TRIAL **INNOVATION** NETWORK

INFORMED CONSENT

TOOLS, RESOURCES, AND LITERATURE

June 2023

Developed by the TIN Informed Consent Work Group

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Introduction to the Toolkit

Informed consent is the process by which a potential research participant is informed about the study being conducted so that they can decide whether to take part. It is a legal and ethical requirement for work with human participants; however, there are challenges to this process, including ineffective communication, use of scientific jargon, and failure to consider cultural issues.

Ineffective Communication

Scientific Jargon

Failure to Consider Cultural Issues

This toolkit was developed by a Trial Innovation Network (TIN) Work Group that met between 2022 and 2023 to discuss tools and resources to improve the informed consent process.

How was the toolkit developed?

The Trial and Recruitment Innovation Centers (TICs and RIC) brought their informed consent tools and resources and together and used a brief template to provide an overview for each tool or resource. The Work Group knew of other complementary resources developed by different groups and wanted to include these so that people interested in informed consent could access this information in one place. An environment scan was done and resources and literature from this scan were added to the toolkit.

You can read an in-depth description of the methods in the Appendix.

Introduction to the Toolkit

Continued

What is included in the toolkit?

The toolkit includes:

- tools and resources developed by the Trial and Recruitment Innovation Centers (e.g., guides for developing informed consent resources, tools for capturing key information on consent forms),
- global tools and resources (e.g., guidelines for improving informed consent),
- national tools and resources (e.g., general national requirements, informed consent toolkits and templates),
- health literacy tools and resources (e.g., resources from MRCT, AHRQ, and the CDC), and
- links to relevant peer-reviewed literature (grouped into the following categories: improving accessibility, broad consent, special population considerations, and supporting consent operations).

For more tools and resources developed for clinical research by the TIN, see the TIN Toolbox: https://trialinnovationnetwork.org/recruitment-retention-toolkit/?key-element=18344

The TIN Toolbox holds resources from across the CTSA consortium that support clinical trials. When using these resources, please keep your institution's policies and procedures in mind.

Introduction to the Toolkit

Continued

Who should use the toolkit?

The toolkit is publicly available for download on the Trial Innovation Network website for use by researchers, research staff, and research support staff who are responsible for developing or delivering informed consent materials. Please note that these resources are offered as a guide and additional expertise may be helpful prior to use. Although most of these resources are freely available, local regulations may vary and your institution's IRB approval is required before consenting study participants.

When should the toolkit be used?

The toolkit should be used when researchers, research staff, and research support staff are developing informed consent materials and approaches.

For example, it will be helpful to people who are:

- Training clinical coordinators or clinical staff to support informed consent
- Trying to write a plain language summary of their study so that it is understandable and actionable
- Considering electronic informed consent
- Developing creative ways to share information via picture and video
- Thinking about inclusivity of special populations
- Planning to collect broad or large-scale consent
- Working across multiple sites

Navigating the Toolkit

The toolkit is divided into five sections:

TIN Informed Consent Group Resources that are divided into the following categories: improving accessibility, special population considerations, supporting consent operations. These resources have accompanying materials that are available in the Appendix of this toolkit.
Global Resources provide informed consent information that is not focused specifically on the US and may be helpful particularly for those who work with international organizations or participants.
National Resources such as those available from the CDC and the NIH offer toolkits, guidance, and templates.
Health Literacy Resources offer templates and tools to support the use of plain language.
Literature Collections are divided into the following categories: improving accessibility, special population considerations, supporting consent operations, and broad or large-scale consent. This section includes peer-reviewed manuscripts relevant to informed consent.

You can jump directly to the accompanying materials section of any resource available through the TIN Informed Consent Work Group Resources by clicking on the title of that resource below. For the global, national, and health literacy resources, you can access more information by clicking on the links provided. For the Literature Collections, you can use the doi or copy/paste the reference into your preferred browser.

TIN Informed Consent Work Group Resources

Improving Accessibility

Informed Consent Concise Summary Template

A template to help the user identify and present key information from the Informed Consent Form.

Interactive Consent (iConsent)

A web-based platform that provides a framework for investigators to customize study materials and uses interactive techniques that can be accessed via devices such as smartphones and tablets.

Developing a Clinical Trial Informational Video

A guide for developing clinical trial informational videos to support informed consent.

It is Smarter to be Understood

A guide for developing study materials that includes strategies and tools to support patient inclusivity and readability.

A Quick Guide to Inclusive Language

A guide to help healthcare providers improve the way they speak to and think about their patients.

Readability, Understandability, and Actionability of Key Information (RUAKI) Indicator

A tool to support the writing of key information on an informed consent form that potential participants can understand and use to make informed decisions.

RIC Recruitment & Retention Materials Content + Design Toolkit

This Recruitment Innovation Center toolkit can be used to created participant recruitment and retention materials, and materials for clinician awareness and study referrals.

Trial Innovation Network Informed Consent Work Group Resources

Special Population Considerations

Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials

An online course that aims to teach people how to enhance the recruitment of racial and ethnic minorities in clinical trials.

Plain Language Informed Consent Forms and Processes to Promote Empowered Decision Making for People Underrepresented in Research – Panel Presentation at Health Literacy Annual Research Conference (HARC)

A panel presentation given by members of the TIN Informed Consent Work Group at the Health Literacy Annual Research Conference (HARC).

Pediatric Informed Consent

Reference material that informs the user how to combine parental permission, assent, and consent into one consent document.

Using a multicultural and multilingual awareness-raising strategy to enhance enrollment of racially underrepresented minoritized communities—the PassITON trial

An online, open access paper that describes best practices in multilingual awareness-raising strategies to increase minoritized enrollment into clinical trials.

Trial Innovation Network Informed Consent Work Group Resources

Supporting Consent Operations

Community Engaged Informed Consent Training for Clinical Research Staff

This training is a combination of online pre-work and virtual synchronous training geared towards clinical research staff to help them learn about and apply skills to communicate informed consent.

Consent Builder

A tool that guides research staff through the sections of an informed consent form. The tool collects study information input by the user and then generates the necessary site forms; it helps to streamline the consent process for multi-center studies.

REDCap-Based eConsent

A REDCap framework that allows research participants to review and sign consent documentation electronically.

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sIRB Two-Part Informed Consent Model

A two-part consent model that includes study level details relevant to all participating sites as well as specific details unique to each site.

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sIRB Two-Part Informed Consent Form Checklist

This checklist accompanies the Two-part Informed Consent Model (above) and helps sites ensure that informed consent is documented correctly.

GLOBAL AND NATIONAL RESOURCES

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Global Resources

Guidelines for Improving Informed Consent: https://i-consentproject.eu/ - “i-CONSENT, funded by the European Union H2020 programme, aims to improve the information that patients receive from clinical studies.”

World Health Organization – Research Ethics Review Committee – Templates for Informed Consent: https://www.who.int/groups/research-ethics-review-committee/guidelines-on-submitting-research-proposals-for-ethics-review/templates-for-informed-consent-forms

National Resources

Department of Health and Human Services – Office for Human Research Protections Informed Consent Resources: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/informed-consent/index.html

Health and Human Services (HHS) Office for Human Research Protections (OHRP). (2018, November 19). Attachment C -new "Key information" informed consent requirements. HHS.gov. Retrieved January 3, 2023, from https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-november-13-2018/index.html

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Emergency Medical Services for Children – Informed Consent Toolkit: https://emscimprovement.center/education-and-resources/toolkits/informed-consent-toolkit/

National Cancer Institute, Cancer Therapy Evaluation Program – Informed Consent Resources: https://ctep.cancer.gov/protocolDevelopment/informed_consent.htm

National Resources

Continued

NIH National Human Genome Research Institute – Required Elements of the Consent Form: https://www.genome.gov/about-genomics/policy-issues/Informed-Consent/Required-Elements-of-Consent-Form

National Institute of Allergy and Infectious Disease – Protocols and Informed Consent: https://www.niaid.nih.gov/research/dmid-protocols-informed-consent

NIH Office of Science Policy, Office of Extramural Research – Informed Consent for Secondary Research with Data and Biospecimens (PDF): https://osp.od.nih.gov/wp-content/uploads/Informed-Consent-Resource-for-Secondary-Research-with-Data-and-Biospecimens.pdf

NIH Office of Human Subjects Research Protections (OHSRP) Consent Templates and Guidance: https://ohsrp.nih.gov/confluence/display/ohsrp/Consent+Templates+and+Guidance

Ohio State University provides online training courses focused on understanding clinical research and the informed consent process; this is an example of open access self-study resources available to the public: https://scarletcanvas.osu.edu/?query=CCTS

National Resources

Continued

The templates on this page are intended to help investigators construct documents that are as short as possible and written in plain language. The informed consent form (ICF) templates provided by the IRB comply with federal regulations. The OHSRP website also contains useful links to external websites that would be key for any Informed Consent Toolbox:

- The Program for Readability in Science and Medicine (PRISM) Toolkit (PDF): https://www.nhlbi.nih.gov/files/docs/ghchs_readability_toolkit.pdf
- PlainLanguage.gov – How to Write Using Active Voice vs. Passive Voice: https://www.plainlanguage.gov/resources/articles/dash-writing-tips/
- PlainLanguage.gov – How to Use Simpler Words and Phrases: https://www.plainlanguage.gov/guidelines/words/use-simple-words-phrases/
- Plain Language – Getting Started or Brushing Up: https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/plain-language/plain-language-getting-started-or-brushing
- FDA - Communicating Risks and Benefits: An Evidence-Based User's Guide (PDF): https://www.fda.gov/media/81597/download
- National Cancer Institute (NCI) – Using Online and Manual Readability Tools to Assess the Reading Level of Informed Consent Documents (PDF): https://www.fda.gov/media/81597/download

HEALTH LITERACY RESOURCES

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Health Literacy

Office of Disease Prevention and Health Promotion. (n.d.). Health Literacy in Healthy People 2030. Healthy People 2023. Retrieved January 5, 2023, from https://health.gov/healthypeople/priority-areas/health-literacy-healthy-people-2030

Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard - Health Literacy in Clinical Research: https://mrctcenter.org/health-literacy/

- Applying Health Literacy to Informed Consent Guide: https://mrctcenter.org/health-literacy/tools/overview/consent-guide/
- Plain Language: https://mrctcenter.org/health-literacy/tools/overview/plain-language/
- Consent: https://mrctcenter.org/health-literacy/trial-life-cycle/overview/consent/
- Glossary: https://mrctcenter.org/clinical-research-glossary/

Agency for Healthcare Research and Quality (AHRQ) Health Literacy website: https://www.ahrq.gov/health-literacy/index.html

- Making Informed Consent and Informed Choice Training Module: https://www.ahrq.gov/health-literacy/professional-training/informed-choice.html
- Health Affairs: Making Informed Consent an Informed Choice (Blog): https://www.healthaffairs.org/do/10.1377/forefront.20190403.965852/full/
- Patient Education Materials Assessment Tool (PEMAT) and User's Guide: https://www.ahrq.gov/health-literacy/patient-education/pemat.html

CDC Health Literacy Website: https://www.cdc.gov/healthliteracy/index.html

- Clear Communication Index: https://www.cdc.gov/ccindex/ccindex.html
- Guidance and Tools: https://www.cdc.gov/healthliteracy/developmaterials/guidancestandards.html
- Plain Language: https://www.cdc.gov/healthliteracy/developmaterials/plainlanguage.html

LITERATURE COLLECTIONS

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Improving Accessibility

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Special Population Considerations

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Special Population Considerations

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Supporting Consent Operations

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APPENDIX

TRIAL **INNOVATION** NETWORK

Environmental Scan Methodology

An environmental scan was conducted to search for additional informed consent information and resources that would complement the resources provided by the TIC and RIC organizations. The Work Group worked with a medical librarian from the University of Utah's Health Sciences Library to better understand what informed consent resources were available for a general audience. The list of resources included were found using the following search term concepts: informed consent in research, health literacy, plain language, informed consent, key information, clinical research, consenting minoritized populations (minorities), informed consent concise summary templates, and E-Consent (electronic consent). Search methods included searching the Pubmed.gov database as well as CINAHL (EBSCO), reference harvesting, targeted website and journal searching, and suggestions from the Work Group.

The environmental scan identified resources from federal institutions, global entities, and cited literature, including citations harvested from the database searches and selected reference lists. The Work Group narrowed the final list of resources and literature to those that would be relevant for a US-based audience interested in health research informed consent.

The collection of literature was categorized in a way that would be helpful to the user, depending on what resources they would be interested in learning about: improving accessibility, special population considerations, supporting consent operations, and broad or large-scale consent. The resources and literature included in the toolkit are not exhaustive but provide helpful information and guidance for thinking about informed consent approach and developing materials that are accessible and inclusive to a broad audience.

Informed Consent Concise Summary Template

Point of Contact: Natalie Dilts, natalie.dilts@vumc.org

Description	A one-page concise summary template that will support investigators to present the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research.
When to Use	This resource should be used to support development of the concise summary during the study start-up process and utilized throughout the study duration to guide participants through the informed consent process.
Audience	Study teams utilize the Informed Consent Concise Summary Template during the study start-up phase as they are drafting the consent form documents. Research participants utilize the resource to understand the key information about the study prior to deciding whether to participate in the trial.
Format	The template is offered in two versions: 1) Graphic flyer (with QR code): http://bit.ly/consent-form-summary 2) Word document.
Use & Measurement	Developed by the Trial Innovation Network (TIN) Recruitment Innovation Center (RIC). The Informed Consent Concise summary has been offered as a resource to all recipients of a RIC consultation since March 2021.
Resource Location	Consultation with the TIN Recruitment Innovation Center https://trialinnovationnetwork.org/definition-of-resources-and-initial-consults/?key-element=1602

Interactive Consent (iConsent)

Point of Contact: Mary Pautler, mary.pautler@hsc.utah.edu

Description	iConsent is a web-based platform that builds upon REDCap's eConsent to improve informed decision making by utilizing adult learning for the concise consent summary. iConsent provides frameworks for investigators to customize for any study utilizing interactive techniques within a user-friendly human-computer interface that works on any electronic device (i.e., smartphones, computers, tablets). Some key features include use of visual imagery to reinforce text, audio recorded text, infographics, and teach-back questions. It was developed from results of a clinical trial that demonstrated significant improvements in knowledge, satisfaction, and clarity of information.
When to Use	This resource is prepared during the study start-up process and utilized throughout the study duration to guide participants through the informed consent process.
Audience	Study participants.
Format	Web-based platform.
Use & Measurement	Comparison of Video, App and Standard Consent Processes on Decision Making for Biospecimen Research: A Randomized Controlled Trial NCT03141307 Rothwell E, Johnson E, Wong B, Goldenberg A, Tarini BA, Riches N, Stark LA, Pries C, Langbo C, Langen E, Botkin J. Comparison of Video, App, and Standard Consent Processes on Decision-Making for Biospecimen Research: A Randomized Controlled Trial. J Empir Res Hum Res Ethics. 2020 Oct;15(4):252-260. doi: 10.1177/1556264620913455. Epub 2020 Apr 3. PMID: 32242760; PMCID: PMC7486234.
Resource Location	Consultation with University of Utah Trial Innovation Center. Contact Mary Pautler, mary.pautler@hsc.uta.edu

Developing a Clinical Trial Informational Video

Point of Contact: Eve Marion, eve.marion@duke.edu

Description	Practical guide for developing clinical trial informational videos.
When to Use	This resource is best used during screening, to educate potential participants about the trial so they can make an informed decision about consent. This resource may be used with specific populations, depending on the needs of the clinical trial.
Audience	The intended audience for this tool includes research managers, investigators, and coordinating centers that help investigators develop their consenting processes.
Format	This resource is a pdf document with embedded links to sample videos.
Use & Measurement	Informational Trial Videos have been used in 11 studies since 2018.
Resource Location	The guide is available on the following pages and on the TIN website: https://trialinnovationnetwork.org/material-details/?ID=175

Developing a Clinical Trial Informational Video

Purpose: This document is a guide for planning and preparing Clinical Trial Informational Videos.

The Trial Innovation Network is a collaborative initiative of the NIH National Center for Advancing Translational Sciences (NCATS) that seeks to address critical roadblocks in clinical trials and accelerate the translation of novel research into clinical practice. For more guides and tools, please visit: https://trialinnovationnetwork.org/

November 2022

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About Trial Informational Videos

Videos can be a useful tool in recruitment for clinical sites to use in conjunction with the informed consent discussion. Videos can add an engaging and visual element to the discussion, and use different faces, voices, and animation to help explain the study for its intended audience.

Ideally, a video will be 3-5 minutes in length and focus on the purpose of the study, description of what participants will experience in the study. We recommend working with a professional communications team to oversee the process, and the use of a professional videographer who can use ideal lighting, camera positioning and editing techniques to make the video as effective as possible.

Examples of Trial Informational Videos

- STRESS – Pilot https://www.youtube.com/watch?v=0sE9Lg0EdGQ
- DOSE – Pilot https://www.youtube.com/watch?v=m5VyQU6iU6g

Considerations before beginning a video

Who is the audience?

- Patients? Caregivers? Clinicians?

What is the intended use?

- In-clinic/supervised vs. direct to participant

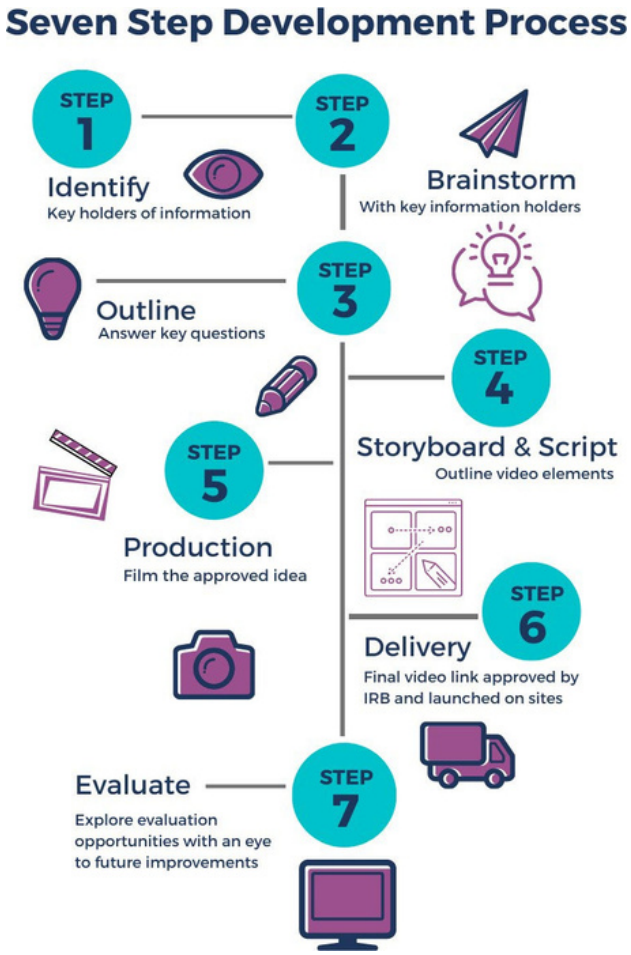
What kind of device access will viewers have?

- Sites and/or participants

Website development

- Will the video be shared on a study website?
- When will the website be live?
- What are potential approval delays?
- Creation of a video can add technical and Regulatory complexity e.g., will the video be imbedded within eConsent?

Seven Steps in the Development Process



Step 1: Identify Key Information Holders

- Clinical Trial Thought Leadership
- PI, Co-Is, Lead Site Staff Involved in Study Implementation
- Patient Advocates
- Patients and/or Parents of Patients that are part of the target population
- Communication/Recruitment Experts
- Video Production Team

Step 2: Brainstorm

- Gather to discuss ideas from key information holders
- Led by Communications/Video Production Team

Step 3. Create an Outline

Questions to answer before beginning a video:

1.What is the purpose of the video?

a. Awareness

b. Informational

c. Recruitment

2. What are the content topics? Suggestions:

a. Purpose of the study

b. Why the study is important?

c. Who can participate?

d. How you can participate?

3. Who is the intended audience?

a. Potential participants

b. Caregivers

c. Clinicians

d. Site staff

4. How long will the video be?

a. 30 seconds-1 minute (recommended for social media recruitment)

b. 1-3 minutes

c. 3-5 minutes

5. Where will the video shoot take place?

a. Remote recording (Zoom)

b. Hospital

c. Clinical

d. Office

e. Outdoors

6. Who will be the on-air talent?

a. Principal Investigator

b. Co -Investigator

c. Past participant/caregiver

d. Other

7. Will IRB approval be required?

a. Yes

b. No

8. How will the video be distributed?

a. General link (Vimeo or YouTube)

b. Project website

c. Embedded in eConsent

d. Social media

e. Sent via email

f. Other

Step 4. Develop the Storyboard/Script and Submit to the IRB:

Prepare a plan for sequencing your video. When your script is finalized, submit it to the IRB for approval.

An example of how to prepare your story board and script is as follows:

Visuals Text on Screen	**Sound/Script**	
Study logo (blends in and Long then fades out)	Study Name Intro music	
PI: Hi, I am Dr. XXXX from XXXX University and a Principal Investigator of the [Short Study Name] study. **PI and participant advisor facing camera**	**Lower third:** PI Name and Title **Lower Third:** Participant Advisor Name	**Participant Advisor:** I am , [general relational description]. I am part of a group of participant advisors working with the research team. We provide the patient perspective to improve the research experience for participants in [Short Study Name]. We want to tell you more about this important study. **PI:** Thanks _____, let's get started.
Study Purpose		
Participant advisor and PI face each other fade to image (s) of older adults and/or text on screen.	Stated purpose of the study including key concept bullets	**Participant advisor:** First, what is [study name]? **PI:** [General description of study]

Step 5. Begin Production:

Production may begin once the script is submitted and approved by the IRB.

N**ote that once the script is approved, any changes to the script made during filming will need to be resubmitted to the IRB before the video can be approved.** Therefore, please make sure the script is correct before beginning production.

Determine the final location of filming and schedule production.

Professional filming is preferred to ensure good lighting, camera angles, and quality of the video. However, at home recording is also an option.

General Tips for Being on Camera

Speaking

- Relax and smile while speaking.
- Speak with more energy that you would use in a normal conversation; you may feel like it is "too much", but high energy translates better on screen.
- Don't be afraid to ask to repeat part of the script or start again; we can edit and cut out a part if you make a mistake.

Clothing

- Please wear something that is comfortable and is business casual- there is no need to dress up for the video.

Colors and patterns

Avoid

- Complicated/tight patterns such as checks, pinstripe, hounds-tooth
- Busy prints with tight patterns
- Highly saturated solid colors: **Red**/**orange**/**yellow**
- Avoid bright white and very light colors
- Avoid black and very dark colors

Preferred

- Something with a collar so there is a place to attach a microphone
- Preferred colors: solid pastel color, off-white, blue, gray, pink, or beige

Jewelry & Accessories

Avoid

- Large shiny objects (large rings, bracelets, dangling earrings) and long necklaces
- Anything that jingles or jangles when you move (will interfere with audio)

Glasses

If you normally wear glasses, wear them. But if your glasses are auto-darkening, plan to leave them off (the bright lights will cause them to darken).

Hair and make-up

Tips

- Plan to shave at least a few hours prior to scheduled shoot.
- Neatly trim any facial hair.

Avoid

- Highly saturated lipstick (bright red or orange).
- Dark reds and maroon

Preferred

- Your routine application
- Style your hair off of your face

General Recording Instructions

You may record on your phone or tablet, or on your computer. Directions below outline how to record on a phone or computer. For all recording formats, plan to upload the files to a shared storage system, such as Box, Google Drive, or SharePoint, rather than sending to an editor by e-mail, as the files will be very large.

Getting ready:

- Get situated in a good spot for filming. We recommend a nicely lit area with more light in front of you than behind you, e.g., facing a window.
- Make sure nothing is covering your computer's camera.

Recording on an iPhone or iPad

1. Go to Camera app on your phone.
2. Swipe to choose video recording feature.
3. Tap red recording button.
4. Video will be saved in your Photos and can be uploaded directly from your iPhone or iPad.

Recording on your computer

How to record a video in QuickTime (for Mac users):

1. On your keyboard, hold down the command-key and press the space bar.
2. Type QuickTime. The field is type-ahead, so as soon as you see it say QuickTime Player, hit the return key.
3. This will open QuickTime Player.
4. Go to File> New Movie Recording.
5. This will pop up a window and you should see yourself in the video window.
6. Move your computer around until you are framed as you like in the video window.
7. In the lower part of the video frame is a record button with a red dot in the middle.
8. To start recording, just click the record button.
9. Record your video.
10. When done, click the record button to stop.
11. Then you can play the video back to review it.
12. If you don't like it, close the window and click the delete button.
13. If you like it, go to File>Save.
14. Give it a name, select a location to save it. We recommend the desktop as this allows for quicker uploading.
15. Upload the video to a shared storage folder.

**Also see QuickTime Player User Guide*

How to record using Zoom

- Start a Zoom meeting as a host
- Choose Record using the button at the bottom of the screen
- Record to the Cloud or your hard drive
- When complete, you may email the cloud recording link or the file from your laptop to your video editor.

Editing and re-shooting may be required, and video editors will let you know if there is an issue with the file.

*Also see Zoom guidance for enabling and starting local recordings

Step 6. Finalize IRB Approval & Deliver Content

- Submit the final video link to be approved by IRB
- Once approved by IRB, post to video content sites

Step 7. Evaluate for Continuous Quality Improvement

Immediate Evaluation Opportunities

- Survey site PI's and Research Coordinators to evaluate:
  - o Usage patterns during enrollment
    - o Usefulness of videos (duration, workflow fit, content, perceived engagement, etc.)
  - o Considerations for future improvements

Additional Evaluation Considerations

- Quantitative evaluation of enrollment rates
  - o Original enrollment targets met - sites using video compared to sites not using video
  - o Improvement in enrollment rates upon implementation in workflow

Key Considerations

Brevity is a key factor for video usage

- 3-4 minutes is ideal. 5 min. maximum
- Site feedback indicates longer videos will not fit compressed time with participant

Exercise caution with inclusion of rapidly changing information

- Re-shooting updates can be costly
- Voiceover/graphic revisions can reduce overall quality of the video
- Regulatory approvals can cause delays and gaps in usage

It is Smarter to be Understood

Points of Contact: Vincent Miller, vincent.miller@duke.edu and Mary Bailey, mary.bailey@duke.edu

Description	A guide to health literacy and readability when creating participant engagement materials. The resource includes strategies to support and confirm participant understanding of study materials and tools to use when designing study materials (e.g., consent forms, concise summaries, websites, flyers, and brochures) to be more inclusive and readable by all potential participants.
When to Use	This resource is most advantageous at the beginning of the trial during the creation of informed consent materials and the development of the study protocol.
Audience	Investigators working with participants, study teams participating in recruitment, diversity, and inclusion initiatives.
Format	Classes and slides along with reference materials/tools and web links.
Use & Measurement	This resource is utilized and taught at Duke University as a part of the Core Course in Engagement, Recruitment, and Retention (ER&R) Curriculum. This course is taught twice a year every Fall and Spring.
Resource Location	Request access to all of the ER&R program materials using this REDCap request form: https://redcap.duke.edu/redcap/surveys/?s=8LE4LCEYDCKWEWFK

A Quick Guide to Inclusive Language

Point of Contact: Jeri Burr, jeri.burr@hsc.utah.edu

Description	Using inclusive language is one way to build respect and trust with patients and study participants. The quick language guide, developed by University of Utah School of Medicine (UUSOM) students, Christina Necessary, Jacob Knight, Raquel Maynez, Bridget Dorsey, Jessica Kunzman, Chieko Hoki, along with Family Medicine physician Tiffany Ho, is a starting point for healthcare providers to improve the way they speak to and think about their patients.
When to Use	May be useful when writing informed consent documents to ensure appropriate inclusive language is incorporated. Using inclusive language can help patients feel comfortable, accepted, and safe. It is a way to start a connection by respecting who the patient is.
Audience	This tool may be helpful to investigators and coordinators who write and prepare informed consent documents.
Format	The Quick Guide is provided as a link to an external website and includes a screenshot of the infographic.
Use & Measurement	This resource was recently developed and has not been used in any research. It is provided strictly as a resource that may be helpful if a study consent form targets a population for which this guide to inclusive language may be useful.
Resource Location	Necessary, C., Knight, J., Maynez, R., Dorsey, B., Kunzman, J., Hoki, C., and Ho, T. (2023, March 6). A Quick Guide to Inclusive Language. Accelerate. https://accelerate.uofuhealth.utah.edu/equity/aquick-guide-to-inclusive-language.

Readability, Understandability, and Actionability of Key Information (RUAKI) Indicator

Sabrina Kurtz-Rossi, sabrina.kurtz_rossi@tufts.edu

Description	**The RUAKI Indicator is an 18-item tool** with evidence of validity and reliability, that research teams can use to evaluate the reading ease or difficulty of key information on informed consent forms. The tool can help you write key information about your research in a way that allows participants to read, understand, and act on to make informed decisions about their participation. The Office of Human Research Protection added a new requirement to the Common Rule that states each consent form begin with "a concise and focused presentation of the key information that is most likely to assist prospective subjects in understanding the reasons why one might or might not want to participate in the research study" and that this key information section "must be organized and presented in a way that facilitates comprehension" **(OHRP 2018)**. The RUAKI Indicator is a practical tool to guide the writing of the newly required key information section on an informed consent form (ICF) that potential participants can understand and use to make informed decisions and enable systematic evaluation.
When to Use	This resource is used during development of a study's ICF, specifically to help guide development of the newly required key information section. At present, the complexity of informed consent forms makes it hard for potential study participants to make informed consent decisions. A systematic review of health literacy and informed consent form highlighted a gap in the evaluation of informed consent practices to improve the process for minoritized and underserved populations. The RUAKI Indicator is an evaluation tool with the goal of better meeting the needs of people who are underrepresented in clinical research. While plain language writing is most helpful to people who do not speak English as their first language or are unfamiliar with research terms and concepts, everyone benefits from information that is short, easy to read, and clearly provides needed information **(McMillan 2020)**.

Readability, Understandability, and Actionability of Key Information (RUAKI) Indicator

Continued

Audience	The intended audience includes investigators and all members of the study team that are involved in developing the study informed consent form.
Format	The RUAKI Indicator is an 18-item check list (on paper) that reviews ICFs for the presence of absence of features that make the information easy to read, understand, and to allow participants to make an informed decision about participating in research. Steps for use: 1) Review items on the RUAKI Indicator, 2) Read the key information section on the informed consent form, 3) Rate each item on the RUAKI Indicator as present (yes=1) or not present (No=0). Rate only the key information section, 4) Add total items present, divide by number of items (18), multiply by 100 to calculate % score. 5) The higher the score the easier the key information is to read, understand and act on.
Use & Measurement	The aim of the RUAKI Indicator and study was to develop a valid and reliable tool to assess key information on informed consent forms applying three constructs of interest: readability, understandability, and actionability. The study established face and content validity with expert review, conducted four rounds of reliability testing with four independent groups of reviewers and conducted end-user testing with potential study participants. See **RUAKI Study Summary of Results** on the following pages.
Resource Location	Available in PDF format: ·**RUAKI Indicator** available on the following pages ·**RUAKI Study Summary of Results** available on the following pages ·**Manuscript in review (not yet available)**

For use with INFORMED CONSENT FORMS

Readability, Understandability, and Actionability of Key Information (RUAKI) Indicator

Purpose: Informed consent forms must BEGIN with a concise presentation of key information, and that key information must be organized and presented in a way that facilitates understanding of why the reader may or may not want to participate in research.[1] The RUAKI indicator is designed to assess key information on informed consent forms for features that make that information easy to read, understand, and act on to make an informed decision.

How to apply:

- Review items on the RUAKI Indicator.
- Read the key information section on the informed consent form (ICF).
- Rate each item on the RUAKI Indicator as present (Yes=1) or not present (No= 0). Rate ONLY the key information section.
- Add total items present, divide by number of items, and multiply by 100 to calculate % score.
- The higher the score, the easier the key information is to read, understand, and act on.

Readability		**Rating**	
Language			
1	**Active voice.** Uses active verbs (e.g. will use) rather than passive verbs (e.g. will be used) all or most of the time, more than 90% of the time.	☐ Yes = 1	☐ No = 0
2	**Word choice.** Avoids scientific jargon (e.g. hypertension). Uses words readers are familiar with (e.g. high blood pressure) all or most of the time, more than 90% of the time.	☐ Yes = 1	☐ No = 0
3	**Topic definition.** Provides a definition of the main disease or topic the study is about.	☐ Yes = 1	☐ No = 0
4	**Numbers.** Avoids mathematical calculations including comparison of numeric probability of risk.	☐ Yes = 1	☐ No = 0
5	**8th grade or below.** Reading grade level calculated in Microsoft Word is Flesch-Kincaid Grade Level 8.9 or below.	☐ Yes = 1	☐ No = 0
Design			

[1] Office for Human Research Protection (OHRP). (2021, March 10). *2018 Requirements (2018 Common Rule). 46.116 General Requirements for Informed Consent*. HHS.gov. https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116

6	**Headers**. Sections or chunks of information are labeled with headers. Headers clearly describe sections so readers can scan and find information.	☐ Yes = 1	☐ No = 0
7	**Font type and size.** Font type or style is easy to read. Font size is at least 11-12 point.	☐ Yes = 1	☐ No = 0
8	**White space.** Uses bulleted or numbered lists to increase white space on the page.	☐ Yes = 1	☐ No = 0
9	**Image.** Contains at least one image that is related to the topic of the study. Not a logo.	☐ Yes = 1	☐ No = 0
Understandability			
10	**Purpose of the study**. Includes a statement that says, "the purpose of the study is…" Purpose of the study is stated, rather than implied.	☐ Yes = 1	☐ No = 0
11	**Main reason to join the study – benefits.** Includes description or list of potential benefits to participants or others.	☐ Yes = 1	☐ No = 0
12	**Main reasons not to join the study – risks**. Includes description or list of potential side effects or risks to participants.	☐ Yes = 1	☐ No = 0
13	**Information being collected.** Describes the information that will be collected from participants and about participants.	☐ Yes = 1	☐ No = 0
14	**Study procedures.** Describes what participants will need to do AND how much time it will take.	☐ Yes = 1	☐ No = 0
15	**Study is research.** Includes a statement that says, "study is research" or "research study" not just consenting to treatment.	☐ Yes = 1	☐ No = 0
16	**Participation is voluntary.** States that participation is voluntary, that participants have a choice to be in the study or not.	☐ Yes = 1	☐ No = 0
17	**Costs and compensation.** Describes any financial payments (or costs) to study participants.	☐ Yes = 1	☐ No = 0
Actionability			
18	**Consent Process.** Describes the process by which the reader gives their consent, either by signing a document, verbal agreement, via computer, or other.	☐ Yes = 1	☐ No = 0

Total	
Divide by	**18**
Multiply by 100	
Score	**%**

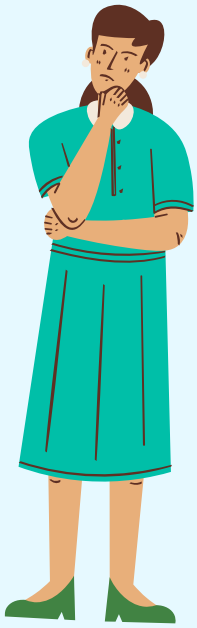
How to calculate sore: Add total items present (Yes = 1). Divide by number of items (18 items). Multiple by 100 to get % score. The goal is 18 / 18 x 100 = 100%.

How to interpret score: The higher the score, the easier the key information is to read, understand, and act on. Key information with a score of 90% is easier to read than key information with a score of 70%. Key information with a score of 70% is easier to read than key information with a score of 40%. Revise items that are not present (No = 0) to improve reading ease, understandability and actionability.

Thank you for participating in the Key Information on Informed Consent Forms Study. We are pleased to share results with you!

Study Results Summary

Why did we do the study?



- Research informed consent forms describe key information about the research study. People need this information to decide if they want to participate in the research study or not.
- Good informed consent forms begin with key information about the study that people can understand and use.
- Our study developed a tool research teams can use to write easy to read key information about their research.
- Easy to read key information on informed consent forms will help more people understand research and benefit from it.

How did we do the study?

- We created a checklist tool to evaluate the reading ease or difficulty of key information on informed consent forms.
- 25 study participants (scientists and health professionals) tested the tool to evaluate key information on 10 informed consent forms. We made changes to the tool based on their feedback.
- 16 participants (people who are not scientists or health professionals) joined a focus group to look at key information evaluated by the tool and talk about what made it easy or hard to read. We made changes to the tool based on their feedback.

What did we learn from the study?

- We learned that people find short key information on informed consent forms easier to read than long blocks of text.
- We learned that scientists can use the new tool to develop easy to read key information about their research.

Tufts CTSI
Tufts Clinical and Translational Science Institute

What did participants say?

After reading key information that scored well by the tool:

- 88% said the information was easy to read
- 94% said all the words were familiar
- 88% said sentences were short and to the point
- 69% said the text was big enough to read
- 88% said they could find the information they wanted

"Where it's just blocks of text, that's always hard to read."

"Was a lot easier to read with the picture and the bullet point"

"As an immigrant whose first language is not English, whenever you use medical jargon that makes it harder to understand."

"If someone, a trusted person, could tell me [about the study] I will be much more trusting of what's written on the paper."

How will we use study findings?

- This study created a checklist tool called the **R**eadability, **U**nderstandability, and **A**ctionability of **K**ey **I**nformation (RU-A-KI) Indicator.
- We will use study findings to work with more scientists to see if they can use the tool to develop key information that helps people understand the research and feel more confident about their informed consent decisions.

RIC Recruitment & Retention Materials Content + Design Toolkit

Point of Contact: Stephanie Mayers, stephanie.mayers@vumc.org

Description	The RIC R&R Materials Content + Design Toolkit is a resource for research teams to utilize for creating: • Participant recruitment and retention materials participants • Materials for clinician awareness/study referrals The toolkit includes three major components: 1. Guidelines, recommendations, and resources for creating content and design for participant recruitment and retention materials 2. Links to free Canva templates for participant recruitment and retention materials, as well as for clinician-facing materials for study promotion and patient referrals 3. Tips and tutorials for creating materials in Canva
When to Use	This resource is utilized during the study start-up process and throughout the study duration to create resources that are centered around study participants.
Audience	Study teams utilize this resource to create participant recruitment and retention materials and/or materials for clinician awareness/study referrals. Note: This toolkit was created by the RIC in collaboration with the RIC Community Advisory Board and has an intentional focus on creating a combination of materials that promote diversity and inclusion in order to authentically reach potential participants.
Format	PDF document
Use & Measurement	Developed by the Trial Innovation Network (TIN) Recruitment Innovation Center (RIC), the Recruitment & Retention Materials Content + Design Toolkit has been offered as a resource to all recipients of a RIC consultation since April 2022.
Resource Location	TIN Toolbox https://trialinnovationnetwork.org/material-details/?ID=156

Faster Together, Enhancing the Recruitment of Minorities in Clinical Trials

Point of Contact: Sheila Kusnoor, sheila.v.kusnoor@vumc.org

Description	This free online course aims to teach people how to improve the recruitment of racial and ethnic minorities in clinical trials. Presented in eight self-paced modules, key topics include the importance of diversity in clinical trials, barriers and facilitators to participation in clinical research, community engagement, effective communication, educating about clinical trials, provider outreach, effective prescreening and enrollment, person-centered consent, and retention.
When to Use	This resource is utilized during the recruitment phase of a study.
Audience	Anyone with the potential to recruit can benefit from this course, whether working in a clinical setting or in the community. The course is split into 8 weeks and can be completed at a user's own pace. There is no charge to enroll or take the course, and quizzes are included to help users learn the material. An optional certificate of completion is available for a fee, which is earned upon successful completion of the course requirements. This can be an excellent way of staying motivated.
Format	Free online course delivered via eight self-paced modules.
Use & Measurement	Developed by the Trial Innovation Network (TIN) Recruitment Innovation Center (RIC). The Faster Together course was launched on Coursera on April 1, 2019, and has been offered as a resource to all recipients of a RIC consultation since this launch date.As of March 2023, there have been 3,449 enrolled users and 5,350 views.
Resource Location	TIN Toolbox https://trialinnovationnetwork.org/material-details/?ID=87

Plain Language Informed Consent Forms and Processes to Promote Empowered Decision Making for People Underrepresented in Research –Panel Presentation at Health Literacy Annual Research Conference (HARC)

Point of Contact: Marisha Palm, mpalm@tuftsmedicalcenter.org

Description	The Health Literacy Annual Research Conference (HARC) is an interdisciplinary meeting for investigators and research teams dedicated to advancing health literacy research and practice. It is an opportunity for researchers to share their work to a full range of investigators engaged in a broad array of public health, health services, epidemiology, translational and intervention research activities. The panel presentation - Plain Language Informed Consent Forms and Processes to Promote Empowered Decision Making for People Underrepresented in Research – introduces four different perspectives on improving informed consent forms and processes from four different research institutions, all with a strong commitment to person-centered informed consent decision-making for people underrepresented in research.
When to Use	Informed consent is a process and there are numerous opportunities within that process to improve potential study participant engagement, understanding, trust, and ultimately, empowered decision making. The four different perspectives on improving informed consent forms and processes touch on 1) the user experience perspective, 2) how to make key information on informed consent forms easier to read, 3) tools to support effective, person-centered consent for racial and ethnic minorities, and 4) informed consent process improvement and communication innovations. This resource can be used at any point.
Audience	Investigators, study teams, researchers, those interested in learning more about using informed consent processes to empower decision making
Format	90-minute recording of virtual panel presentation via Zoom
Use & Measurement	The panel was held on October 24, 2022. Approximately 60 people from across the country attended the virtual panel presentation, which was held immediately after the keynote.
Resource Location	You can watch the recording on YouTube: https://www.youtube.com/watch?v=cphoiSyhGnk

Pediatric Informed Consent

Point of Contact: Jeri Burr, jeri.burr@hsc.utah.edu

Description	Additional protections for children are required by the federal regulations. As defined in 21 CFR 56, children are vulnerable subjects. As such, it is required that adequate provisions be made for obtaining assent from children and informed permission from their parents when conducting pediatric research. • **Parental Permission** - The agreement of parent(s) or guardian to the participation of their child or ward in research. • **Assent** - A child's affirmative agreement to participate in research. Failure to object to participation should NOT be considered assent. • During clinical studies, there may be a requirement for obtaining adequate **informed consent** from pediatric participants once a child reaches the age of legal consent. The ability to combine documents is an option when managing a pediatric clinical trial that requires informed consent, parental permission, and teen assent. These elements can be combined into a single, layered consent document that collects both parental permission, assent, and consent for a child reaching age of legal consent.
When to Use	This resource could be used anytime a pediatric research study requires parental permission and assent for children to reduce the number of documents needed to be managed.
Audience	Investigators working with children as research participants, their parents who may or may not be participants, and coordinating centers that help investigators design a pediatric assent and permission process with accompanying documents.

Pediatric Informed Consent

Continued

Format	Links provided below to support those developing pediatric informed consent materials.
Use & Measurement	University of Utah Data Coordinating Center (DCC) has extensive pediatric expertise utilizing layered consents and Consent Builder to build Pediatric Informed Consent materials.
Resource Location	• 45 CFR 46, subpart D • 21 CRF 50, subpart D • ICH E11: "Clinical Investigation of Medicinal Products in the Pediatric Population" • American Academy of Pediatrics (AAP) - "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations"

Using a multicultural and multilingual awareness-raising strategy to enhance enrollment of racially underrepresented minoritized communities—the PassITON trial

Point of Contact: Jasmine Bell, jasmine.bell@vumc.org

Description	An online, open access paper that describes best practices in multicultural and multilingual awareness-raising strategies used by the Recruitment Innovation Center to increase minoritized enrollment into clinical trials. The Passive Immunity Trial for Our Nation is used as a primary example to highlight real-world application of these methods to raise awareness, engage community partners, and recruit diverse study participants.
When to Use	This resource can be used during the planning and recruitment phases of a study.
Audience	Anyone with the potential to recruit can benefit from this resource, whether working in a clinical setting or in the community. The paper includes methods for culturally tailored messaging, community outreach, and accounting for health literacy.
Format	HTML full text; PDF document.
Use & Measurement	Published online on December 7, 2022, researchers have viewed the HTML full text 101 times and the PDF 144 times as of May 2023.
Resource Location	https://doi.org/10.1017/cts.2022.506

Community Engaged Informed Consent Training for Clinical Research Staff

Point of Contact: Kris Markman, training@tuftsctsi.org

Description	Tufts Clinical and Translational Science Institute (CTSI) conducts twice-yearly trainings for clinical research staff to learn and apply the practical skills of communicating informed consent in a low-stakes context that simulates real world situations. Further details on the development and evolution of this training and the role of community stakeholders can be found in the article "Community Engaged Informed Consent Training".* The intention of these trainings is to bridge the gap between the study team's knowledge of informed consent and the practical interpersonal skills needed to communicate informed consent procedures effectively with potential research participants. To do this, the training is offered in a blended format: an asynchronous, required, online pre-work tutorial followed by a synchronous online session that includes role play exercises with community members, many of whom were past research participants. Participants must also provide proof that they have previously completed basic human subjects research training (e.g., CITI training certificate or equivalent). The online pre-work tutorials provide didactic training on best practices for effective informed consent conversations. The tutorials are modified to reflect the specific topic of the training session. The tutorials are built using the Articulate Storyline 360 e-learning software and typically include a mix of text slides and video clips demonstrating best practices. The online pre-work also includes the consent form that will be used for the live session role play. Participants are encouraged to read and annotate the consent form prior to the live session. The consent form is typically drawn from publicly available studies on ClinicalTrials.gov. Participants receive the Zoom link for the live session after completing the pre-work tutorial and downloading the consent form. All online pre-work is delivered through the Tufts CTSI I LEARN learning management platform.

Community Engaged Informed Consent Training for Clinical Research Staff

Continued

Description (Continued)	Live sessions are typically scheduled for 2 hours. The typical outline for a live session is: Part 1: Welcome and overview (20 minutes) Introduction to team, goals of training, brief review of concepts from pre-work, expectations for the live role play. Participants are assigned to breakout groups. Part 2: Role play exercise (2 40-minute rounds) Breakout groups with 3-5 participants, 1 staff facilitator and 1-2 community member simulated patients. Each participant is given 5-8 minutes to role play the consent conversation with the simulated patient, followed by 2-3 key feedback takeaways from the simulated patient. After all participants have done the role play, the facilitator leads a group debrief conversation. For Round two, each breakout group gets a new facilitator and simulated patient, and they repeat the process. The lead moves from group to group to observe during both rounds. Part 3: Debrief (20 minutes) After the second round has completed, all participants, facilitators, and simulated patients return to the main Zoom room to debrief about the experience as a whole. Simulated patients are given first opportunity to provide observations. Budget Considerations • Simulated patients are compensated at an hourly rate for 1 hour of preparatory training, the 2-hour live session, and the 1-hour post-training debrief meeting. • Interpreters are similarly compensated when needed for the non-English speakers version of the training. • Facilitators are typically Tufts CTSI or Tufts Medical Center staff who do not receive additional compensation, however a minimum of 3-hours of staff time per facilitator is required per training, including 1 hour of preparatory training and the 2-hour live session.

Community Engaged Informed Consent Training for Clinical Research Staff

Continued

When to Use	This resource is best used before study teams begin recruiting for research projects. Tufts CTSI has developed different versions of this training to teach skills that are unique to special populations, including consenting non-English speakers, minors, and individuals with temporarily diminished capacity. While the base training covers the fundamental skills for having informed consent conversations, material for these special populations can be also be made available. The materials are suitable to be adapted to other research populations.
Audience	The intended audience is study team members whose responsibilities include consenting potential research participants.
Format	This resource is a training. Components include: Facilitator and simulated patient training documents, sample live session agendas and slide decks, multimedia tutorials, and demonstration videos.
Use & Measurement	Participation data for the February 2021 through February 2022 trainings are described in the manuscript hyperlinked below. A further 23 individuals were trained in June 2022 and January 2023. Complete participation data for the 2019 and 2020 trainings is not available. Evaluation methods and outcomes are described in Markman et al., 2023*
Resource Location	This resource can be made available to institutions and research teams that would like to better train research team members to communicate informed consent with community members. For access to curricular materials, email Kris Markman at training@tuftsctsi.org. Please include “Informed Consent Training” in the subject line for all inquiries. *Markman KM, Weicker NP, Klein AK, Sege RS. Community engaged training in informed consent. Journal of Clinical and Translational Science. 2023:1-21. https://doi.org/10.1017/cts.2023.534

Consent Builder

Point of Contact: Mary Pautler, mary.pautler@hsc.utah.edu

Description	Consent Builder guides research staff through the required consent form sections with instructions and examples. Consent language is collected via a web-based survey. Once study information is collected, research staff can generate the necessary site forms with the click of a button. The tool aggregates the information and compiles the data to produce a high-quality informed consent document in PDF format.
When to Use	Consent Builder is used heavily in the study start-up phase and maintains usefulness throughout the study lifecycle by providing easily amendable documents.
Audience	Study team are target users. Clinical Coordinating Centers who assist sites with informed consent preparation for submission to the sIRB.
Format	Web based resource. REDCap Survey. End format is PDF Consent/Assent form.
Use & Measurement	21 Trials have used Consent Builder at 116 sites as of May 2023. Sward KA, Enriquez R, Burr J, Ozier J, Roebuck M, Elliott C, Dean JM. Consent Builder: an innovative tool for creating research informed consent documents. JAMIA Open. 2022 Oct;5(3):ooac069. doi: 10.1093/jamiaopen/ooac069. eCollection 2022 Oct. PubMed PMID: 35911667; PubMed Central PMCID: PMC9329658
Resource Location	To access this web-based resource, consult with the University of Utah Trial Innovation Center. Contact Mary Pautler, mary.pautler@hsc.utah.edu

REDCap-Based eConsent

Point of Contact: Colleen Lawrence, colleen.lawrence@vumc.org

Description	An eConsent framework was developed within the REDCap platform, allowing research participants the ability to rapidly review and sign consent documentation via web, tablet or smartphone. Electronic consent forms can leverage standard REDCap survey features including: multi-lingual language capacity for information rendering and capture; video, audio and/or image rendering; 'read it to me' accessibility options; skip logic to support comprehension questions or trigger 'help needed' events; 'wet' signatures; document upload; and camera integration for photos and images. Upon completion, the system documents the 'consent transaction' and stores final, "frozen" consent PDFs in REDCap, allowing researchers to retrieve information on the consent type, status, and version at any time. Consents are also stored in a separate secure document system for safety and permanent archival. Our eConsent framework has been 21 CFR Part 11 validated at Vanderbilt.
When to Use	REDCap-based eConsent is used heavily in the study start-up phase and maintains usefulness throughout the study lifecycle by providing an easily accessible framework to consent participants for research studies both in person and remotely.
Audience	Study teams are a target audience as the creators of the eConsent forms and managers of the eConsent database. Research participants should also be considered audience members as many of the customizations offered by the platform can be used to enhance the accessibility of the consent document for participants.
Format	Study team: Web-based resource including a REDCap Survey Research participants: PDF Consent/Assent form
Use & Measurement	As of January 2023, the eConsent Framework has been enabled at 3,380 institutions, with 45,235 eConsent projects, and nearly 3.5M eConsents completed.
Resource Location	Available to all REDCap users who enable the eConsent Framework. For additional information, consult with the Vanderbilt University Medical Center Trial Innovation Center/Recruitment Innovation Center.

sIRB Two-Part Informed Consent Model

Point of Contact: Jeri Burr, jeri.burr@hsc.utah.edu

Description	The 2-part consent model is a single consent document with two main parts. Part 1 includes study level details that will be consistent for all participating sites. Part 2 includes site specific details that are unique to each participating site. Utilizing the 2-part method makes it easier for the IRB to review site-specific sections when formatting is consistent across sites. The sIRB is much better-equipped to provide board members with notes about the differences between forms when the forms are all basically uniform with the exception of the site-specific sections. Eliminating duplicative IRB review is expected to reduce unnecessary administrative burdens and systemic inefficiencies without diminishing human subjects protections.
When to Use	This resource is used in multi-center studies using a single IRB (sIRB). Use of this model should be considered early during study startup when the informed consent document is being developed.
Audience	Lead study teams of multicenter studies Clinical Coordinating Centers who assist sites with informed consent preparation for submission to the Single IRB
Format	Resources available in PDF and Microsoft Word
Use & Measurement	The 2-part consent model is a TIN Innovation and used in many multicenter studies that have been supported by the network.
Resource Location	The checklist and instructions are available on the TIN Toolbox. https://trialinnovationnetwork.org/material-details/?ID=168 The checklist is also available below.

sIRB Two-Part Informed Consent Form Checklist

Points of Contact: Karen Lane, klane@jhmi.edu, and Jordyn Carll, jcarll3@jhmi.edu

Description	The Informed Consent Form Checklist (ICF Checklist) is to help sites ensure they are using the most current version of their two-part consent form provided by the sIRB of record and that consent is correctly documented prior to any study intervention or activities.
When to Use	This resource is intended to be used during or immediately after informed consent and prior to randomization and/or any study activities.
Audience	Clinical coordinating centers should recommend the study-wide implementation of an ICF checklist. However, if not implemented study-wide, sites could specifically choose to use an ICF checklist.
Format	There is a checklist document in Word format as well as a slide deck presentation that offers guidance for using the checklist. The Word format is provided below (and has been converted to a PDF). Sites can complete the checklist on paper or as an alternative to completing a paper copy, study teams can consider developing the ICF checklist as an electronic case report form (eCRF) in the electronic data capture (EDC) system.

sIRB Two-Part Informed Consent Form Checklist

Continued

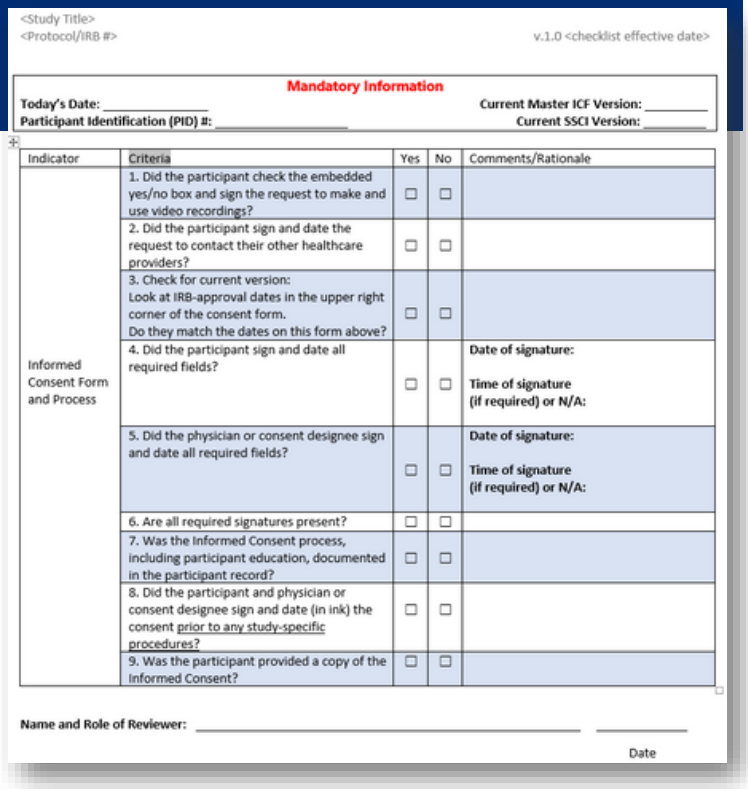
Use & Measurement	The checklist was used in a multi-center trial in 2021. An analysis of checklist usage and effectiveness was attempted; but the sample size was too small for comparison. The use of an ICF checklist is hypothesized to lead to fewer consent-related errors and protocol deviations as a result of the requirements built into the checklist. The ICF checklist requires the study coordinator or consenter to perform activities, such as reviewing ICF IRB approval dates, confirming that the ICF is current and the correct version, confirming that all signature locations and checkboxes are completed, and ensuring that there are correct dates entered next to signatures; activities that contribute to fewer consent errors. The Johns Hopkins BIOS Clinical Trials Coordinating Center will conduct a prospective study to test the consent checklist hypothesis in a multi-center clinical trial with 80+ sites as a means to improve the quality of future clinical trials. **This proposal is currently under IRB review.** Hypothesis: Enrolling teams who are required to use an electronic consent checklist within the EDC prior to randomization will have fewer consent errors than enrolling teams who will not be prompted to complete the electronic consent checklist prior to randomization. Primary objective: To determine the effectiveness of the informed consent form checklist at reducing consent errors relative to control. Participating sites will be randomized in a 1:1 ratio into either the experimental arm requiring the use of the ICF checklist case report form in the VISION electronic data collection (EDC) system prior to randomization of the participant (test) or the control arm where they will use their local site-standard practice for consenting.
Resource Location	The checklist and instructions are available on the TIN Toolbox. https://trialinnovationnetwork.org/material-details/?ID=168 The checklist is also available below.

INFORMED CONSENT FORM CHECKLIST

OVERVIEW AND GUIDELINES FOR USE

PURPOSES

1. Two-part informed consent version control
2. To ensure all required components of the ICF are completed
3. To ensure consent is correctly documented prior to any study procedures



<Study Title>
<Protocol/IRB #>
v.1.0 <checklist effective date>

Mandatory Information

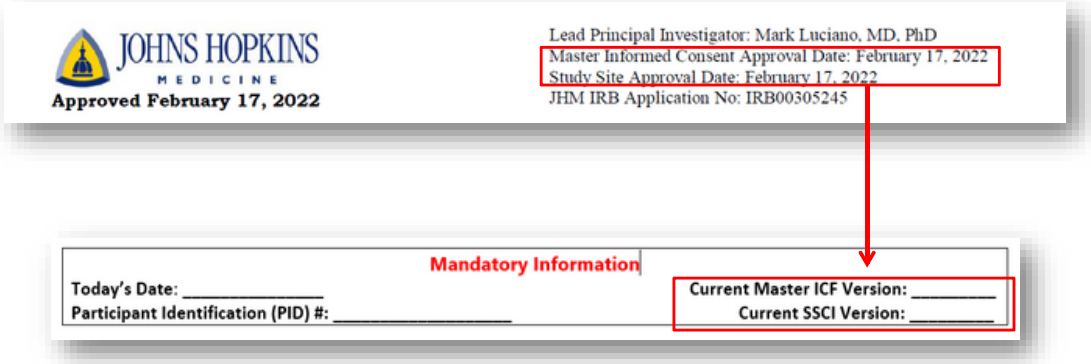
Today's Date: _____ **Current Master ICF Version:** _____
Participant Identification (PID) #: _____ **Current SSCI Version:** _____

Indicator	Criteria	Yes	No	Comments/Rationale
Informed Consent Form and Process	1. Did the participant check the embedded yes/no box and sign the request to make and use video recordings?	☐	☐	
	2. Did the participant sign and date the request to contact their other healthcare providers?	☐	☐	
	3. Check for current version: Look at IRB-approval dates in the upper right corner of the consent form. Do they match the dates on this form above?	☐	☐	
	4. Did the participant sign and date all required fields?	☐	☐	**Date of signature:** **Time of signature (if required) or N/A:**
	5. Did the physician or consent designee sign and date all required fields?	☐	☐	**Date of signature:** **Time of signature (if required) or N/A:**
	6. Are all required signatures present?	☐	☐	
	7. Was the Informed Consent process, including participant education, documented in the participant record?	☐	☐	
	8. Did the participant and physician or consent designee sign and date (in ink) the consent prior to any study-specific procedures?	☐	☐	
	9. Was the participant provided a copy of the Informed Consent?	☐	☐	

Name and Role of Reviewer: _____ _____
Date

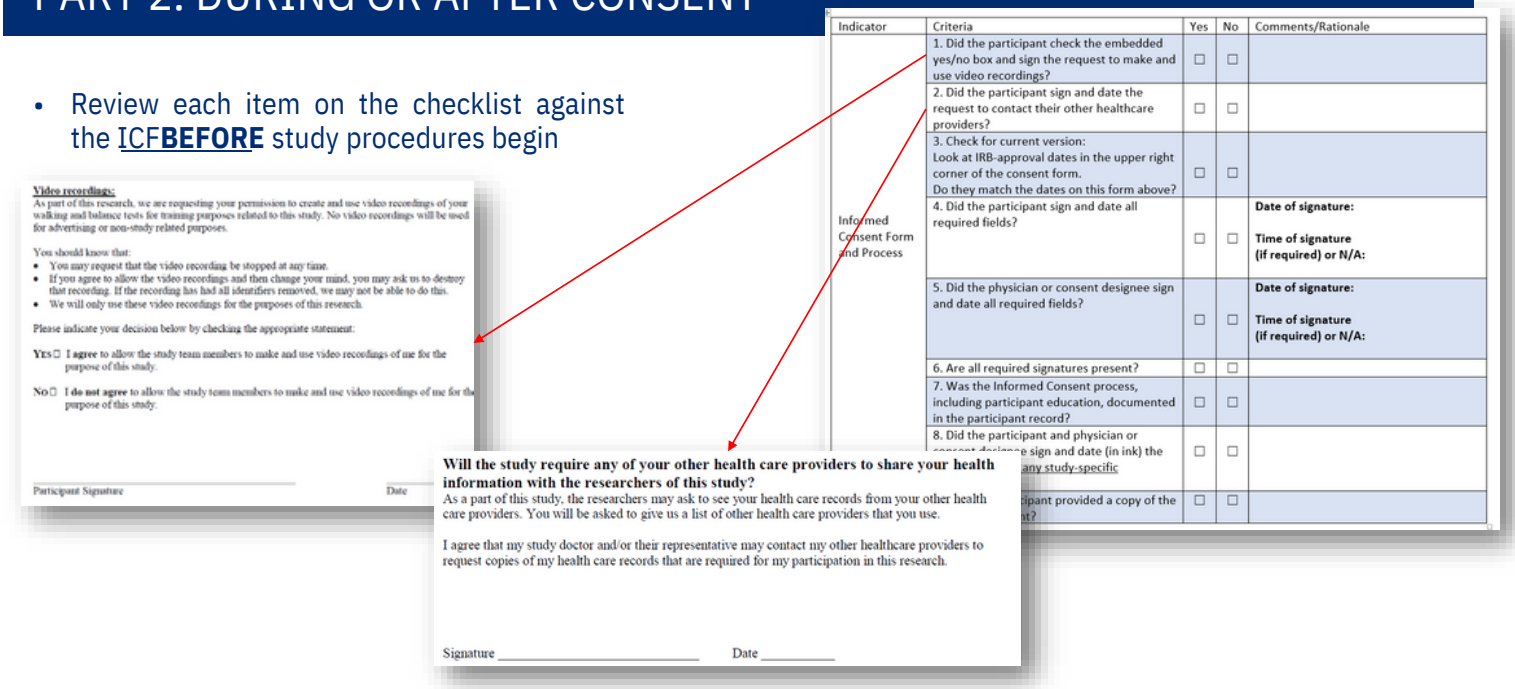
PART 1: PRIOR TO CONSENT

- ICF(s) should be pulled the day of consent
- Record MasterandSiteSpecificConsentInformation (SSCI) versiondateson the ICF checklist



PART 2: DURING OR AFTER CONSENT

- Review each item on the checklist against the ICF**BEFORE** study procedures begin



Video recordings:
As part of this research, we are requesting your permission to create and use video recordings of your walking and balance tests for training purposes related to this study. No video recordings will be used for advertising or non-study related purposes.

You should know that:
- You may request that the video recording be stopped at any time.
- If you agree to allow the video recordings and then change your mind, you may ask us to destroy that recording. If the recording has had all identifiers removed, we may not be able to do this.
- We will only use these video recordings for the purposes of this research.

Please indicate your decision below by checking the appropriate statement:

YES ☐ **I agree** to allow the study team members to make and use video recordings of me for the purpose of this study.

NO ☐ **I do not agree** to allow the study team members to make and use video recordings of me for the purpose of this study.

Participant Signature Date

Indicator	Criteria	Yes	No	Comments/Rationale
Informed Consent Form and Process	1. Did the participant check the embedded yes/no box and sign the request to make and use video recordings?	☐	☐	
	2. Did the participant sign and date the request to contact their other healthcare providers?	☐	☐	
	3. Check for current version: Look at IRB-approval dates in the upper right corner of the consent form. Do they match the dates on this form above?	☐	☐	
	4. Did the participant sign and date all required fields?	☐	☐	**Date of signature:** **Time of signature (if required) or N/A:**
	5. Did the physician or consent designee sign and date all required fields?	☐	☐	**Date of signature:** **Time of signature (if required) or N/A:**
	6. Are all required signatures present?	☐	☐	
	7. Was the Informed Consent process, including participant education, documented in the participant record?	☐	☐	
	8. Did the participant and physician or consent designee sign and date (in ink) the any study-specific	☐	☐	
	ipant provided a copy of the nt?	☐	☐	

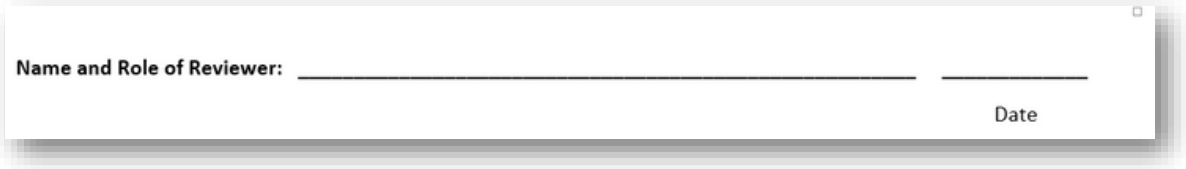
Will the study require any of your other health care providers to share your health information with the researchers of this study?
As a part of this study, the researchers may ask to see your health care records from your other health care providers. You will be asked to give us a list of other health care providers that you use.

I agree that my study doctor and/or their representative may contact my other healthcare providers to request copies of my health care records that are required for my participation in this research.

Signature _____ Date _____

PART 3: ONCE ICF CHECKLIST IS COMPLETED

- Person completing the ICF checklist signs and dates
- It isstrongly recommended that the person that obtained consent is the person that completes the ICF checklist
- Store ICF checklist in the same location as the signed consent form.



HOW TO GET STARTED

Download the ICF checklist template in word format.

- Modify the criteria of the ICF checklist to match ***each and every*** check box and/or signature line on the IRB approved consent form.

If there are additional site-specific requirements, modify the checklist to include the additional requirements.

- For example, additional signature lines required by specific institutions/state laws.

Add study protocol title and number, and the version and effective date to the header.

WHEN YOUR CHECKLIST NEEDS UPDATING

If significant ICF changes impact the ICF checklist, modifications should be made to the checklist that correspond with the new IRB approved consent form

- Update the header information.

For multi-center trials:

- Each site should track its own versioning of the ICF checklist.
- Site-specific updates to the consent form could potentially cause site specific changes to the ICF checklist. Monitor carefully!

EDC BUILD:
ICF CHECKLIST IN THE EDC

As an alternative to completing a paper copy of the ICF checklist, study teams can consider developing the ICF checklist as an electronic case report form (eCRF) in the electronic data capture (EDC) system.

	If consent is obtained...	Answer	Comment
	Current Master ICF Version Date	01-Jul-2022	-
	Current SSCI Version Date	01-Jul-2022	-
1.	Did the participant check the embedded yes/no box and sign and date the request for a brain MRI to be obtained at day 5 or day of discharge?	Yes / No	
2.	Did the participant check the embedded yes/no box, sign and date the request for future contact?	Yes / No	
3.	Check for current version: Look at IRB-approval dates in the upper right corner of the consent form. Do they match the dates on this form above?	Yes / No	
4.	Did the participant or Legally Authorized Representative sign and date all required fields?	Yes / No If yes, date and time of consent. Who consented? Participant / LAR / Both Date: 01-Aug-2022 Hour: 11 Minute: 15 Please upload the signed consent on Source Docs page.	
5.	Did the physician or consent designee sign and date all required fields?	Yes / No If yes, date and time of consent. Date: 01-Aug-2022 Hour: 11 Minute: 25	
6.	Are all required signatures present?	Yes / No	
7.	Was the Informed Consent process, including participant education, documented in the participant record?	Yes / No	
8.	Did the participant and physician or consent designee sign and date (in ink) the consent prior to study-specific procedures?	Yes / No	
9.	Was the participant provided a copy of the Informed Consent?	Yes / No	
10.	Was a copy of the informed consent uploaded to the electronic medical record?	Yes / No	

Consent Signature

In signing this form, you are attesting that the informed consent process has been appropriately documented in the patient's medical chart, that the original fully-executed consent is appropriately on file at the research site, and that the patient/legal representative has been given a copy of the consent.

Check the box to sign