Using and Sharing Existing Specimens and Data for Secondary Research: Expectations for Consent and IRB Approval

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NIDA Clinical Rounds -- October 7, 2021

Secondary Human Subjects Research (HSR)

Definition of Secondary Human Subjects Research:

When investigators have access to identifiers and plan to conduct new human subjects research (*not addressed in the original protocol and consent form*) with existing specimens or data.

Common Examples of Secondary HSR

- Analyzing *existing* identifiable specimens or data to meet a new research objective
- Sharing *existing* coded specimens or data with a collaborator and receiving individual-level results* as part of a new research project

* *Which can be linked to identifiers*

PRINCIPLES

Principle #1: Informed Consent Language Matters

- The sharing and secondary research with existing materials must comply with the terms of the original informed consent document.
- Researchers are expected to review all previous versions of consent forms to determine “who” consented to “what”.

Principle #2: Consistency Between Sharing/Research Plan and Consent

- If the original consent form addresses the use and sharing of specimens or data for future research, the **plan for sharing and research should be consistent with the language** in the original consent document.

Principle #3: Conflicting Consent Language Means "No Go"

- If there is language in the original consent form which is contrary to sharing or future research or conflicts with the sharing and research plan, the investigator cannot proceed with the plan.
  - This is true, even if the specimens and data are being used or shared in a de-identified* manner, or if the subjects are deceased. This is an ethical issue.

**The recipient can't re-identify (may be coded and linked (and the sender retains the code key) or may be completely anonymized)*

Examples of Consent Issues

- When the NIH investigator is collaborating with an outside investigator who want to use the NIH specimens and data to study diabetes:
  - "Your specimens will be destroyed at the end of this study."
  - "Your specimens and data will be used for future research on cancer."
  - Some subjects opted out of future research with specimens or data by checking a box. The NIH investigator never tracked this information anywhere.

More Examples of Consent Issues

- “Your data will never be shared outside of the NIH research team” (or outside of the NIH).
- Some subjects opted out of the sharing of their specimens or data by checking a box. The NIH investigator never tracked this information anywhere.

Option to Re-Consent Subjects

If the original consent form included language which is contrary to the investigator's sharing or research plan, he or she has the option to locate and re-consent the subjects to be able to move ahead with the project.

Principle #4: Silence Allows Flexibility

- If the original consent form (for protocols approved before January 21, 2019) was silent on the topic of sharing and future research, in most cases, it is acceptable to share the materials and use them for future research.

Changes with the Revised Common Rule

- Per the revised Common Rule (or studies approved on or after January 21, 2019), consent forms must address:
  - That specimens and data might be anonymized and shared and used for research, or specimens and data will never be shared or used for future research;

    and

  - If specimens may be used for commercial profit and whether the subject will or will not share in this profit

Principle #5: Consent for Future Research is Only the Beginning

- Consent to use specimens and data for future research **is not sufficient to allow the investigator to move forward with secondary research** with identifiable specimens and data.
  - This type of consent language simply allows the investigator to store the materials for future research (or use the materials once completely anonymized).

Principle #6: IRB Approval for Secondary Research

- If the investigator will conduct new research using existing identifiable specimens and data, *generally* he or she is expected to submit a new research protocol and seek IRB approval.

Principle #7: Consent or a Waiver is Required

- If the investigator will conduct secondary research (including a research collaboration) using existing identifiable specimens or data, he or she must:
  - Conduct consent to obtain permission to use the specimens or data for the new research;

    or

  - Request a waiver of consent for the new research in the protocol and provide a justification

WAIVER OF INFORMED CONSENT

Waiver of Informed Consent

- Waiver of Consent: Waiver of the requirement to obtain informed consent for research
- May request a waiver of informed consent under certain circumstances
  - Limits to approvability might include accessing new information about the subjects or conducting genomic research without prior consent.

Does Not Apply to Sharing

- A waiver of consent applies to human subjects research, not sharing.
  - The investigator cannot request a waiver of consent **to get around the fact that** the original consent form said that materials would not be shared or used for future research
  - If the consent was silent on sharing, there is also no need to request a waiver of consent.

Does Not Apply to Broad Future Research

- A waiver of consent **cannot be requested to allow for broad research** with existing specimens and data **in the future**.

Criteria for a Waiver of Consent (i)

- When requesting a waiver, address and provide justification for the **five*** specific regulatory criteria in the protocol:

- (i) The research involves no more than minimal risk to the subjects;
  - Example of a justification: The only risk to subjects is a possible breach of confidentiality.

*based on the revised Common Rule

Criteria for a Waiver of Consent (ii)

- (ii) The research could not practicably be carried out without the requested waiver or alteration (i.e., it is not possible to conduct the research unless consent is not required);
  - Example of a justification: The required sample size is so large that it would impede scientific validity and introduce bias if only those who were willing to consent were included.
  - Example of a justification: Many of the subjects are lost to follow-up, or the research team has not been in contact with them for many years.

Criteria for a Waiver of Consent (iii)

- (iii) The research could not practicably be carried out without using such information or biospecimens **in an identifiable format**;
  - Example of a justification: The research involves specimens and different types of data (medical records, imaging, lab results) that all must be linked together by subject identifier.

Criteria for a Waiver of Consent (iv)

- (iv) The waiver will **not adversely affect the rights and welfare** of the subjects;
  - Example of a justification: Conducting the planned research with existing specimens and data (originally collected under informed consent) will not cause any harm to subjects.

Criteria for a Waiver of Consent (v)

- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with **additional pertinent information** after participation.
  - Example of a justification: We do not intend to contact subjects to share the results of our research. The results of this research will not generate new clinically actionable findings.

Contact Info & Websites

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?QUESTIONS?