

Logistics and Ethics of Postmortem Neuropathology Research

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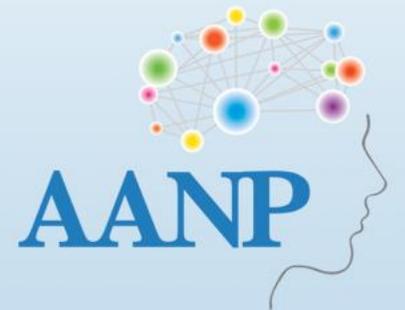
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03/30/2026

Disclosures

Portion of salary paid by NIH NeuroBioBank

I have no other relevant financial relationships to disclose



Learning Objectives

1. Construct a postmortem neuropathology research protocol that maximizes tissue viability for molecular testing and other advanced ancillary testing techniques.
2. Compare ethical and legal principles of family consented versus forensic postmortem research.
3. Identify several strategies to ensure postmortem neuropathology research in your institution follows current best ethical practices.



Outline



- I. Background
- II. Logistics and other fundamental considerations
- III. Ethical considerations
- IV. Summary



BACKGROUND

POSTMORTEM NEUROPATHOLOGY RESEARCH

Research Principles: A Brief History

- Nuremberg Code
- Tuskegee, Henrietta Lacks
- National Research Act of 1974
 - National Commission for the Protection of Human Subjects
 - The Belmont Report
- Institutional Review Boards (IRB)
- **IRBs are governed by individual Institutions**

“IRBs help to ensure the protection of the rights and welfare of human subjects by applying the ethical principles of the Belmont Report, respect for persons, beneficence, and justice, in their review of research projects.” – Keren R. Dunn (2022)

<https://www.hhs.gov/ohrp/international/ethical-codes-and-research-standards/index.html>

Dunn, K.R. (2022). Institutional Review Boards and Ethics Committees. In: Piantadosi, S., Meinert, C.L. (eds).

Moon MR, Khin-Maung-Gyi F (2009). The history and role of institutional review boards. PMID: 23195065.



Research Principles: A Brief History, cont.

- World Medical Association Declaration of Helsinki
 - Ethical principles of medical research involving human participants
 - Principles apply to ALL organizations, institutions, and individuals
 - **Not legally binding**

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN PARTICIPANTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

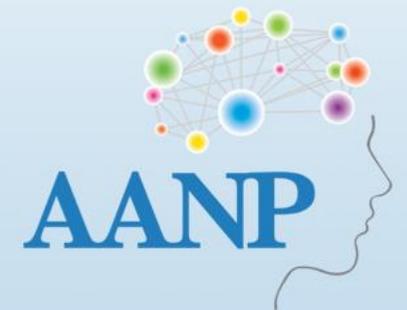
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

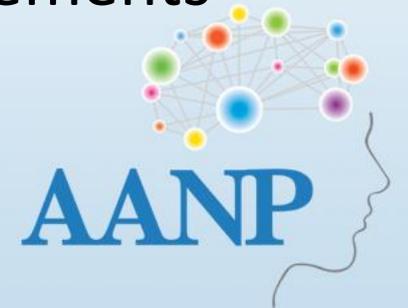
64th WMA General Assembly, Fortaleza, Brazil, October 2013

and by the 75th WMA General Assembly, Helsinki, Finland, October 2024



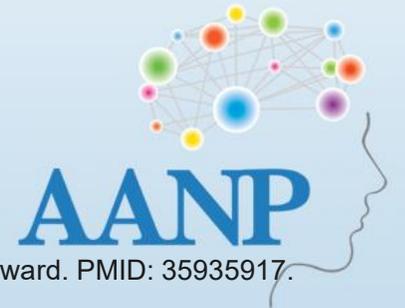
THE FINAL RULE AND THE COMMON RULE

- The Common Rule: 1991
 - Codified ethical framework for medical research involving human subjects
 - Framework for broad consent, biospecimen collection and storage, including identifiable; may differ from traditional informed consent
- The Final Rule: 2017
 - New regulatory pathway for broad consent
 - U.S. Department of Health and Human Services (HHS) now publishes broad consent templates containing all required consent elements



Ethical, Legal and Social Implications (ELSI)

- Began with the Human Genome Project / NIH
- Joint working group formed in 1990
- *“Ethical, legal and social implications of genetic and genomic research for individuals, families and communities”*
- Expected component of NIH (and many other) grants



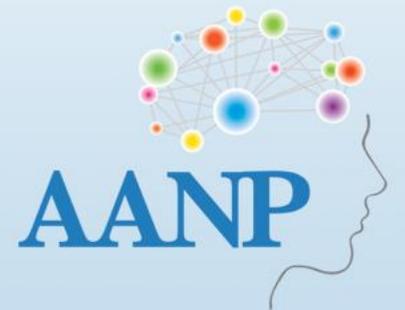
Postmortem Neuropathology Research: Brain Banking

- Hand-in-hand with history of autopsy and education
- Began end of nineteenth century
- In United States, initiated in 1960s
- Huge demand from clinicians and researchers
- Available tissue declining along with autopsy rates

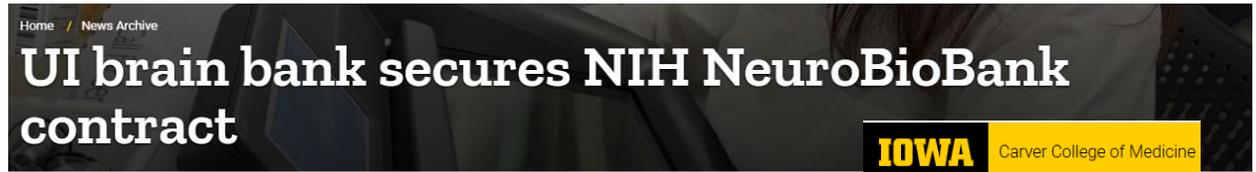
Carlos AF et al (2019). From brain collections to modern brain banks: A historical perspective. PMID: 30775417

Kretschmar H (2009). Brain banking: opportunities, challenges and meaning for the future. PMID: 190507.

Danner et al. (2024). Brain banking in the United States and Europe: Importance, challenges, and future trends. PMID: 38506125.



NIH NeuroBioBank



222 • *Journal of Neuropathology & Experimental Neurology*, Vol. 83, No. 4, 2024

Monday, January 5, 2026

Since 2013, the NIH [NeuroBioBank](#) (NBB) has catalyzed scientific discovery through the centralization of resources aimed at the collection and distribution of human post-mortem brain tissue to understand conditions of the nervous system. The NBB network distributes samples to the research community studying neurological, developmental, and psychiatric disorders. Now, the [Carver College of Medicine's](#) brain bank, called the [Iowa Neuropathology Resource Laboratory](#) (INRL), is part of the NBB network.



- Established in 2013
- National resource for postmortem brain tissue / biospecimens
- Seven biorepositories

Figure 3. Locations of participating institutions of the National Institutes of Health NeuroBioBank.

Danner et al. (2024). Brain banking in the United States and Europe: Importance, challenges, and future trends. PMID: 38506125.

<https://neurobiobank.nih.gov/>

<https://pathology.medicine.uiowa.edu/news/2026/01/ui-brain-bank-secures-nih-neurobiobank-contract>



NIH NeuroBioBank

Our Goals

1

To increase the availability of human disease and control brains and related biospecimens by increasing public awareness of the value of tissue donation for understanding brain disorders.

2

To facilitate the distribution of high-quality, well-characterized human post-mortem brain tissue for the research community.

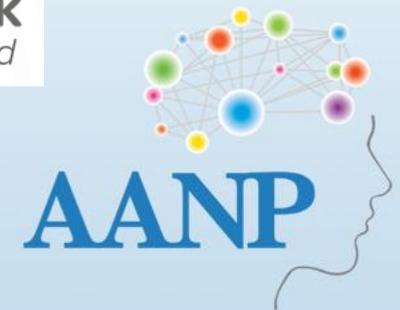
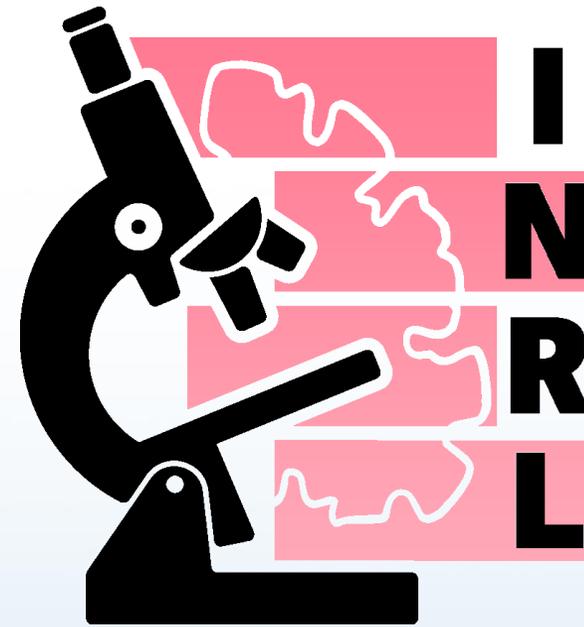
3

To make available to the research community, a centralized resource of best practices and protocols used by our networked sites in the acquisition, preparation, and distribution of tissue.



Postmortem Neuropathology Research: Rapid Autopsy

- Preserves tissue viability
- Began several decades ago
- Biobanking and (whole/half) brain banking
- Neurodegenerative disease and neoplasia
- Individual cases / research projects
 - Clinical team or researcher-driven



> Arch Pathol Lab Med. 1997 Jun;121(6):615-8.

Rapid brain autopsy. The Joseph and Kathleen Bryan Alzheimer's Disease Research Center experience

C M Hulette ¹, K A Welsh-Bohmer, B Crain, M H Szymanski, N O Sinclair, A D Roses

Affiliations — collapse

Affiliation

¹ Joseph and Kathleen Bryan Alzheimer's Disease Research Center, Department of Medicine, Duke University Medical Center, Durham, NC 27710, USA.

PMID: 9199629

Abstract

Objective: To develop a system for retrieving brain tissue within 1 hour after death in an effective and useful manner.

Design: Nurse clinicians were employed as study co-ordinators and were available to families 24 hours each day.

Setting: Autopsies were performed at Duke University Medical Center, Durham, NC, from 1985 through 1995.

Participants: Neuropathology faculty, fellows, and residents, autopsy technicians; and brain bank staff.

Results: Fifty-one rapid autopsies with a postmortem interval of less than 1 hour have been performed. Four of these were normal controls, three were disease controls, and 44 represented Alzheimer's disease patients. Tissue retrieved at rapid autopsy has been distributed to 93 research teams, 30 of these located at Duke University Medical Center. Many researchers have received multiple shipments of tissue.

Conclusions: The Bryan Alzheimer's Disease Research Center Rapid Autopsy Program at Duke University Medical Center has been successful in retrieving tissue from individuals with dementia and also from controls within 1 hour of death. The critical features of the success of this program have been the use of nurse clinicians who work closely with patients and their families to ensure a successful autopsy at the time of death and the maintenance of a 24-hour call schedule for nurses and neuropathology staff. Similar programs can be implemented for experimental work into the pathogenesis of a wide variety of human diseases in which the examination of human tissue is required.

> Cancer. Author manuscript; available in PMC: 2020 Sep 1.

Published in final edited form as: Cancer. 2019 May 15;125(17):2915-2919. doi: [10.1002/cncr.32184](https://doi.org/10.1002/cncr.32184)

Rapid Research Autopsy is a Stealthy but Growing Contributor to Cancer Research

Eleonora Duregon ¹, Jowaly Schneider ¹, Angelo M DeMarzo ¹, Jody E Hooper ^{1,*}

▶ Author information ▶ Article notes ▶ Copyright and License information

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PMCID: PMC6690796 NIHMSID: NIHMS1026146 PMID: [31090935](https://pubmed.ncbi.nlm.nih.gov/31090935/)



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Rapid Autopsy and Procurement of Cancer Tissue

STATUS: ACTIVE

⊕ Open all ⊖ Close all

Description

Background: - Individuals with cancer of the lung, chest cavity, ovary, or bladder, as well as patients who have been treated with adoptive cell therapy unfortunately commonly succumb to their disease. Some agree to donate their bodies to cancer research that may help the medical community better understand these diseases. Studies of cancer tumor tissue obtained soon after death may be used to answer questions about the origins, progression, and treatment of cancer. Researchers want to conduct a study that involves planned collection of cancer tumor tissue shortly after death. To do so, they will arrange to provide inpatient hospice care for people with lung cancer, ovarian cancer, bladder cancer, or patients who have been treated with adoptive cell therapy. <TAB>

> J Vis Exp. 2017 Mar 7;(121):55360. doi: 10.3791/55360.

A Protocol for Rapid Post-mortem Cell Culture of Diffuse Intrinsic Pontine Glioma (DIPG)

Grant L Lin ¹, Michelle Monje ²

Affiliations — collapse

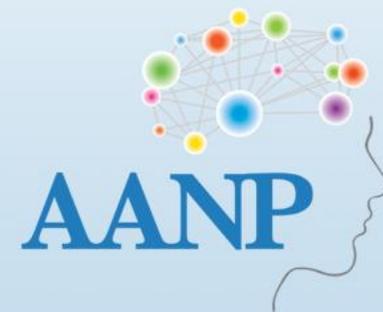
Affiliations

- ¹ Graduate Program in Neuroscience, Department of Neurology, Institute for Stem Cell Biology and Regenerative Medicine, Stanford University School of Medicine.
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PMID: 28362421 PMCID: [PMC5409295](https://pubmed.ncbi.nlm.nih.gov/PMC5409295/) DOI: [10.3791/55360](https://doi.org/10.3791/55360)

Abstract

Diffuse Intrinsic Pontine Glioma (DIPG) is a childhood brainstem tumor that carries a universally fatal prognosis. Because surgical resection is not a viable treatment strategy and biopsy is not routinely performed, the availability of patient samples for research is limited. Consequently, efforts to study this disease have been challenged by a paucity of faithful disease models. To address this need, we describe here a protocol for the rapid processing of post-mortem autopsy tissue samples in order to generate durable patient-derived cell culture models that can be used in in vitro assays or in vivo orthotopic xenograft experiments. These models can be used to screen for potential drug targets and to study fundamental pathobiological processes within DIPG. This protocol can further be extended to analyze and isolate tumor and microenvironmental cells using Fluorescence-activated Cell Sorting (FACS), which enables subsequent analysis of gene expression, protein expression, or epigenetic modifications of DNA at the bulk cell or single cell level. Finally, this protocol can also be adapted to generate patient-derived cultures for other central nervous system tumors.





LOGISTICS

POSTMORTEM NEUROPATHOLOGY RESEARCH

WHO ARE YOUR STAKEHOLDERS?

- Clinicians
- Researchers
- Medical examiners / coroners
- Hospital and departmental leadership
- Hospital legal team
- National Institutes of Health
- Funders
- Families
- Your institution
- Your department
- Your trainees
- Post docs

***IDENTIFYING
STAKEHOLDERS IS
THE FIRST STEP***



FUNDING

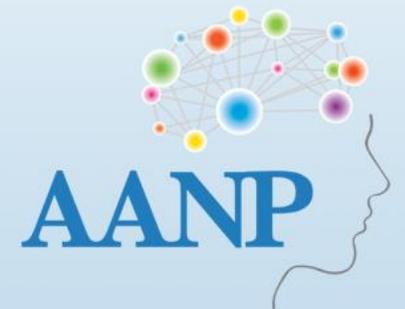
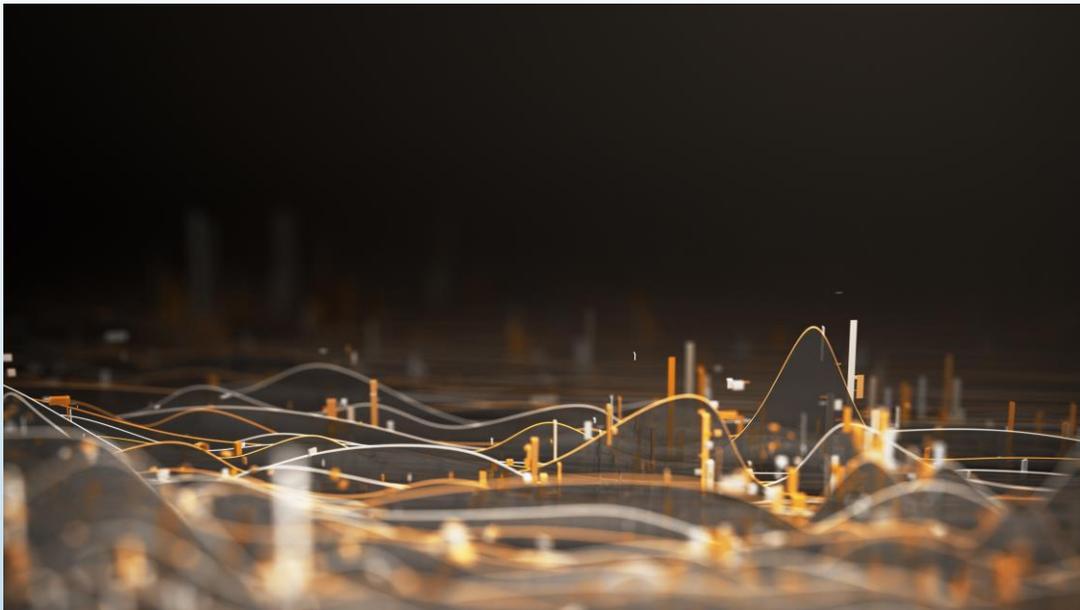
TYPES

- Government
- Independent / private
- Philanthropy



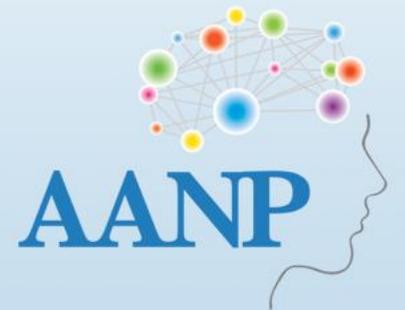
SOURCES

- Clinicians
- Other researchers
- Institutional
- Departmental
- Self



CONSENT

- Who will obtain?
 - Organ and Tissue donation agencies?
 - Funded position?
- How do I determine next-of-kin (NOK)?
- WHAT will it include?
 - IRB / Institutional guidelines
 - Study-specific guidelines



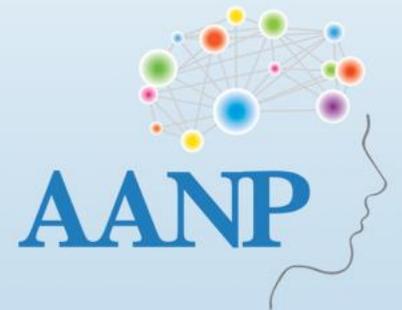
CONSENT GUIDELINES

- Most IRBs consider postmortem research separately
- Institutional
 - Legal / risk management
- State
 - Next of kin (NOK) definitions
 - Ability to sign consent prior to death
 - Medical examiner jurisdiction
- National
 - NIH
- Study-specific



CONSENT: ETHICAL GUIDELINES BEYOND THE IRB

- Biobanking
 - Identified or de-identified?
 - Indefinite storage
 - Sharing with other institutions
 - For-profit potential
- Molecular testing
- Cell lines
- **Medical examiner cases**



CONSENT: MEDICAL EXAMINER CASES

Jurisdiction determines
Statutory duty to determine
Cause and Manner of Death

Homicide

Suicide

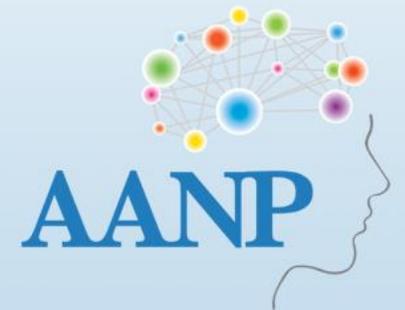
Accident

Natural

Undetermined



<https://ifs.harriscountytexas.gov/Pages/PathologyEducationTraining.aspx>



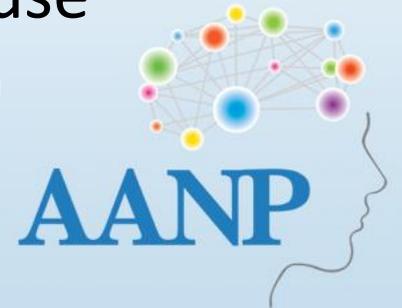
HOSPITAL VS. FORENSIC AUTOPSY: DIFFERENCES

HOSPITAL (FAMILY CONSENT)

- Require NOK consent
- Requested by clinical team and/or family
- Person doing autopsy different from person completing death certificate
- Focus on natural disease and medical interventions

FORENSIC (ME/C ORDERED)

- Do not require consent
- Ordered by medical examiner / coroner / Justice of the Peace
- Legal mandate
- Person doing autopsy completes death certificate
- Focus on underlying cause (important for Manner)



ANCILLARY STUDIES: NOW & FUTURE

- QA testing
- Molecular testing
 - DNA / RNA
 - RNA seq
- Flow cytometry
- Flash-frozen tissue
- CSF

www.impactjournals.com/oncotarget/

Oncotarget, Vol. 7, No. 41

Research Paper

Quantification of nucleic acid quality in postmortem tissues from a cancer research autopsy program

Jun Fan¹, Raya Khanin², Hitomi Sakamoto¹, Yi Zhong¹, Chelsea Michael³, Derwin Pena³, Breanna Javier¹, Laura D. Wood⁶, Christine A. Iacobuzio-Donahue^{3,4,5}

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⁶Department of Pathology, Sol Goldman Pancreatic Cancer Research Center, Johns Hopkins University School of Medicine, Baltimore, MD, 21231, USA

Correspondence to: Christine A. Iacobuzio-Donahue, **email:** iacobuzc@mskcc.org

Keywords: autopsy, RNA, post-mortem, RNA sequencing, metastasis

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REVIEW ARTICLE

<https://doi.org/10.1038/s41467-021-21587-5>

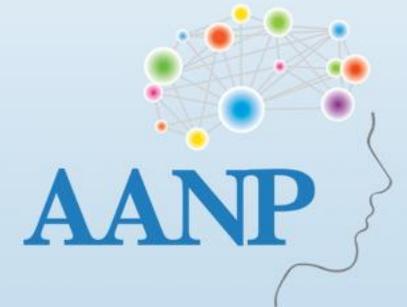
OPEN



DNA stability: a central design consideration for DNA data storage systems

Karishma Matange¹, James M. Tuck² & Albert J. Keung¹

Data storage in DNA is a rapidly evolving technology that could be a transformative solution for the rising energy, materials, and space needs of modern information storage. Given that the information medium is DNA itself, its stability under different storage and processing conditions will fundamentally impact and constrain design considerations and data system capabilities. Here we analyze the storage conditions, molecular mechanisms, and stabilization strategies influencing DNA stability and pose specific design configurations and scenarios for future systems that best leverage the considerable advantages of DNA storage.



Example: extracted DNA, CSF, studies on flash-frozen tissue: 4°C, up to 7 days (RNA up to 72 hrs)

ANCILLARY STUDIES: NOW & FUTURE

- Formalin fixed paraffin embedded (FFPE)
- Cell culture
- Xenografting
- Organoids



ANCILLARY STUDIES: POSTMORTEM INTERVAL

 **HHS Public Access**
Author manuscript
Cancer. Author manuscript; available in PMC 2020 September 01.

Published in final edited form as:
Cancer. 2019 September 01; 125(17): 2915–2919. doi:10.1002/cncr.32184.

Rapid Research Autopsy is a Stealthy but Growing Contributor to Cancer Research

Eleonora Duregon, M.D., Ph.D., Jowaly Schneider, Angelo M. DeMarzo, M.D., Ph.D., Jody E. Hooper, M.D.*
Department of Pathology, The Johns Hopkins University, Baltimore, Maryland, 21287, USA.

Journal of Neuro-Oncology (2019) 145:349–355
<https://doi.org/10.1007/s11060-019-03302-z>

CLINICAL STUDY 

Increasing value of autopsies in patients with brain tumors in the molecular era

Jared T. Ahrendsen¹ · Mariella G. Filbin² · Susan N. Chi² · Peter E. Manley² · Karen D. Wright² · Pratiti Bandopadhyay² · Jessica R. Clymer² · Kee Kiat Yeo² · Mark W. Kieran^{2,5} · Robert Jones² · Hart G. Lidov⁴ · Keith L. Ligon^{3,4} · Sanda Alexandrescu^{2,4} 

 Journal of Visualized Experiments www.jove.com

Video Article

A Protocol for Rapid Post-mortem Cell Culture of Diffuse Intrinsic Pontine Glioma (DIPG)

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²Departments of Neurology, Neurosurgery, Pathology and Pediatrics, Institute for Stem Cell Biology and Regenerative Medicine, Stanford University School of Medicine



ARTICLE

DOI: 10.1038/s41467-017-02772-x OPEN

The effects of death and post-mortem cold ischemia on human tissue transcriptomes

Pedro G. Ferreira *et al.* 

MODERN PATHOLOGY

Recovery and Expression of Messenger RNA from Postmortem Human Brain Tissue
Modern Pathology, 14, 1157-1161

[Thomas J Cummings, M.D.](#)   · [Jay C Strum, Ph.D.](#) ² · [Lawrence W Yoon](#) ² · [Mari H Szymanski](#) ¹ · [Christine M Hulette, M.D.](#) ¹

Flow cytometry analysis of synaptosomes from post-mortem human brain reveals changes specific to Lewy body and Alzheimer's disease

[Nadia O Postupna](#) ¹ · [C Dirk Keene](#) ¹ · [Caitlin Latimer](#) ¹ · ... · [Jeffrey G Ojemann](#) ² · [Thomas J Montine](#) ¹ · [Martin Darvas](#) ¹   ... [Show more](#)

Affiliations & Notes  Article Info  Laboratory Investigation, 94, 1161-1172

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² Department of Neurological Surgery, University of Washington, Seattle, WA, USA



RAPID AUTOPSY: WHERE TO START?

- Stakeholders
- Funding
- Resources
- Physical space
- Storage
- Consent
- Volume
- Workflow

Harmonization of postmortem donations for pediatric brain tumors and molecular characterization of diffuse midline gliomas

Madhuri Kambhampati^{1,2,17}, Eshini Panditharatna^{1,2,3,17}, Sridevi Yadavilli^{1,2}, Karim Saoud^{2,2}, Sulgi Lee^{2,2,15}, Augustine Eze^{2,2}, M. I. Almira-Suarez^{4,15}, Lauren Hancock^{2,5}, Erin R. Bonner^{4,2,15}, Jamila Gittens^{4,5}, Mojca Stampar⁴, Krutika Gaonkar⁷, Adam C. Resnick⁷, Cassie Kline^{8,16}, Cheng-Ying Ho⁹, Angela J. Waanders¹⁰, Maria-Magdalena Georgescu¹¹, Naomi E. Rance¹², Yong Kim¹³, Courtney Johnson², Brian R. Rood^{2,5}, Lindsay B. Kilburn^{2,5}, Eugene I. Hwang^{2,5}, Sabine Mueller^{8,14}, Roger J. Packer², Miriam Bornhorst^{1,2,15,18} & Javad Nazarian^{1,14,15,18}

Bacon et al. *Translational Medicine Communications* (2020) 5:23
<https://doi.org/10.1186/s41231-020-00074-x>

Translational Medicine
Communications

PROTOCOL

Open Access

Building a rapid autopsy program – a step-by-step logistics guide



Eliza R. Bacon^{1*}, Kena Ihle¹, Peter P. Lee² and James R. Waisman¹

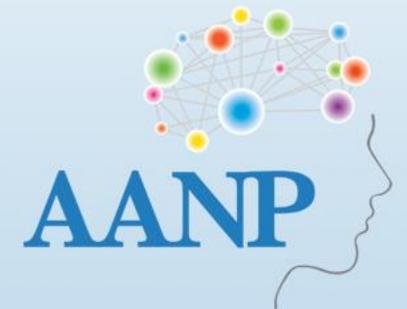
Abstract

Background: Rapid Autopsy Programs offer an opportunity to collect tissue from patients immediately after death, providing critical biological material necessary to develop more effective therapies and improve patient outcomes. Here, we present a step-by-step guide to build a cancer-focused Rapid Autopsy Program, based on our own experiences building “The Legacy Project” at the City of Hope Comprehensive Cancer Center.

Methods: The linear timeline of events is separated into four phases: 1) Building the Infrastructure, 2) Recruiting and Consenting, 3) Preparing for Death, and 4) Tissue Collection and Follow up. Important considerations and methods for adaptation are discussed throughout the protocol.

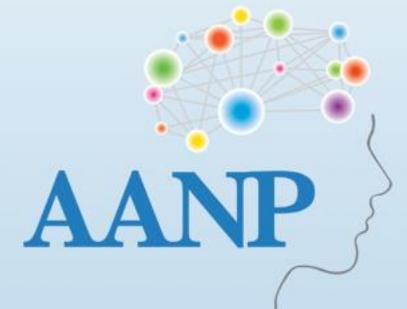
Discussion: Using these methods, we successfully collected a total of 533 specimens from 9 subjects. The average time from death to last specimen acquisition was 6.1 h (range: 4.03–7.66 h; median: 5.71 h). A diverse team with various areas of expertise is critical for successful program implementation. Our goal herein this protocol is to provide a comprehensive framework and foundation for other institutions to use as a model.

Keywords: Rapid autopsy program, Warm autopsy, Rapid tissue donation, Cancer research, Metastatic, Tumor heterogeneity



RAPID AUTOPSY: Personal Experience

- Pathologist –driven
- Solicited input from hematology-oncology clinicians and basic science researchers within our hospital
- Contacted national leaders in RAP methods for strategic planning
- Exchanged protocols
- Literature review of best postmortem tissue collection practices
- Ensured -80C storage capacity within existing biobank



RAPID AUTOPSY: Personal Experience

- List of standardized sections allowing for case-by-case modification
- Detailed autopsy workflow checklists
- Established mortuary transport contract for prompt transportation for autopsy at no charge to families
- Revised current hospital autopsy consent form was revised to accommodate general autopsy research protocols
- All rapid autopsies followed appropriate hospital and state written consent and Institutional Review Board guidelines.



RAPID AUTOPSY: LOGISTICAL WORKFLOW



Oncology contacts pathology
on behalf of family

RAP team provides instructions to oncologist, family, hospice nurse, including autopsy consent



Child passes away in home or hospital

Nurse/ hospice contacts clinician attending

Death pronounced/ ME called

ME release - contact pathology

We arrange paid transport to TCH

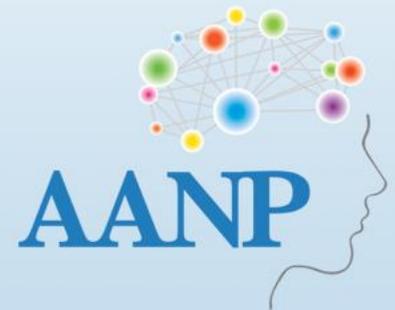
Detailed autopsy report issued in 60 days

Body taken to funeral home chosen by family

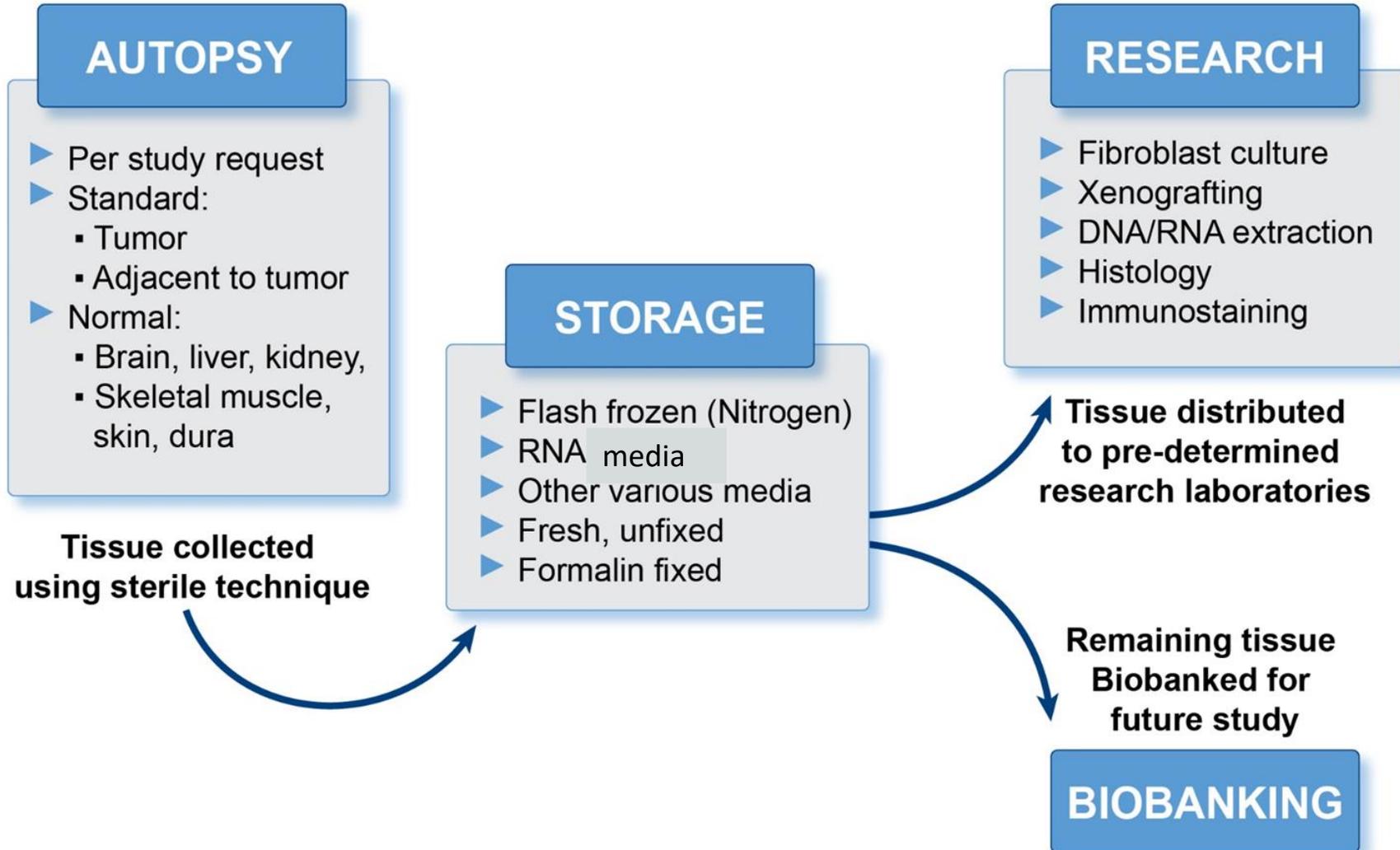
Samples distributed or biobanking

TCH Rapid Autopsy

Body brought to TCH for autopsy



RAPID AUTOPSY: COLLECTION & DISTRIBUTION



RAPID AUTOPSY CASE #1:

- Teenage boy with sarcoma
 - PMI: > 72 hours
 - Successful DNA sequencing
 - 92 snap frozen tissue samples
 - 58 cryopreserved samples for xenografts and cell culture

RAPID AUTOPSY CASE #2:

- Teenager with diffuse midline glioma enrolled in a CAR-T clinical trial
 - PMI: 6 hours
 - Approximately 40 cryopreserved samples
 - 10 fresh samples for flow cytometry
 - patient-derived xenografts

Journal of Clinical Oncology®
An American Society of Clinical Oncology Journal

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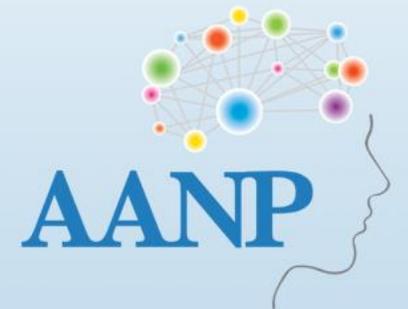
Phase I Trial of GD2.CART Cells Augmented With Constitutive Interleukin-7 Receptor for Treatment of High-Grade Pediatric CNS Tumors

"Postmortem tumor was examined in one case (patient 8) 3 months after C7R-GD2.CART infusion, at which time the C7R transgene, but not GD2.CAR, was detectable by transgene analysis and flow cytometry."



RAPID AUTOPSY: LESSONS LEARNED

- Clinicians, researcher, or pathologist driven?
- Consent support options
- Laboratory space
- Work with departmental needs to create mutually beneficial on-call schedule
- Tracking de-identified specimens and outcomes
- Data sharing agreements / material transfer agreements
- Optimal postmortem interval??



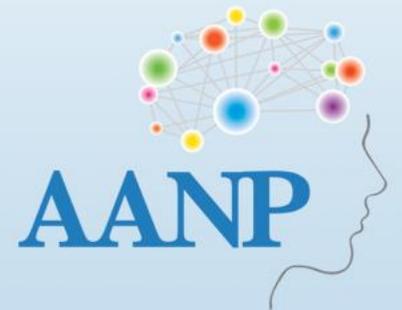


ETHICS

POSTMORTEM NEUROPATHOLOGY RESEARCH

AUTOPSY ETHICS

- As physicians, bound by ethical principles
- Consented vs. medical examiner / coroner jurisdiction
- IRB/Institutional guidelines may NOT emphasize
- *“Just because it’s legal, doesn’t mean it’s ethical.”*



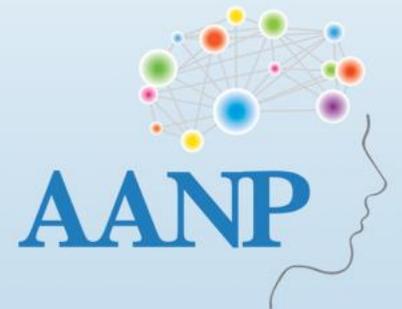
BACK TO THE IRB

Dear Dr. _____,

Thank you for submitting your project titled “Building a Rapid Autopsy Program to Study Neurodegeneration.” I have determined that your project does not require review by the IRB. This activity is limited to research on deceased individuals therefore, from a regulatory standpoint, does not involve human subjects.

Warm regards,

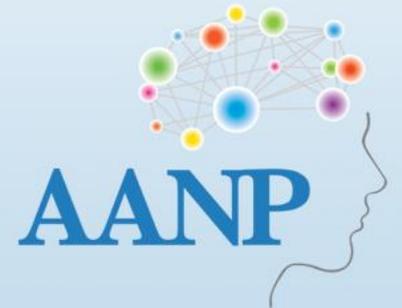
Your Institution’s IRB



BIOBANKING CONSENT

In addition to Federal, State and Institutional guidelines, should:

- Include language informing human subjects that their specimens may be used for commercial product and/or drug development
- Discuss possibility of distributing biospecimens outside of the institution, to companies, etc.
- Include information on DNA and RNA extraction, and possibility of immortal cell line creation



BIOBANKING CONSENT

- *“The complexity and breadth of biobanking practices generate risks, benefits, and responsibilities that have not been adequately identified or resolved.”*

> [Lancet Public Health](#). 2019 Jun;4(6):e274-e275. doi: 10.1016/S2468-2667(19)30081-7.

The complex ethical landscape of biobanking

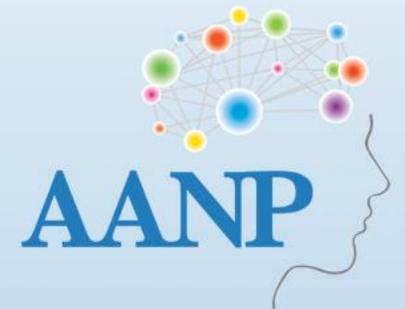
Jonathan W Ashcroft ¹, Cheryl C Macpherson ²

Affiliations

Affiliations

- 1 UK Public Health Rapid Support Team, Public Health England, Porton Down SP4 0JG, UK; London School of Hygiene & Tropical Medicine, London, UK; Windward Island Research and Education Foundation, St George's, Grenada. Electronic address: jonathan.ashcroft@phe.gov.uk.
- 2 Bioethics Division, Department of Clinical Skills, St George's University, St George's, Grenada; Windward Island Research and Education Foundation, St George's, Grenada.

PMID: 31155216 DOI: [10.1016/S2468-2667\(19\)30081-7](https://doi.org/10.1016/S2468-2667(19)30081-7)



BROAD CONSENT

- The Common Rule: 1991
- The Final Rule: 2017



U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

[HHS](#) </> [OHRP](#) </> [SACHRP Committee](#) </> [SACHRP...](#)

Navigate to:



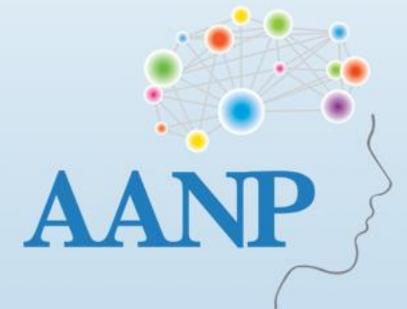
Attachment C - Recommendations for Broad Consent Guidance

Recommendation Approved by SACHRP July 26, 2017

Guidance on Broad Consent under the Revised Common Rule

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-august-2-2017/index.html>

U.S. Department of Health and Human Services (HHS) publishes broad consent templates containing all required consent elements



<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html>

HOW DO LIVING PATIENTS FEEL ABOUT BROAD CONSENT?

Published in final edited form as:

J Empir Res Hum Res Ethics. 2018 April ; 13(2): 115–124. doi:10.1177/1556264617751204.

Broad Consent for Research on Biospecimens: The Views of Actual Donors at Four U.S. Medical Centers

Teddy D. Warner¹, Carol J. Weil², Christopher Andry³, Howard B. Degenholtz⁴, Lisa Parker⁴, Latarsha J. Carithers^{5,9}, Michelle Feige⁶, David Wendler⁷, and Rebecca D. Pentz⁸

¹University of New Mexico (USA)

²National Cancer Institute (USA)

³Boston Medical Center (USA)

⁴University of Pittsburgh (USA)

⁵National Cancer Institute, National Institutes of Health (USA)

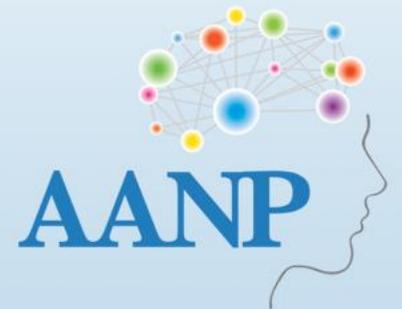
⁶Association for the Accreditation of Human Research Protection Programs, Inc. (USA)

⁷National Institutes of Health (USA)

⁸Winship Cancer Institute, Emory University School of Medicine (USA)

⁹Now at the National Institute of Dental & Craniofacial Research (USA)

“Concerns regarding future uses were limited to for-profit research and research by investigators in other countries. These results support the use of broad consent to store and use biological samples in future research.”



WHAT ABOUT DECEASED, “NON HUMAN SUBJECT” RESEARCH AND CONSENT?

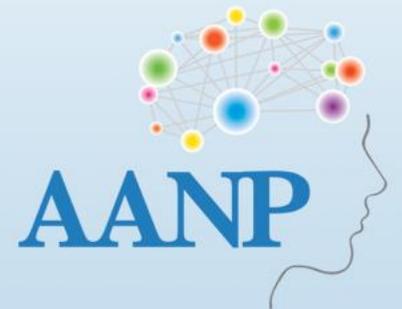
- Can stored biobank material from deceased persons still be used on the basis of their broad consent?
- Biobank research participants are susceptible to no or only negligible risk of bodily harm... so no consent has traditionally been regarded as necessary for using stored tissue from hospital biobanks.

Research ethics

PAPER

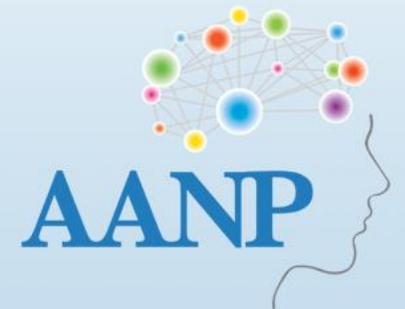
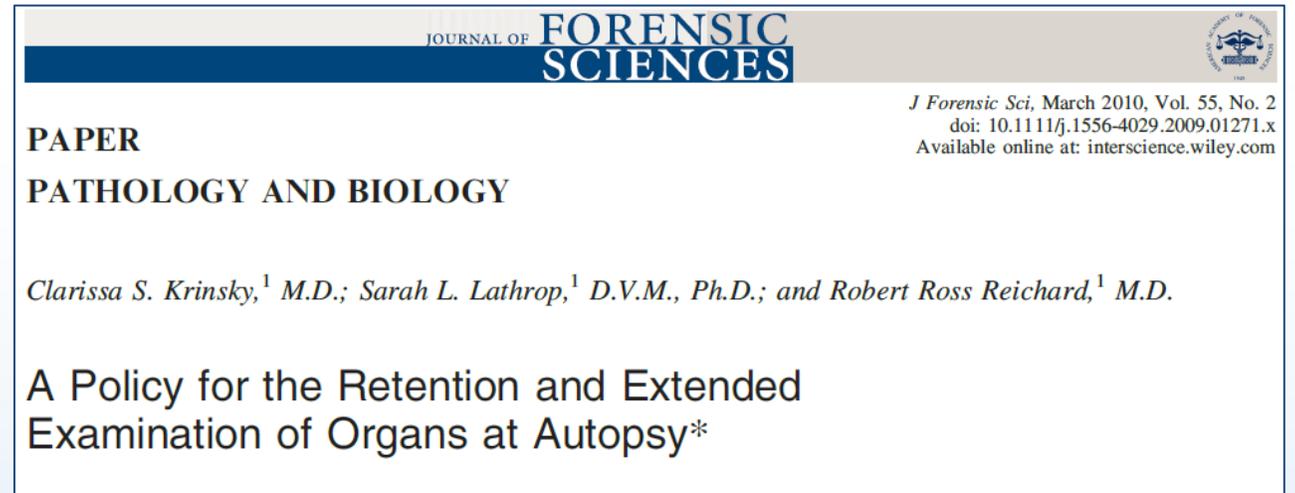
Ethics of dead participants: policy recommendations for biobank research

Lars Ursin, Maria Stuifbergen



TISSUE RETENTION & FORENSIC PATHOLOGY

- Medical examiners trained to be careful with tissue retention
- Some offices inform families about saving organs for sub-specialty examination



TISSUE RETENTION & FORENSIC PATHOLOGY

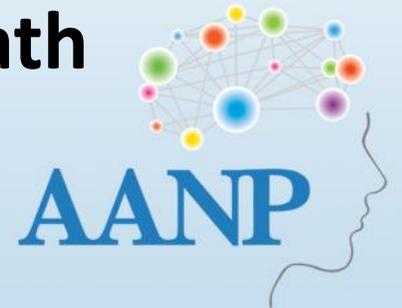
- Medical examiners trained to be careful with tissue retention
- Some offices inform families about saving organs for sub-specialty examination

Perceptions of the Ethical Acceptability of Using Medical Examiner Autopsies for Research and Education

A Survey of Forensic Pathologists

*Laura Weiss Roberts, MD; Kurt B. Nolte, MD; Teddy D. Warner, PhD; Teresita McCarty, MD;
Lizabeth Stolz Rosenbaum, BA; Ross Zumwalt, MD*

Statutory duty to determine Cause and Manner of Death



RESEARCH ON MEDICOLEGAL AUTOPSIES



Principles to Promote Research in Medicolegal Death Investigation

A resource document prepared by the Organization of Scientific Area Committees (OSAC) for Forensic Science's Medicolegal Death Investigation (MDI) Subcommittee, part of the Medicine Scientific Area Committee

Correspondence may be directed to Laura Gould (Laura.Gould@nyulangone.org)

Keywords: autopsy; biospecimens; cause of death; informed consent; manner of death; medicolegal death investigation; medicolegal death investigation system; next of kin; research

Summary

The National Institute of Standards and Technology (NIST) Organization of Scientific Area Committees (OSAC) for Forensic Science Medicolegal Death Investigation (MDI) Subcommittee, which is comprised of stakeholders including medical examiners, coroners, medicolegal death investigators, public health researchers and others, have identified several barriers to research in MDI.



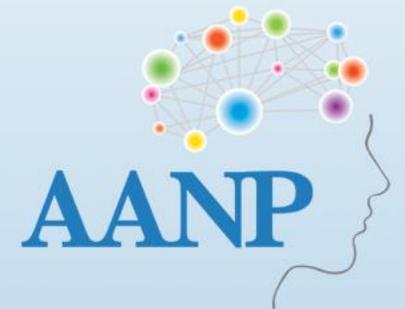
GENETIC TESTING

- Implications for living family members
- Appropriate communication of results, support
- Data and specimen storage

The ethics of conducting molecular autopsies in cases of sudden death in the young

Amy L. McGuire,^{1,6} Quianta Moore,^{1,2,6} Mary Majumder,^{1,6} Magdalena Walkiewicz,³ Christine M. Eng,³ John W. Belmont,³ Salma Nassef,³ Sandra Darilek,³ Katie Rutherford,⁴ Stacey Pereira,¹ Steven E. Scherer,^{3,5} V. Reid Sutton,³ Dwayne Wolf,⁴ Richard A. Gibbs,^{3,5} Roger Kahn,⁴ Luis A. Sanchez,⁴ and the Molecular Autopsy Consortium of Houston (MATCH)⁷

¹Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, Texas 77030, USA; ²Rice University Baker Institute for Public Policy, Houston, Texas 77005, USA; ³Department of Molecular and Human Genetics, Baylor College of Medicine, Houston, Texas 77030, USA; ⁴Harris County Institute of Forensic Sciences, Houston, Texas 77030, USA; ⁵Human Genome Sequencing Center, Baylor College of Medicine, Houston, Texas 77030, USA



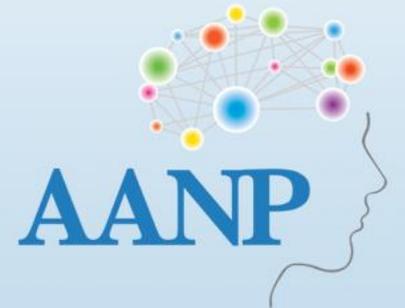


SUMMARY

POSTMORTEM NEUROPATHOLOGY RESEARCH

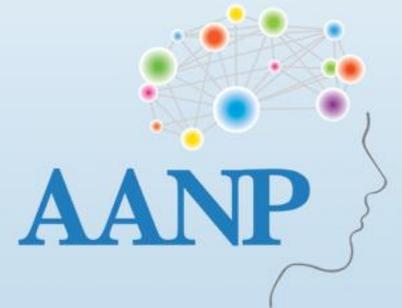
Key Take-Aways: LOGISTICS

- Identify stakeholders when building / expanding a research program
- Know where to find regulatory information
- Reach out to colleagues – many are willing to help!
- Identify at least one clinician with which to collaborate, who shares the vision and can assist with funding, personnel, etc.
- Ascertain if your regional organ/tissue donation agencies are able to obtain research consent for you



Key Take-Aways: ETHICS

- Legal ≠ ethical
- Decedents are not technically human subjects
- ***TREAD CAREFULLY, ESPECIALLY WITH MEDICOLEGAL CASES!***
- Biobanking still relatively new; not all IRBs are caught up
- NIH (HHS) has broad consent biobanking guidelines
- Forensics:
 - If you're an ME, reach out to your local procurement agencies for consent assistance, etc.
 - Communicate ME research limitations to the team receiving your subspecialty neuropathology



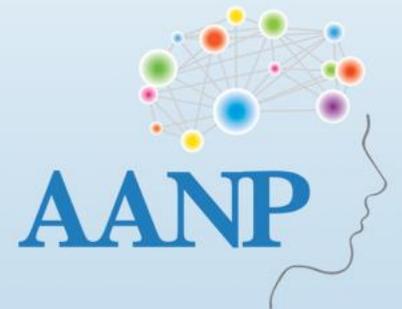
Incorporating into Autopsy Report

Case Summary:

The decedent is a 2 year old female recently diagnosed with diffuse midline glioma via imaging who rapidly progressed ... parents requested a complete autopsy, including collection of tissues for research.

Preliminary Autopsy Diagnosis:

1. Diffuse midline glioma, H3 K27-altered (neuropathology pending)
2. Post research donation for Gift from a Child and Children's Oncology Group

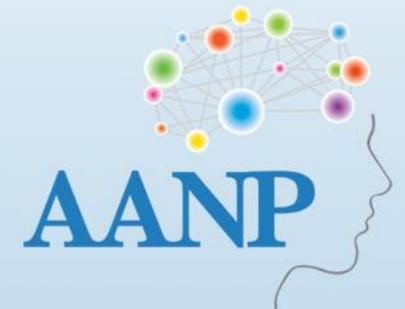


Acknowledgements

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- Russell Ray
- Bilal Omer
- Frank Lin
- Donald W. Parsons
- Darryl Kinnear
- Marlene Green
- Jesse Barrera
- University of Iowa Colleagues
- **Patients and their families**



Caroline Wiess Law Fund for Research in Molecular Medicine at Baylor College of Medicine
Children's Oncology Group Young Investigator Program



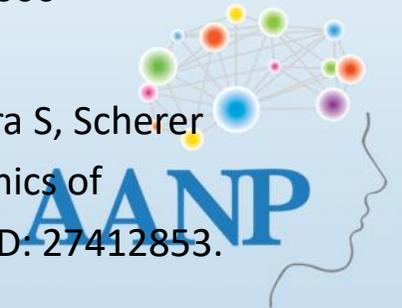
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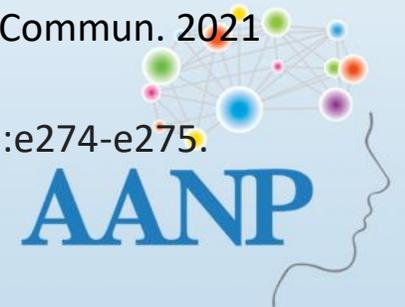
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A network diagram with various colored nodes (green, blue, purple, grey) connected by lines, set against a blue background.

THANK YOU!!

QUESTIONS / DISCUSSION

melissa-blessing@uiowa.edu