

Native American Cancer Research (NACR) Corporation: Native Cancer 101 Module 8: Biospecimens and Biobanking Fact Sheet



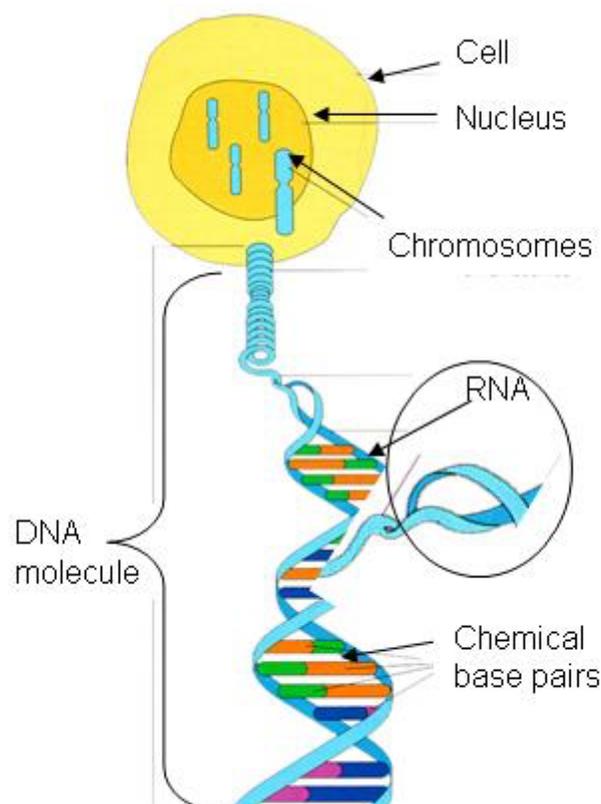
- 🍵 Biospecimen and genetics research is leading to more effective and tailored disease (including cancer) treatments
- 🍵 Some American Indian tribal Nations feel the protection of privacy and confidentiality in such studies is insufficient
- 🍵 You need to be comfortable that your privacy and confidentiality rights are protected
- 🍵 Donating biospecimens to biobanks / repositories may help scientists find cures; but, you need to first learn if your tribal Nation provides any guidance about sharing genetic / biospecimens for research studies
- 🍵 Now you know. Now you can.

What are biospecimens?

- 🍵 Refers to materials taken from the human body
- 🍵 Primarily to study DNA, RNA and Proteins
 - ⊕ Because these molecules may contain information, about the human being and also about their disease
 - ⊕ The DNA code is comprised on the chemical base pairs
- 🍵 RNA is copied from DNA
- 🍵 RNA can also be copied many times which makes it a good biospecimen

What are common sources biospecimens?

- 🍵 Blood
- 🍵 Saliva
- 🍵 Hair root
- 🍵 Fingernails
- 🍵 Flaked off skin cells (e.g., from clothing)
- 🍵 Liver biopsy tissue
- 🍵 Lung bronchoscopy
- 🍵 Extra tissue from diagnosis and treatment procedures
- 🍵 Excess normal or tumor tissue
- 🍵 NOTE: Some specimens violate cultural values (e.g., hair) for specific tribes and should not be donated without tribal approvals



What can damage the biospecimens?

- 🍵 Routine handling during collection
- 🍵 Processing
- 🍵 Storage
 - ⊕ Padding protection
 - ⊕ Temperature controlled
 - ⊕ Exposure to air / oxygen)
- 🍵 Duration (time) from donor to laboratory

What type of anecdotal information is frequently included with the biospecimen?

- Personal and medical information associated with a biospecimen.
 - Age
 - Gender
 - Ethnicity
 - Disease
 - Environmental exposures
- Most personal, identifying information (phenotype) is stripped from the specimen prior to inclusion in repository

What are examples of research uses of biospecimens?

- To diagnose a condition
- To treat a person's disease
- For research
- To educate medical students and providers
- In forensics
- Example of use of hair follicle or hair strand specimen: researcher can learn what types of foods, beverages and/or drugs the individual consumed



Rose Lee (Navajo), former NACR Navigator educating a community member

How are biospecimens collected?

- Blood draw
- Cheek swab
- Urine collection
- Hair pull (need follicle)
- Biopsy
- Surgery



What is a "Biobank"?

- Also called "repositories"
- Federal Repositories and many "grant-supported" repositories are required to make all specimens available to anyone who requests them
 - No individual informed consent
 - Any study focus (diabetes, CYP 450, drug abuse, new medical treatments, schizophrenia, bi-polar,, etc.)
 - PI from anywhere in the world
- May be managed by local organization or institution (state government, academic or research setting)
 - Rarely if ever stored and managed by tribal / urban Indian setting because:
 - Requires a freezer that controls minus 80 degrees (~\$100,000+)
 - Must have back-up generator in case there are interruptions in electrical power

What is the difference between "storage" of specimens and "biobanking"?

- "Storage" of specimens is usually limited to a specific research or medical study
 - Specimens are not accessible to others outside the research field
 - Further use of the specimens typically requires active informed consent from the participants
 - At the conclusion of a study, specimens should be destroyed following tribal protocols / ceremonies
- Banking is saving samples specimens or data
 - For future analysis
 - No consent for future studies
 - And may or may not be related to the study from which the specimen was originally taken
 - "Libraries" of stored biospecimens that are made available to scientists for research purposes (not for transplants).
- NIH Repositories are shared internationally with responsible scientists
 - Private repositories may charge a fee for researchers to access specimens



Fatimah Jackson, Professor Applied Biological Anthropology University of Maryland at College Park

What happened to Havasupai?

- 🍵 Several violations of trust occurred:
 - ⊕ Insufficient informed consent process
 - ⊕ Specimens were shared with others without permission from Havasupai
 - ⊕ Tribal members thought they were agreeing to a single study on diabetes
 - ⊕ Research team thought the tribal members agreed to have specimens included in a repository allowing others to use them
 - ⊕ Research was conducted on Havasupai specimens for schizophrenia markers without tribal approvals



Who was Henrietta Lacks and why are her cells "immortal"?

- 🍵 Diagnosed with cervix cancer in 1950
- 🍵 Hers were the 1st cells that were able to be grown in a laboratory (Immortal) and distributed worldwide
- 🍵 Used for millions of experiments
- 🍵 No informed consent
- 🍵 Family was traumatized by what they considered misuse of their family member

How is a donor's privacy protected?

- 🍵 Tissue is coded with a unique identifier.
- 🍵 Categories of biospecimens:
 - ⊕ Identified
 - ⊕ Identifiable
 - ⊕ Anonymized
 - ⊕ Anonymous
- 🍵 According to Fatimah Jackson, no specimen is truly anonymous... science is expanding as such a rate that within a decade, it will be possible to identify from whom a specimen was collected
 - ⊕ This is an issue of concern to some tribal

What are examples of biospecimen / genetic research issues to which some tribes object?

- 🍵 NOTE: Tribal Nations vary in their willingness to take part in biospecimen / genetic research
 - ⊕ Example: Alaska Native villagers have taken part in several studies on prevention of obesity (UAF 2004-present)
- 🍵 Creator, not scientists, has the role to "prevent" the disease
- 🍵 One large tribe issued sanction prohibiting tribal members from taking part for multiple reasons, including genetic research protections are insufficient to protect individual and tribal privacy and confidentiality
- 🍵 Tribal cultural practices impacting "autonomy" such as for some tribes the eldest female makes health decisions rather than the individual patient
- 🍵 Publication of family tree (pedigree) and loss of "anonymity"
- 🍵 "Justice" ethical concerns that new medications that evolve from the research will result in patents that will be too expensive for Natives to access
- 🍵 Tribal Nations need to own and store their own data
- 🍵 All future studies (following the original study when donation of specimen was made) should include active informed consent (you have to say "yes" for your specimen to be included)

What is the Belmont Report

- 🍵 Issued in 1979 by a national commission
- 🍵 Sets forth three principles for the ethical conduct of research:
 - ⊕ Respect for persons
 - ⊕ Beneficence
 - ⊕ Justice

What is the purpose of the Institutional Review Board (IRB)?

- 🍵 Reviews research and consent forms to determine if the rights and welfare of subjects are protected.
- 🍵 Works for the benefit and respect of the community
- 🍵 Multiple legal and ethical roles and responsibilities
- 🍵 IRB shares responsibility with the research investigator for protecting the:
 - ⊕ Privacy
 - ⊕ Safety
 - ⊕ Confidentiality of the people who participate in the study

What is the purpose of the informed consent process?

- 🍵 To ensure that the patient has sufficient knowledge to make an informed choice regarding study participation
- 🍵 More than a form or a signature
- 🍵 An ongoing process for information exchange that typically includes:
 - ⊕ Verbal instructions
 - ⊕ Written materials
 - ⊕ Question and answer session
 - ⊕ Agreement documented by signature



What is “Privacy”?

- 🍵 Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- 🍵 Examples of “private” information?
 - ⊕ Your name
 - ⊕ Your address
 - ⊕ Your tribal affiliation or ethnic information

What is confidentiality (in research context)?

- 🍵 Confidentiality pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged without permission to others in ways that are inconsistent with the understanding of the original disclosure.
 - ⊕ Participants give information about themselves to the research team in a relationship of trust.
 - ⊕ Participants expect that the information will be shared only as necessary.
 - ⊕ The research team must respect the participant's trust and not betray the confidence placed in them.

What “informed consent” is NOT

- 🍵 A legal contract
- 🍵 Binding on the part of the participant
- 🍵 Simply a set of instructions on how medications are given
- 🍵 Protect the researcher from malpractice

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