**SAMPLE INFORMED CONSENT LANGUAGE LIBRARY: DESCRIBING TECHNOLOGIES USED IN RESEARCH**

**Advances in technology and analytical tools** enable discoveries that are essential to our understanding of health and disease, and ultimately to the improvement of human health, healthcare delivery, and healthcare technology itself. Because of these advances, the health information and data of research participants are increasingly being collected, stored, and shared using more powerful and prolific technologies. The increased power and ease of these tools, as well as the increased demand for privacy, raise issues of vital concern to prospective research participants.

Research participants contribute their time, data, and health information, and it is fundamental that their rights, welfare, and interests are respected throughout the research process, starting with the process of obtaining informed consent. Investigators must enable prospective subjects to sufficiently understand and make informed decisions concerning the collection and use of their personal data, and the risks and benefits of participation. As part of a research study, a research participant’s personal data may:

- Be stored and used indefinitely.
- Be subjected to risks that are uncertain or unclear.
- Be reinterpreted and change in relevance over time.
- Raise privacy concerns, in part because of the risk of re-identification, as well as the possibility of breach of confidentiality.

Investigators must not only consider and address these factors when designing a research study, but also find meaningful and effective ways to describe these and other technology-specific factors within the informed consent process and consent form.

**PURPOSE OF THE INFORMED CONSENT RESOURCE LIBRARY**

This resource provides advanced information and sample language to assist investigators in describing technologies used in research within the informed consent form. Given the complexity of the scientific and ethical issues that arise when conducting human research, this library is not intended to provide universal suggestions or solutions, but rather to provide language that clearly conveys this complex but important information, and which may be adapted on a study-by-study basis.

The sample consent language in this document has been adopted from real-world examples, and provides investigators with a dynamic reference to support the development of appropriate informed consent materials. Investigators should use this resource when developing consent documents in consultation with collaborators and Institutional Review Boards (IRBs), as well as with research participants and communities.

SUBMIT SUGGESTIONS, ASK QUESTIONS, AND SHARE SAMPLE CONSENT LANGUAGE BY CONTACTING REGULATORY@CATALYST.HARVARD.EDU.