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Perspective

Concise informed consent to increase data and biospecimen access may accelerate innovative Alzheimer's disease treatments

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Abstract

Introduction: Informed consent forms that restrict the distribution of data and samples have been an impediment to advancing Alzheimer's disease (AD) understandings and treatments. The Coalition Against Major Disease public-private partnership developed concise addenda to responsibly broaden data access of informed consent forms.

Methods: Coalition Against Major Disease members identified key elements for ensuring data and biospecimen access, and patient privacy protection according to applicable US law. Collaboration with the Alzheimer's Association established the understandability and relevance of the addenda with AD patients and Care Partners.

Results: Two key findings are (1) patients with dementia and Care Partners were shocked that their data and samples are not broadly shared and (2) with diverse feedback, two concise addenda were created to enable data and sample sharing both within and outside future sponsored studies (see Boxes).

Discussion: Increasing the access of valuable anonymized patient-level clinical trial data has the potential to inform the foundational and regulatory science required to deliver innovative treatments for AD.

Keywords: Alzheimer disease; Biospecimen; Consortia; Databases; Data sharing; Drug development tools; Informed consent; Regulatory sciences

1. Introduction

HeLa cells were one of the most important tools in medicine in the 20th century, vital for developing the polio vaccine, gene mapping, in vitro fertilization, and more. The original researchers at Johns Hopkins shared the cells freely and extensively for research. With time, a major industry was developed around the cells that were being bought and sold by the billions. *He*nrietta *La*cks, the woman who had unknowingly contributed those cells in 1951 remained unknown, when her legacy family was unable to afford health insurance. Central to the outrage expressed by her family is that the cells were taken and used without her informed consent.

Informed consent forms (ICFs) are now a central requirement of clinical research in the United States, intended to ensure that prospective participants understand the risks and benefits of the study and the purpose of the research before they agree to participate. This straightforward goal has been complicated in recent decades as ICFs have evolved into lengthy and technical forms designed to protect both the patients and the sponsors of the research study [1].

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Box 1
Informed consent form addendum to ensure future data and sample sharing

Overview

The information collected in this study will be used to:

- see if the study drug works and is safe;
- compare the study drug to other potential or approved therapies;
- examine the relationship of the data and samples to that of other diseases;
- develop new tests;
- improve the design of future studies;
- advance the understanding of health and disease; and
- accelerate other activities (e.g., creation of clinical tools that improve the delivery of innovative treatments by advancing basic and regulatory science).

You will not be identified in any publication from this study or in any data files shared with other researchers. Your identity will be protected as required by law.

When the information from this study is shared outside the study site, the information that identifies you will be removed. In addition, the sponsor, like other sponsors, provides access to clinical data that have been further deidentified so that outside researchers can use these data. Information that could directly identify you will not be included.

Your rights: data and samples

You have the right to decide whether to participate in the study. If you decide to participate in the study, the following are groups with whom your study team may share your data and samples to improve new treatments or the conduct of clinical trials:

- Health authorities throughout the world (e.g., Food and Drug Administration, European Medicines Agency, and other governing bodies that review clinical trials).
- Institutional Review Boards that oversee and review the ethics of the research.
- The study sponsor and those working for or with the sponsor, which may include affiliates of the sponsor located in your country or other countries.
- Other groups: Examples of which include academic, government, or industry researchers; public-private partnerships; and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.

At no time will the data or samples be allowed to be sold by an individual or group for profit.

Your data and samples will be deidentified or anonymized. This means that your data or samples will not be linked with information that would allow any person or organization to determine that the data directly corresponds to you.

The health information you contribute will be protected by U.S. federal law (the Health Information Portability and Accountability Act).

New results obtained with your data and samples will be reported back to the sponsor and the results made publicly available.

You have the right to withdraw your permission for us to use or share your information up until the time that your data and samples are deidentified and pooled together into a database. Your data and samples will be used and shared as described in this form.

Potential benefits and risks

Benefits

Allowing your deidentified data and samples to become available to research and regulatory organizations could advance new treatments. By giving approval now for your data and samples to be shared for research purposes, your valuable contributions have the best chance to be used as effectively as possible for research not only today but also in the future as new research questions and technologies emerge.

Risks

Your deidentified or anonymized data may be shared for research purposes. Because your data and samples are deidentified (anonymized), the potential is extremely small that a person or organization could determine that it belongs to you.