The Elements of Informed Consent

A Toolkit
Governance Team | Sage Bionetworks
Welcome!

We’re glad you’re here.

We hope this toolkit will help you make your consent and informing experience the best that it can be.

Inside you’ll find:

- **What We Know**: Use cases describing our approach to the informed consent process, including eConsent

- **Real Examples**: What do these ideas look like when they are put into practice

- **Consent Checklist**: Run through these questions to make sure you’ve thought it through

- **Additional Resources**: Check out some of the other resources we consult when doing our work
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How to Use this Resource

If you are a Researcher...

Think about what information your participants need to know to make an informed decision about participating in your study. Think about the words, images, or videos you will use to convey this information in a way participants will understand.

Sections to review:
- Consent in the 21st century
- Should I use a quiz?
- Keeping it legal

If you are a designer...

Think about the audience and how your design may facilitate participant learning.

Sections to review:
- Know your audience
- Persons of cognitive decline
- Designing and developing your eConsent

If you are curious...

Think about how providing adequate information in a way that is engaging and understandable may build trust and facilitate autonomy.

Sections to review:
- Do your own readability analysis
- Defining the narrative arc
- What is app-mediated consent
Getting Started

// The Elements of Informed Consent

The Code of Federal Regulations for the protection requires that investigators obtain legally effective informed consent prior to enrolling human subjects in research (45 CFR 46).

The CFR mandates the following elements be included in any informed consent for human subject research:

1. **Description**: Tell your participants this is research. Explain the purpose of the study, how long it will last, and the procedures.
2. **Risks or discomforts**
3. **Benefits**
4. **Alternatives to procedures or participation**
5. **Compensation**
6. **Who to contact with questions**
7. **Participation is voluntary and procedure for withdrawal**

Here at Sage Bionetworks, we use these elements as a **starting point** in our approach to informed consent for research. We encourage researchers to focus on transparency and clarity in all aspects of informed consent.

**Note**: The Code of Federal Regulations will be revised in 2019. Starting in 2019 investigators will be required to include the following elements in their informed consent experience:

- Begin with a concise and focused overview of information
- Explain how confidentiality of participants will be maintained
- Explain whether there will be compensation or medical care for injury incurred during participation in the research
- Address future use (secondary research) of identifiable information

Additional Resources

Common Rule starting in 2019:
[https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML)

Here is an informed consent template that we developed and use at Sage Bionetworks:
Important disclaimer: we are not lawyers. That said, here are some resources that we have developed for navigating regulatory compliance in the U.S.

Some of the terms commonly used in U.S. state/territory-specific regulations:

- **Access to records**: a required statement within the informed consent indicating that participants have the right to access specific records about themselves.
- **Age of majority**: age at which a person can consent themselves to participation in research.
  
  In the U.S., the age of majority with respect to research participation is 18 with two exceptions. In Puerto Rico the age of majority is 21. In Alabama, the age of majority with respect to research participation is 19, with the notable exception of IRB-approved research conducted by a federally-accredited college or university.
- **Bill of rights**: formal declaration of the rights of the research participant (e.g., California Experimental Research Subject’s Bill of Rights).
- **eSignature**: an essential facilitator of entirely remote consent interactions.
- **Sensitive data confirmation**: persons must specifically acknowledge the release of sensitive data types contained within their records (e.g., sexual health).
- **Witness signature**: some states require participants to have a person who can attest to their identity witness the participant’s signature on the informed consent.
- **Expiry**: Some states require a *date or term* of expiry be stated within the informed consent form. A *date of expiry* is an actual date (e.g., December 31, 2099). A *term of expiry* describes a time period or event (e.g., 12 months from signature).

Sage Bionetworks completed a review of state/territory-regulations across the U.S. for several domains of human subject research for the *All of Us* Research Program (AoU). AoU is a longitudinal national cohort program funded by the U.S. National Institutes of Health (NIH), with investigators, study infrastructure, data management systems, and governance schema distributed across the U.S. You can read our paper using the link to the right.

Additional Resources

Here is the link to the pre-print version of our survey of U.S. state/territory regulations. It will be published in Pacific Symposium on Biocomputing in early 2019:

// Consent in the 21st Century

If your study includes electronic data capture of any type, it is essential that your study’s informed consent process address data security and transferability. Additionally, if you employ a mobile app and/or wearable sensor for your study, you may need to include information from one or more privacy policies and/or terms of service.

If your study includes data capture from a mobile phone (directly or through an app), consider describing within the informed consent:
- If there will be passive data collection of any kind, such as from GPS
- If your study will pull data from other apps, such as HealthKit or Fitbit
- If you want permission to access phone features, such as push notifications

If your study uses a mobile app for research, such as those developed using ResearchKit or ResearchStack, consider describing:
- Who is developing the app?
- Will the data be encrypted at rest and in transmission?
- Who will receive/store/use the data: the research team, a third party, or both?

Describe to participants who else will have access to their data besides the research team:
- Are there required disclosures by law?
- Address selling or “renting” participant data to third parties
- Will there be data sharing for future use beyond the original research team?

If you are using a mobile app for research, some or all of this information may be found in the privacy policy or terms of service for your app. For more information, see page 7.

Additional Resources

For perspective on the consent landscape in app-mediated research, see our paper: Consent Processes for Mobile App Mediated Research: Systematic Review: https://mhealth.jmir.org/2017/8/e126/
Privacy Policies (PP) and Terms of Service (ToS) are traditionally used by apps, websites, and wearable devices (like fitness monitors) to describe acceptable use and the data they collect.

Specifically, privacy policies focus on the collection and use of the app/website user’s personal information. PP are required for all ResearchKit apps. Terms of service cover the rules and requirements of website and/or app use, for example, copyright, allowed uses, and definition of abuse.

PP/ToS have not traditionally been considered part of the informed consent process. However, they can have a tremendous impact on privacy and confidentiality of research data and therefore are increasingly being considered by ethics review boards.

Issues to look out for:
- PP/ToS are often difficult for regular people to understand because they’re long and written at a high grade level and contain lots of legal jargon with sections in ALL CAPS.
- PP/ToS are often written with the protection of the developer in mind rather than the participant
- PP/ToS are often not integrated within the informed consent process. For example, PP/ToS may not have any requirement for the participant to signal that they have reviewed and agree to the PP/ToS.

Consider:
- Review Privacy Policy and Terms of Service as you would a consent document
  - Shorten document
  - Reduce reading level
  - Avoid jargon and writing in ALL CAPS
  - Ensure harmonization between the informed consent and PP/ToS
  - Integrate PP/ToS within the informed consent process for your study

Additional Resources

For an example of a good ToS, see the All of Us Research Program’s: https://www.joinallofus.org/en/terms-of-service


For perspective on the consent landscape in app-mediated research, including PP and ToS, see our paper: Consent Processes for Mobile App Mediated Research: Systematic Review: https://mhealth.jmir.org/2017/8/e126/
Know Your Audience

// Introduction

The goal of informed consent is to explain to interested participants what your study entails. You need to clearly define the intended audience and to think carefully about how best to communicate with them.

This list is far from exhaustive, but here are a few major domains to consider:

- Adaptations for physical impairment: can people with visual, auditory, or physical impairment understand and navigate your informed consent?
- Readability: can people of different reading abilities understand your consent?
- Adaptations for people with mild cognitive impairment: how do you engage and inform people who are competent to consent but may be struggling with memory decline or other cognitive impairment?
// Adaptability: Ensuring Your Consent is Navigable

No matter if you are creating a paper consent to be used in person or a self-navigated electronic consent, ensure that your study’s consent is accessible to people who are blind, deaf, and/or have mobility impairment.

For content that is electronic, there are standards that guide adaptations to ensure accessibility. In the U.S., Section 508 of the Rehabilitation Act of 1973 requires federal agencies to make electronic assets of all kinds accessible to people who will use adaptive technology. The Department of Health and Human Services has created excellent guides to applying these standards.

As the HHS guides outline, there are straightforward adaptations you can implement to ensure that that electronic content adheres to formatting standards that allow automated accessibility tools to parse the content without the use of a mouse or a keyboard. This involves tasks like structuring HTML, word processing, and PDF files such that they are easily digested by these accessibility tools. For example, using headings properly, alt text on figures, and using XML formatting structure.

If you are working with a technology or implementation vendor, be sure to discuss adaptive technology. Double check that when your study documents are uploaded and made available that adaptive features are not lost.

Additional Resources

From the US Department of Health and Human Services, more on Section 508: https://www.hhs.gov/web/section-508/index.html


// Readability: Using Language Your Participants Understand

**Readability** is the ease with which a person can understand written text. Two of the most common measures of readability are the Flesch-Kincaid grade level and the Flesch reading ease.

**Readability analysis** is when you apply readability tools to your copy. Readability analysis is an essential step in developing the informed consent process for your study.

**Check it out:**

Here is an example of the same informed consent content presented two different ways. About 10% of Americans will be able to read the text on the left, while about 80% will be able to read the text on the right.

<table>
<thead>
<tr>
<th>Grade level: 12.1 Reading ease: 46.3</th>
<th>Grade level: 5.4 Reading ease: 80.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you decide to join the study you will need to download the free study application on your mobile device and register to the study. Then, periodically we will ask you to answer survey questions and/or perform activities on or while holding your mobile phone. In addition, if you are able to sustain moderate activity, we may send you motivational prompts to remain active. Your study data will include your responses to surveys and the measurements from the phone itself when you perform an activity.</td>
<td>If you decide to join the study, you will need to download the mPower study app on to your phone. The app is free from your phone’s app store. Then you will need to register for the study. As part of the study, we will ask you to answer questions on the app. Also, we will ask you to do activities while holding your phone. We might send you notifications through the app telling you to keep up the good work. Your answers to the questions and the measurements from your activities are your study data.</td>
</tr>
</tbody>
</table>

**Additional Resources**

Here is an amazing map of U.S. health literacy levels by U.S. Census track: [http://healthliteracymap.unc.edu/](http://healthliteracymap.unc.edu/)


A tool to help you write your content in plain language: [http://www.hemingwayapp.com](http://www.hemingwayapp.com)

Learn more about using everyday words in health communications on the CDC’s health literacy resource website: [https://www.cdc.gov/healthliteracy/](https://www.cdc.gov/healthliteracy/)

**Grade level:** 12.1 **Reading ease:** 46.3

**Grade level:** 5.4 **Reading ease:** 80.1
Do Your Own Readability Analysis

One of the easiest ways to do readability analysis on your copy is by using the readability tools in Microsoft Word. Highlight the text you wish to check, click Tools > Spelling and Grammar > Check Document. At the end of your check you will see a box that looks like this:

![Readability Analysis](image)

**Flesch Reading Ease:** scored out of 100. You want this number to be high, ideally above 75.

**Flesch-Kincaid Grade level:** scored out of 16. You want this number to be low, ideally 8 or below.

Review our full primer on readability analysis [here](#).

### Consider:

- Use plain language
- Use active voice
- Keep your sentences short; avoid multiple clauses
- **Consistency** in grade level/reading ease is more important than average grade level/reading ease

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**Additional Resources**


*Simply Put,* CDC’s guide to creating easy-to-understand materials is another excellent resource: [https://www.cdc.gov/healthliteracy/simply_put.pdf](https://www.cdc.gov/healthliteracy/simply_put.pdf)
// Considering Persons with Cognitive Decline

People with memory issues or other forms of cognitive decline may still be competent to consent for research participation. In collaboration with Emory University and the University of Wisconsin Madison, Sage Bionetworks investigated the informed consent needs of people with cognitive decline as part of the Alzheimer’s Disease Research Center (ADRC) study.

The consent design uses a tile design as well a summative evaluation questions to test mastery of key concepts (for more information about tile design, see page 18, Defining the Narrative Arc). Study coordinators are informed of participants’ answers to quiz questions, allowing them to focus their efforts on clarifying and remediating specific topics rather than reviewing the entire consent with participants.

Consider:

- Use icons meaningfully and consistently to aid memory and retention
- Present concepts in small increments
- Intersperse quiz questions within the consent process
What is Different in the Remote Setting?

// Points to consider

Remote electronic consent is a powerful tool for many reasons: It is scalable. It may reduce pressure on participants, researchers, and clinicians. It allows for diverse, integrated information presentation methods, including video, audio, and other interactive approaches.

Before you jump in, here are some important points to consider before using remote electronic consent for your study:

1. **Ensure participants meet the eligibility criteria for the study.**
   Sage Bionetworks has relied on participants’ self-report of eligibility for remote studies or have confirmed eligibility criteria at an in person visit as part of the study, for example as in the *All of Us* Research Program.
2. **Identity confirmation.** For example, of people providing permission for children to participate in research. The FeverPrints app-mediated research study asks adults to hand their phone to the child, and ask the child to complete steps on the phone, using physical proximity as a proxy for guardianship. (left image)

3. **eSignature.** In the remote electronic setting, signing consent forms (including HIPPA authorizations) has become standard. Participants use their finger or a mouse to sign, or type their name to indicate their consent. The signature is appended to a copy of the consent form and emailed to the participant for their records. (right image)
Should I Use A Quiz?

// Formative assessment

Entirely remote consenting limits the ways in which teach back can be used. As an alternative, using a formative assessment may encourage people considering participation to reflect on their informedness prior to joining. Sage Bionetworks has implemented formative assessments in many mobile health studies, including within the All of Us Research Program.

Either throughout or at the end of the consent process, the research team poses questions about key aspects of the study. After answering, participants are presented with the correct answer, reinforcing understanding. Prospective participants can be offered the opportunity to go back and review specific content areas or talk with a member of the study team before joining.
By contrast to formative assessments, a **summative assessment** can be used as a gate for research participation. Summative assessments measure a person's mastery of content and may be appropriate in eConsent for studies targeting vulnerable populations, such as those with cognitive impairment. Sage Bionetworks uses a summative approach to content mastery assessment in the Parkinson mPower Study and ADRC.

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**Additional Resources**

Designing and Developing your eConsent

// What is App-Mediated Consent?

There are three components of electronic informed consent: the eConsent, long form consent (LFC), and privacy policy and/or terms of service (PP/ToS).

1. eConsent
2. Long Form
3. Privacy Policy/ Terms of Service

- **eConsent** is a series of screens that present information traditionally highlighted by the study coordinator during the informed consent process.
- **LFCs** are the traditional “informed consent documents” and are commonly interpreted to be required by U.S. regulation. Participants are presented with an LFC for review and electronic signature following eConsent.
- **PP/ToS** are traditionally used within apps and by websites to alert users to the app/website’s data gathering, use, management, storage and disclosure by the organization hosting the app or website. For this reason, PP/ToS are critical to electronic informed consent processes.

**Additional Resources:**

John Wilbanks and Meg Doerr give an overview of consent Overview video from OHRP (their presentation starts at 2h57min into this video file) [https://videocast.nih.gov/summary.asp?live=28334&bhcp=1](https://videocast.nih.gov/summary.asp?live=28334&bhcp=1)

// Defining the Narrative Arc

There are different ways to present the narrative arc of your consent experience.

**Linear:** A linear presentation of information leads participants from one topic to the next. Participants can only navigate forward or backward, not between content areas. This design allows researchers to present the informed consent like a story, with each screen building on the one before.

**Grid/Tiles:** Presenting informed consent topics in a grid or “tiles” allows participants to navigate topics in the order of their choosing. Participants click through from the main grid to learn more about each of the topics presented. This design allows participants to see the breadth of information you will cover in the informed consent process in one glance. It also facilitates participant-driven information seeking, but may require you to repeat information so that each “tile” stands on its own.

Example of linear presentation

Example of grid/tiles presentation
// Information Presentation

We strongly suggest that you think carefully about layout of the information you present on each eConsent screen. Keep word count to a minimum and use videos or icons to help anchor the concepts you present.

At Sage Bionetworks, we have two standard templates for eConsent screens. The video screen template is on the left. The icon screen template is on the right.
// Layered Information

Using a layered approach to information allows the participant to choose if they wish to learn more about a particular topic within the consent experience.

In the example (left), the participant is presented with the screen on the left which opens the screen to the right.

Images from My Heart Counts (Stanford University)
Check Your Consent

Read through the checklist to identify questions most relevant to your specific project or consent experience. After you have determined questions applicable to your project, go back to review specific sections of this document. Assess whether you need to make adjustments to your consent experience.

☐ Elements of informed consent: Have you included all required elements of informed consent under the Code of Federal Regulations?

☐ Readability: Did you use words that your participants can understand? Did you check your readability score?

☐ Keeping it Legal: Have you reviewed any relevant state or federal laws that apply to your project? Consider the jurisdiction in which you operate and review any applicable laws or regulations.

☐ Consider your participant audience: Have you considered accessibility and readability? Will you recruit people with cognitive decline?

☐ Consent in the 21st century: Will your study include electronic data capture? If so, have you harmonized PP/ToS with the study’s consent? Have you highlighted PP/ToS to participants?

☐ Remote setting: If applicable, have you accommodated for consent in a remote setting? Have you prompted your participant audience with eligibility criteria?

☐ PP/ToS: Do you need to include a privacy policy or terms of service in your consent experience? Have you used words that your participant audience will understand? Have you checked the PP/ToS’s readability score?

☐ Did you consider using a quiz to serve as a teach back method or to assess participant understanding?

☐ Did you present your consent experience in an engaging way for your participant audience? Did you consider using icons, text, videos, or audio?

☐ How will your participant audience navigate through your consent experience? Will they determine the order or have your predefined the narrative arc?
About the Sage Bionetworks Governance Consent Toolkit

Sage Bionetworks’ *The Elements of Informed Consent* toolkit will help researchers think through what information participants should receive as part of the consenting process in order to make an informed decision about whether or not to join a study. We believe that informed participants make the best participants; they understand the study, its risks and benefits, and how their data will be treated.

This toolkit can help inform your consent design, especially if you are considering using technology. Always the goal is to present pertinent information to your potential participants in a way they can understand and comprehend.

This is V.1.0 of this toolkit, uploaded on November 6, 2018. We will update this toolkit over time.

Copyright information
All the materials in this toolkit not otherwise copyrighted are copyrighted by Sage Bionetworks, and licensed to the public under the Creative Commons Attribution 4.0 license. You are welcome to use, share, and adapt any of these resources in whole or in part under this license. We ask that you give appropriate credit as you do so.

Limits to using this resource
*The Elements of Informed Consent* toolkit is not legal advice. It is a compendium of the practices and principles we at Sage Bionetworks are using in our informed consent work. We will update this document over time as we grow our body of work and learn more about best practices in informed consent.

Contact us

**Feedback?** Did you use or consult our Consent Toolkit? **Use this form** to share your feedback or suggestions with us.

**Email:** If you would like to contact our team about working on a consent-related project or to ask a question, please email megan.doerr@sagebionetworks.org

**Tweet us!** @SageBio
About Sage Bionetworks

Sage Bionetworks is a nonprofit that develops and implements collaborative practices and technology to support the integration of data science into biomedical research. Sage sits at a unique nexus of the fields of data science, open-access technology platform development, and data governance. We are located in Seattle and we are supported through a portfolio of philanthropic donations, competitive research grants, and commercial partnerships. Learn more about Sage Bionetworks at sagebionetworks.org

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