Logistics and Ethics of Postmortem Neuropathology Research

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Case-Based Questions (please see page 3 for answers)

1.	Your department chair tasks you to develop a "rapid autopsy" program in your hospital to support neurodegenerative disease research. Your first step is to:	
	a.	Develop a detailed budget
	b.	Document stakeholder goals
	c.	Hire ancillary staff for 24/7 availability
	d.	Create a "rapid autopsy" neuropathologist call schedule
	e.	Consult your institution's legal team for guidance

2.	Your regional medical examiner wishes to send all neuropathology consult brains to your institution. You have several active grants requiring small portions of normal brain as control tissue. You tell the medical examiner:	
	a.	Next-of-kin (NOK) must sign consent for research before they send the consult
	b.	Nothing; no one will notice tiny pieces of missing tissue
	c.	An organ and tissue donation representative will attempt to obtain NOK research consent
	d.	All postmortem brains undergo collection of control tissue in your institution
	e.	All postmortem brains from individuals dying of natural disease undergo collection of control tissue in your institution

3.	Your neuropathology fellowship is coming to an end. You interviewed for your dream position in a large academic center where you would manage and expand the brain biobank which was founded in 1960. Before accepting the position, you ask:	
	a.	Does the biobank consent form follow the institution's legal team guidelines?
	b.	Does the biobank consent form follow the autopsy medical director's guidelines?
	c.	Does the biobank consent form follow regional organ and tissue donation guidelines?
	d.	Does the biobank consent form follow Institutional Review Board (IRB) guidelines?
	e.	Does the biobank consent form follow National Institutes of Health (NIH) guidelines?

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Correct Answers and Rationales

Question 1 Correct Answer and Rationale: **B. Document stakeholder goals**

Rationale: Developing a rapid autopsy program is a complex undertaking with several stakeholders. Having clear, detailed knowledge of stakeholder goals, including current and anticipated future goals, is an essential first step. Once those are known, additional steps can be prioritized, added, or removed.

Question 2 Correct Answer and Rationale: **C. An organ and tissue donation representative will attempt to obtain NOK research consent**

Rationale: While autopsies ordered by a medical examiner (or coroner / equivalent) do not require next-of-kin consent, research does. This includes even small pieces of tissue that would likely go unnoticed. Having a system to obtain consent from next-of-kin prior to collecting these tissues is essential. But, how this necessary consent is obtained varies by hospital and region and can be creative. In some cases, research consent is obtained by regional organ and tissue donation organizations in tandem with donation consent (check your local laws!). Natural deaths may fall under ME jurisdiction.

Question 3 Correct Answer and Rationale: **E. Does the biobank consent form follow National Institutes of Health (NIH) guidelines?**

Rationale: All the above individuals and/or groups are important stakeholders in biobank consent and other logistics. However, an institution's legal team is often unfamiliar with medical ethics, including those guiding postmortem research. The same is true for organ and tissue donation agencies. Most Institutional Review Boards explicitly state that deceased individuals are research exempt and may accept less detailed consent forms. Pathologists are often the "experts" regarding the ethics of postmortem research and must know where to obtain current biobanking standards. Even if the biobank isn't NIH funded, publicly available NIH biobanking guidelines are most likely to incorporate medical ethical guidelines, as well as legal and logistical guidelines. Of course, the most important question is if you, the new brain biobank director, will have the authority to evaluate and update the consent form and other policies.