tiesinga, MD
Laboratory Medical Director
With gracious assistance from
Kate Gallin Heffernan, JD
Verrill Dana, LLP, Boston, MA
ANMC Department of Pathology maintains a repository of tissues sent to the Lab for examination and diagnosis. The Lab also maintains data pertaining to these tissues (e.g., patient demographics, clinical history, procedure, date of resection, diagnosis, etc.) as part of this repository. The purpose of this repository is clinical; it is not developed or maintained for research purposes.
Pathology Tissue: Path of Workflow

1. Tissue specimen (e.g., tumor resection, biopsy, aspiration, etc.) accessioned into laboratory;
2. Specimen examined and dissected by Pathologist;
3. Helpful tissue embedded in paraffin wax (“blocks”); unhelpful tissue kept in a preservative (formalin);
4. Paraffin-embedded tissue (“blocks”) cut into thin slices, slices placed on a piece of glass (“slides”) and stained, stained slides examined under microscope by Pathologist who renders a diagnosis;
5. Paraffin blocks and slides placed in storage after diagnosis.
Differences Between Clinical Banks and Research Banks

Developing and maintaining an identifiable repository of data or specimens for research purposes *is* research (even before you use the stored data / specimens for a specific study)

- Generally requires patient informed consent (unless eligible for an IRB waiver or exemption determination)
- Requires adherence to IRB banking protocol (unless exempt)

Neither is required to store / bank clinical materials and data.

Heffernan
Minimum Requirements for Pathology Storage

There must be a documented policy for protecting and preserving the integrity and retrieval of pathology materials and records. The retention period should be extended, when appropriate, to provide documentation for adequate quality control and medical care. Minimum storage requirements are:

- Unhelpful tissue (fresh or formalin-fixed) – 2 weeks after final report
- Paraffin blocks – 10 years
- Glass slides – 10 years
- Pathology reports (paper or electronic format) – 10 years

Many Pathology Departments (including ANMC’s) keep their materials and records longer than the 10-year minimum requirement.
Requests for Clinical Materials

• Clinical banks that receive requests for samples to be sent out for “further workup” and / or “research” have to ensure release is appropriate.  **Due diligence is required!**
  • Important to know purpose of request:
    • To establish treatment / diagnosis / prognosis via the standard of practice?
    • Clinical research protocol?
    • Something else (e.g., not recognized as the standard of practice, has no immediate value to patient, etc.)?
  • Important to know what rules apply:
    • Is patient’s written authorization required (HIPAA)?
    • Is IRB authorization required; has it been obtained?

Heffernan
Special Considerations for Research

- There are no restrictions on the release of tissues for purposes of ("standard of practice") treatment, diagnosis, prognosis as long as release is consistent with patient privacy regulations (e.g., HIPAA).
- Similarly, there are no restrictions on the release of tissues for patients on research protocols; however, organizational and / or IRB approval ("enrollment") is typically required.
- Paraffin blocks cannot be released for two years to any outside research facility engaged in other types of research. And, after two years, IRB approval is typically required.
Who Owns the Tissue / Data?

What rights do [Alaska Native] patients / subjects have in their own tissues and resulting products:

- Recognized argument in case law that the value of stored tissue is generated by researchers, or the potential for research; standing alone, tissue is of no real value to the patient.
- Tribal vs. Individual (the patient’s right to direct disposition of one’s own tissue for a research purpose, now or in the future);
- Jurisdictional rules may apply (e.g., State law / public health, etc.);
- Important for institutions to have clear policies regarding repository ownership. When in doubt, call your IRB!

Heffernan
Role of Alaska Native Tumor Registry

• The Alaska Native Tumor Registry is managed by the ANTHC Epidemiology center.
• The registry collects data on the diagnosis, treatment, and current status of all Alaska Native People with cancer.
• The registry has historically been used to facilitate tissue research using ANMC’s Clinical Tissue Repository. Examples of recent studies include:
  • Cervical cancer and HPV
  • Head and Neck cancer and HPV
  • MSI and colorectal cancer
• Access to the registry requires both IRB approval as well as approval through the SCF and ANTHC Scientific Review Boards.
• Approval can take up to two years.
Other Issues Affecting Clinical Banks

There are challenges for clinical banks to manage volume of stored materials; for example, banks must adequately address various future scenarios (beyond future research):

- How long is storage contract for? What fees apply?
- At what point can or must bank dispose of stored materials?
- Is or should there be a notification requirement before disposal?
- What happens if storage fees are not paid?
- What happens if client / patient dies? Can bank dispose or do they revert to an identified beneficiary?
- Are clients / patients required to update contact information?
- Will renewal consents [for future research] be obtained at any identified interval?
- If materials are stored for third party treatment [e.g., cord blood, genetic testing, etc.], who ultimately controls their use / disposal?
- Can the bank sell unused materials?

- Many of these issues not dictated by law, so consent / policy will govern
- Legally effective consent may not always be sufficient from a risk management perspective; case by case analysis.
Thank you!

Questions?