

# **Biospecimens and data in the proposed changes to the Common Rule**

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# Disclosure

- I am a strong proponent of the collection and use of biospecimens and data for research
- I have been deeply involved in the creation and evolution of BioVU, our DNA biobank from leftover blood samples, and in research using that resource

# Conclusion

- The biospecimen exceptionalism embodied in the NPRM is unwarranted and incoherent
- Focus on elaborate consent rather than engagement, transparency, and accountability is misguided

# Improving Informed Consent in General (2)

## **Major revision to introduction of §116 does the following:**

- The core required information should be in “main” part of consent form, which should be short
- Appendices can include any other information that is desired to be given – no restrictions on that
- Goal is to counter current trend to have long consent forms with most important information buried

# Required for collection of biospecimens that can be used for research

## Stated goal is to honor autonomy

- Risks to the subject
- Benefits to subject or others
- Extent of protection for confidentiality of records
- Whom to contact for questions or research-related injury
- Statement that specimens may be used for commercial profit and how much subject will share in the profit
- Whether and how individual results will be returned to the subject
- Option to refuse to allow investigators to recontact individuals for more data or samples or other studies
- General descriptions of types of research that will be conducted, what information will be used, and what institutions will do the research
- “A clear description of the types of biospecimens or [identifiable private] information that were or will be collected and the period of time during which biospecimen or information collection will occur. This may include all biospecimens and information from the subject’s medical record or other records existing at the institution at the time informed consent is sought.”
- Ten year limit on the period of time that specimens that were not collected primarily for research can be collected
- How long specimens can be used for research
- A statement that participation is voluntary and that withdrawal will not lead to penalty
- Names of institutions where specimens and identifiable private information will be collected
- If applicable, they will not be informed about specific research studies
- “If applicable, a statement notifying the subject or the representative of the expectation that the subject’s information and biospecimens are likely to be used by multiple investigators and institutions and shared broadly for many types of research studies in the future, and this information and the biospecimens might be identifiable when shared.”
- An option for adults to agree to allowing open access to data that has been de-identified according to HIPAA safe harbor

# Some questions

- Will disclosure proposed in the NPRM for biospecimens
  - Help people to make informed choices and exercise autonomy?
    - What about limited understanding of the scientific enterprise?
  - Become routine in all hospital forms?
  - Increase trust?
  - Increase participation?

# Some questions

- Should written consent be required for virtually all collection and use of biospecimens?
  - Current regulations allow use of previously collected clinical samples without identifiers without consent
  - Many people think this is OK
  - Many people think opt out is OK

# How Do these Proposals Affect Secondary Research with *Data*?

- Core rules relating to secondary research with de-identified data are unchanged: it would still not constitute a human subject, and not be under the regulations
- Furthermore, new rules relating to biospecimens do not alter rules relating to secondary research with data, regardless of whether data had been obtained from a biospecimen or some other way
- All data, regardless of source, treated same way



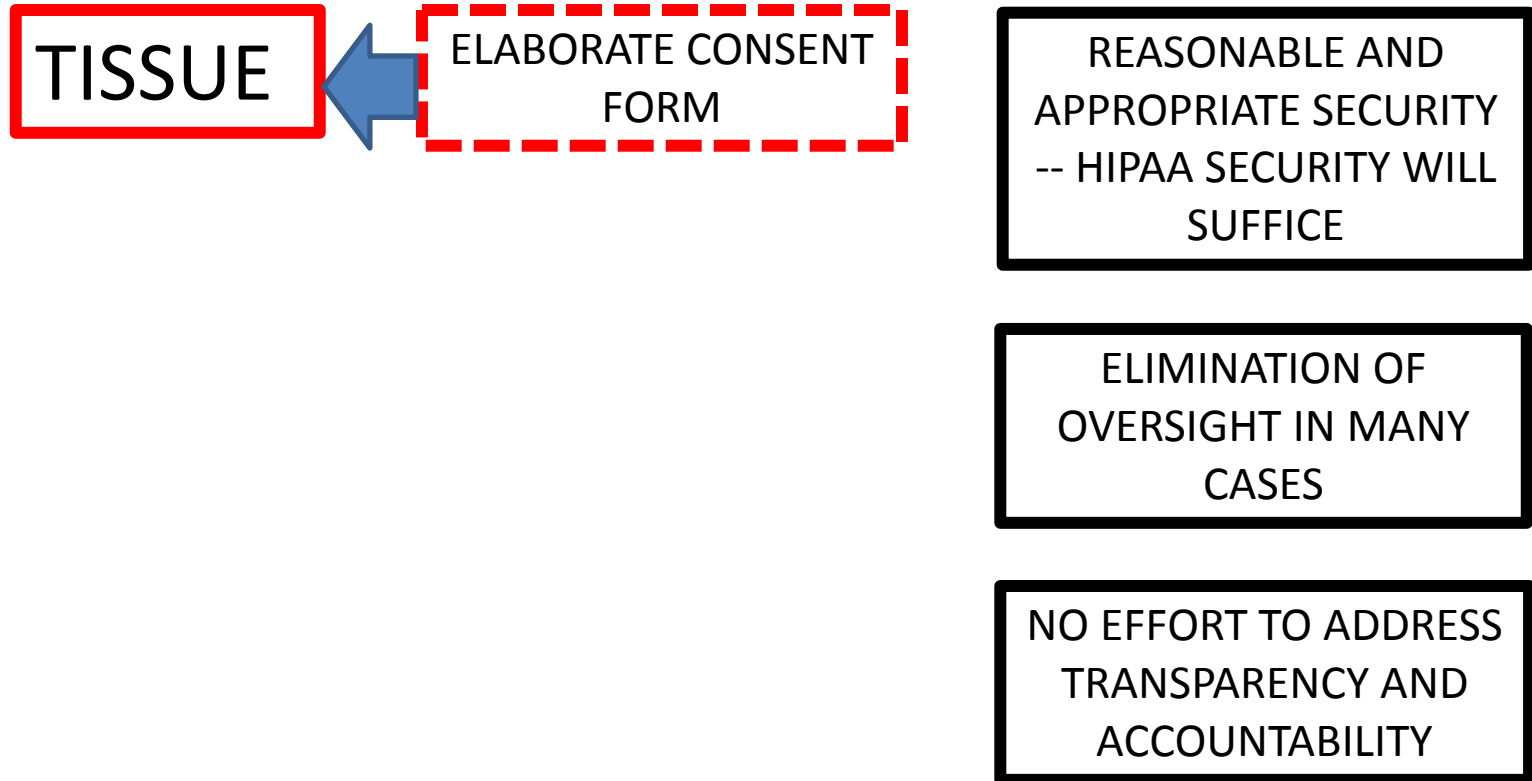
# How Do these Proposals Affect Secondary Research with *Data*?

- In several ways, proposals increase ability to conduct research with identified data without consent, assuming appropriate protections in place
- While new broad consent forms can be used by researchers to obtain consent for secondary use of identifiable data, that is merely a new option
- Unlike for biospecimens, there are many other options for data researchers apart from obtaining broad consent

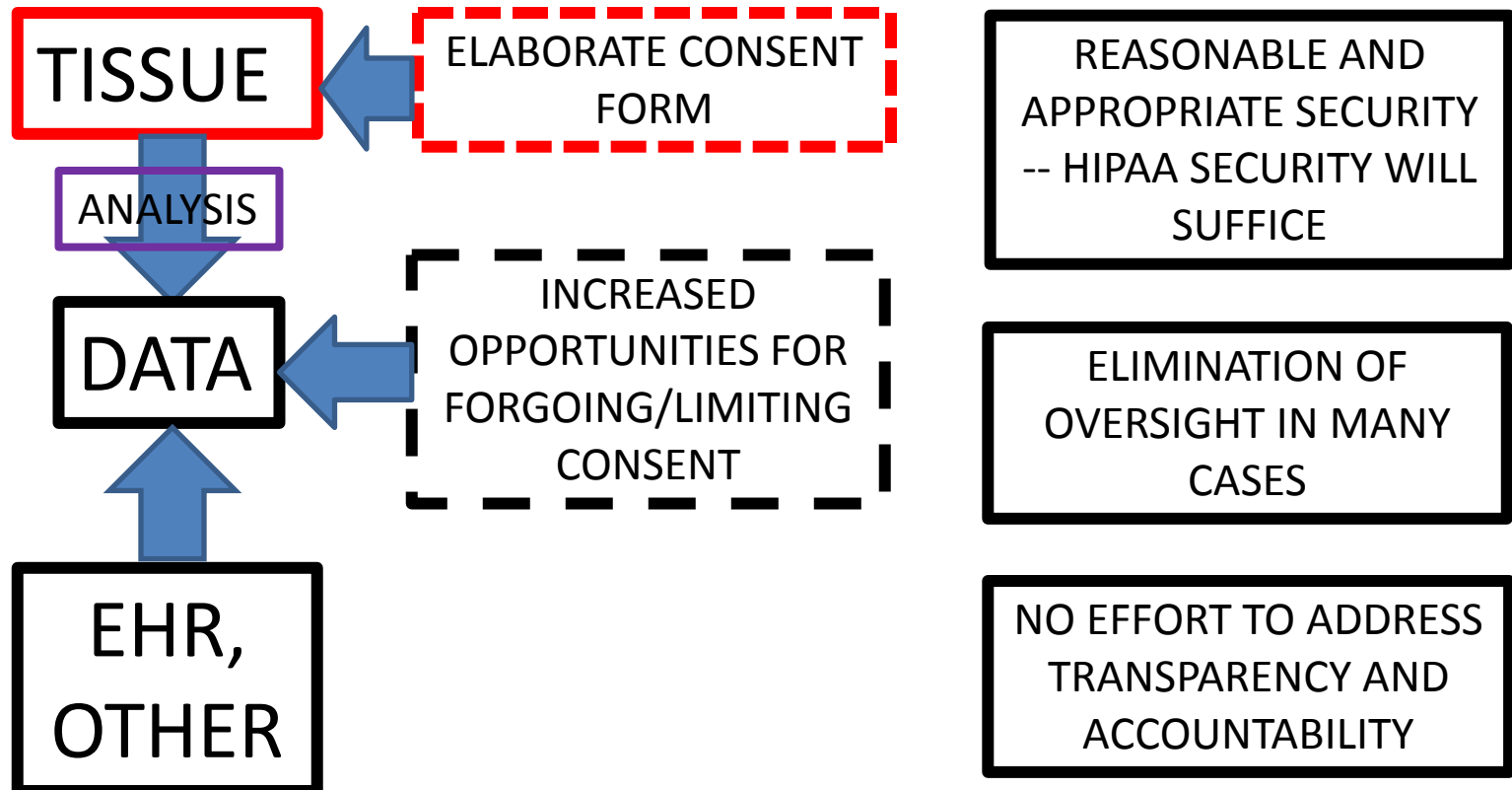
# How Do these Proposals Affect Secondary Research with *Data*?

- Researchers could
  - Use data stripped of identifiers
  - Keep a one-way link to identifiers
  - Obtain IRB waiver allowing use of identifiers
  - Use new exemption allowing use of identifiable data with notice instead of consent
- Any one of these might be preferable to obtaining broad consent (in contrast to few options for research with biospecimens)

# So what does this mean?



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# Some questions about biospecimens versus data

- Is it appropriate to treat biospecimens differently from everything else, *including the data from obtained from specimens?*
  - People want to be asked about clinical data, too
  - They are also concerned about data from biospecimens
  - The decision to make de-identified genetic information more available for research is particularly striking
  - Opinion  $\neq$  policy

# Conclusion

- The distinction in the proposed rule is incoherent
- The proposed consent requirements will not enhance autonomy
- The focus should be on engagement, transparency, and accountability