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ART OF MEDICINE

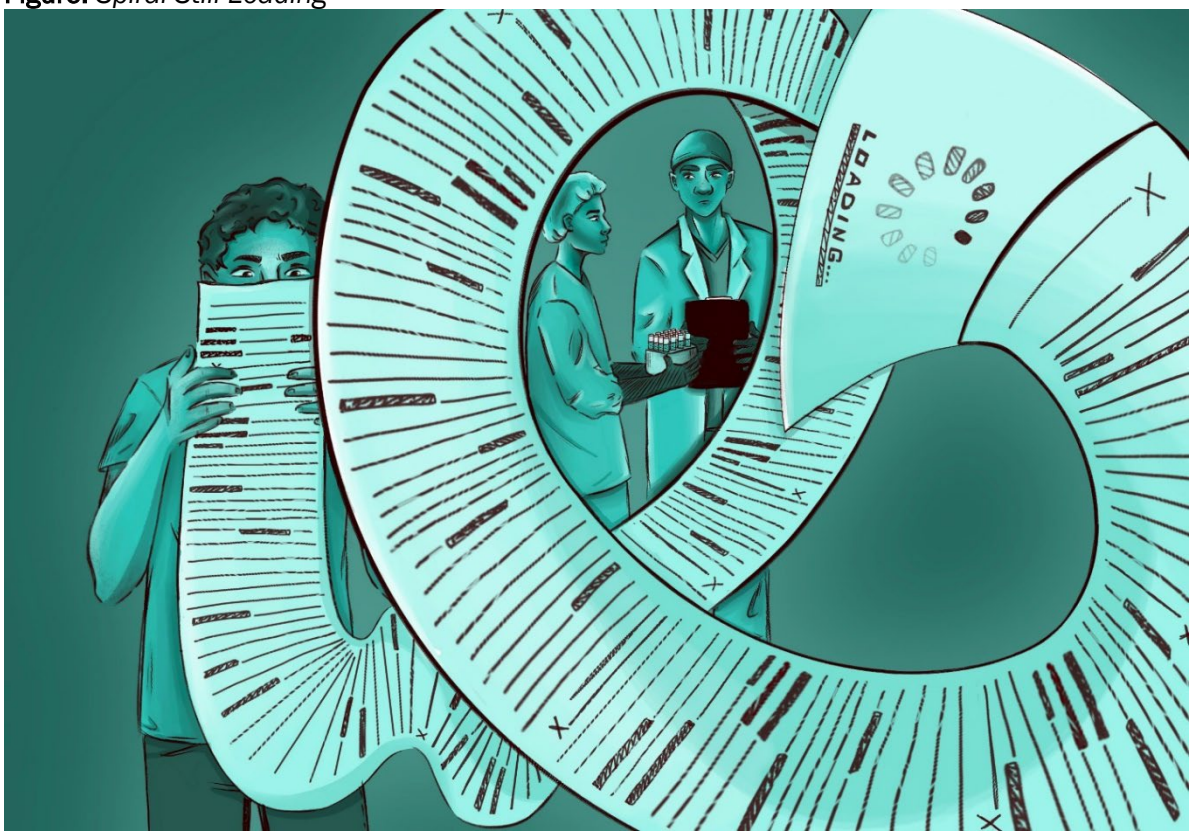
Decision-Making About Biospecimens

Anaid Kassidy Corona-Andaverde

Abstract

This digital drawing considers a signatory's experience of some consent processes in health decision-making that might involve their biospecimens' use in standard care, clinical research, or diagnostic research of the Undiagnosed Diseases Network.

Figure. *Spiral Still Loading*



Media

Digital illustration made with Wacom Cintiq, Krita, and iPad Procreate.

This digital drawing of a long, spiraling document suggests a confusing and lengthy consent process. Prospective risks and benefits of a clinical intervention can be too numerous to cover in a single clinical encounter, and risks of participating in clinical trials can be unknown. In both standard care and research settings, genomic and genetic biospecimen sampling adds to a list of social, psychological, and physical risks that can permanently alter the lives of participants and, at times, their biological relatives or descendants.[1] Psychological risks of participating in research, especially, can be "subtle and poorly defined" despite their importance.[1]

In 2019, the US Department of Health and Human Services revised the Common Rule to "provide key information and promote [the] autonomy" of subjects.[2] Revisions to informed consent regulations, in particular, also included an updated definition of the term *human subject* and updated informed consent exceptions.[2,3] Improvements in regulations or consent forms, "including simplified language, illustrations, shorter length, and teach-back approaches, have led to only modest improvements" in subjects' clearer understandings of research protocols and goals.[1] Consent processes that prioritize personal interactions between clinician-investigators and patient-subjects tend to hold more promise for promoting patient-subjects' understandings of their roles in research[4] and of how their biospecimens might be used.

References

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Anaid Kassidy Corona-Andaverde is a student at the School of the Art Institute of Chicago in Illinois who is studying architectural design.

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