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# INFORMED CONSENT

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DEPARTMENT OF BIOETHICS  
NIH CLINICAL CENTER

# Disclaimer

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The views expressed are mine and do not necessarily represent the policies of the CC, Department of Bioethics, NIH, or DHHS.

I have no conflicts of interest to disclose

# Informed consent

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BASICS

CHALLENGES

CHANGES

# Consent

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A moral and legal protection from unauthorized invasions of one's body and property

A facilitative moral power- making certain interpersonal conduct permissible that otherwise would be prohibited as wrong

Well entrenched in societal values, jurisprudence, and health care



# *Informed* consent

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Authorization of an activity based on understanding what the activity entails.

A legal, regulatory, and ethical requirement in most health care and most research with human subjects

A process of reasoned decision making (not a form or an episode)

Autonomous authorization (Faden and Beauchamp 1986)

# Ethical basis

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Respect for autonomy – respect for an individual's capacity and right to define his/her own goals and make choices consistent with those goals.

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided...[when] informed consent [is] satisfied.

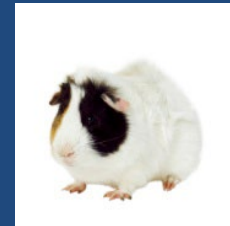
**Belmont Report**

# Informed consent in clinical research

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The goal of research is to produce knowledge to benefit others and not necessarily the participant.

Special importance to the ethical injunction against using people for the benefit of others without their valid consent.



One aspect of conducting ethical clinical research

**ASSENT**  
— VS —  
**CONSENT**





# Informed consent in clinical research

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Required by virtually all codes of research ethics, regulations, and laws (limited exceptions ):

- US Federal Regulations (Common Rule (45CFR46) and FDA (21CFR50))
- ICH-GCP
- Declaration of Helsinki, CIOMS
- National, state, institutional requirements

# Regulatory requirements

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...no investigator may involve a human being as a subject in research ..unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative...(45CFR.46.116, 21CFR.50.20) (limited exceptions )

Informed consent must be sought prospectively, and documented to the extent required under 45 CFR 46.117 and 21CFR50.27.

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Informed consent involves providing a prospective subject, or their legally authorized representative (LAR), with adequate information to allow for an informed decision about participation in the clinical investigation prior to enrollment. Informed consent also involves facilitating the prospective subject's understanding of the information, providing adequate opportunity for the prospective subject to ask questions and to consider whether to participate, obtaining the prospective subject's voluntary agreement to participate prior to enrollment, and continuing to provide information as the clinical investigation progresses or as the enrolled subject or situation requires.

FDA. Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors. August 2023.  
<https://www.fda.gov/media/88915/download>

# Informed consent

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(Capacity to consent)

Providing adequate information

Understanding

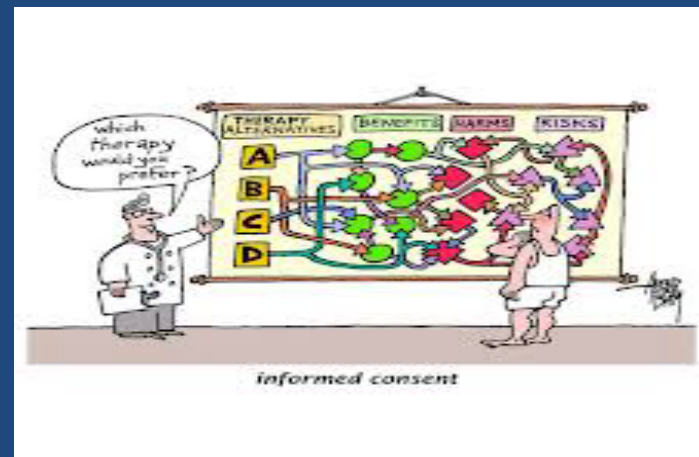
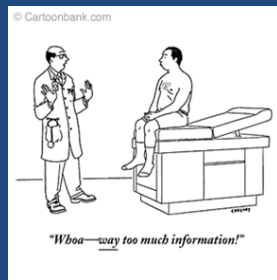
Voluntariness

(Consent authorization)

# Providing adequate information

What information should be disclosed? Adequate, accessible, relevant information?

How should information be presented so that it is understandable, considering circumstances, setting, population?



# Informed consent

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§\_\_\_.116 (a)(3) The information given to the subject or LAR shall be *in language understandable to the subject or LAR.*

§\_\_\_.116 (a)(4) .... *that a reasonable person would want to have in order to make an informed decision.*

# Informed consent

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§\_\_\_.116 (a)(5)(i) ...*must begin with a concise and focused presentation of the key information* that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate...*organized in a way that facilitates comprehension.*

§\_\_\_.116 (a)(5)(ii) ...*in sufficient detail...and that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding*

# Health literacy

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> one third of US adults (~80 million) have basic or below basic health literacy

(Majority (53 percent)-Intermediate health literacy, ~22% basic, ~14% below basic).

<https://nces.ed.gov/pubsearch/pubsinfo.asp?pubid=2006483>

Limited health literacy affects adults in all racial and ethnic groups

> one-half of U.S. adults have basic or below basic numeracy, thus are challenged by numerical presentations of health, risk, and benefit data.

Numeric literacy is lower among those who report worse health status. [https://nces.ed.gov/surveys/piaac/national\\_results.asp](https://nces.ed.gov/surveys/piaac/national_results.asp)



# Consent forms

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Readable, understandable *forms* that explain the study. Including ads, pamphlets, fliers (approved by the IRB)

Length, format, reading level, complexity, are all important

Using written or visual material in discussion

# Consent forms

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The consent form serves several purposes, including:

- helping to ensure that prospective subjects receive the required information,
- providing a "take home" reminder of the elements of the clinical investigation,
- providing contact information in case additional questions or concerns arise, and
- documenting prospective subjects' voluntary agreement to participate as well as the date of their agreement. [FDA. Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors. August 2023. <https://www.fda.gov/media/88915/download>](https://www.fda.gov/media/88915/download)

# Length and readability

**Reading level is high-** rarely written at or below the recommended 8<sup>th</sup> grade level [LoVerde et al, 1989](#); [Grossman et al 1994](#); [Paasche-Orlow et al. NEJM 2003](#); [Sharp S Am J Clin Oncol.2004](#); [Santel F et al. Cont CT 2019](#); [Emanuel and Boyle JAMA Open 2021](#); [Gelinas et al. J Clin Trans Science 2023](#)

**Consent forms are long,** and have increased in length over time [Baker and Taub JAMA 1983](#); [Tarnowski et al 1990](#); [Beardsley et al 2007](#), [Albala et al. IRB 2010](#); [Gelinas et al. J Clinical Translational Science 2023](#)

**Required or relevant elements are often missing**

[Silverman et al. Critical Care Medicine 2001](#); [Horng et al, NEJM 2002](#); [Beardsley et al. JCO 2007](#); [Abeyseena C et al Ind J Med Ethics 2012](#); [Dukaew N et al Clinical Trials 2023](#)



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-D-0390]

**Use of Electronic Informed Consent—Questions and Answers; Guidance for Institutional Review Boards, Investigators, and Sponsors; Availability**

**AGENCY:** Food and Drug Administration and Office for Human Research Protections, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS), are announcing the availability of a guidance entitled “Use of Electronic Informed Consent—Questions and Answers.” The guidance is intended for institutional review boards (IRBs), investigators, and sponsors engaged in or responsible for oversight of human subject research under HHS and/or FDA regulations. The guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof. This guidance finalizes the draft guidance entitled “Use of Electronic Informed Consent in Clinical Investigations—Questions and Answers” issued in March 2015.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comments as follows:

**Electronic Submissions**

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

**Written/Paper Submissions**

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2015-D-0390 for “Use of Electronic Informed Consent—Questions and Answers; Guidance for Institutional Review Boards, Investigators, and Sponsors; Availability.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The

comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 312.63, applicable disclosure requirements, information about FDA’s comments to public, 56469, September 2015, the information [www.regulations.gov](http://www.regulations.gov) default.htm

**Docket:** read back electronic received [www.regulations.gov](http://www.regulations.gov) docket number heading “Search” and/or go to Management 1061, Rockville, MD 20852.

See section **FOR FURTHER INFORMATION:** written requests guidance and for a guidance document.

**FOR FURTHER INFORMATION:** Cheryl Grandinetti, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3348, Silver Spring, MD 20993-0002, 301-796-2500; Nicole Wolanski, Office of Good Clinical Practice, Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5108, Silver Spring, MD 20993, 301 796-6570; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; Irfan Khan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3459, Silver Spring, MD 20993, 1-800-638-2041 or 301-796-7100; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., suite 200, Rockville, MD 20852, 240-453-6900.

**SUPPLEMENTARY INFORMATION:**

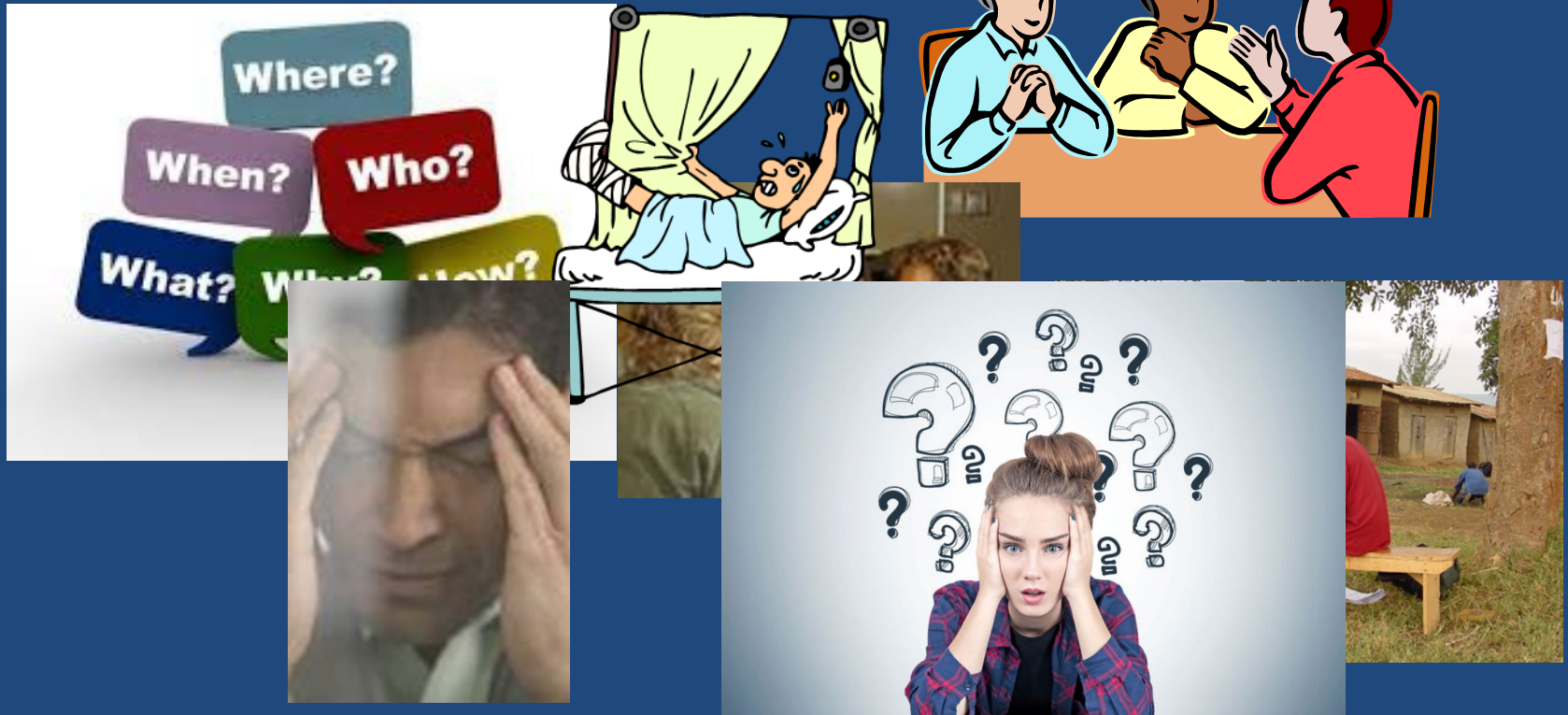
**I. Background**

“...electronic consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.”



# Presentation and setting

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# Challenges

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“Easy reading is damn hard writing.”

Nathaniel Hawthorne ~1840

Written informed consent protects the institution, sponsor, investigator

IRBs often want more information- making forms longer and more complex

# Participant Understanding Data

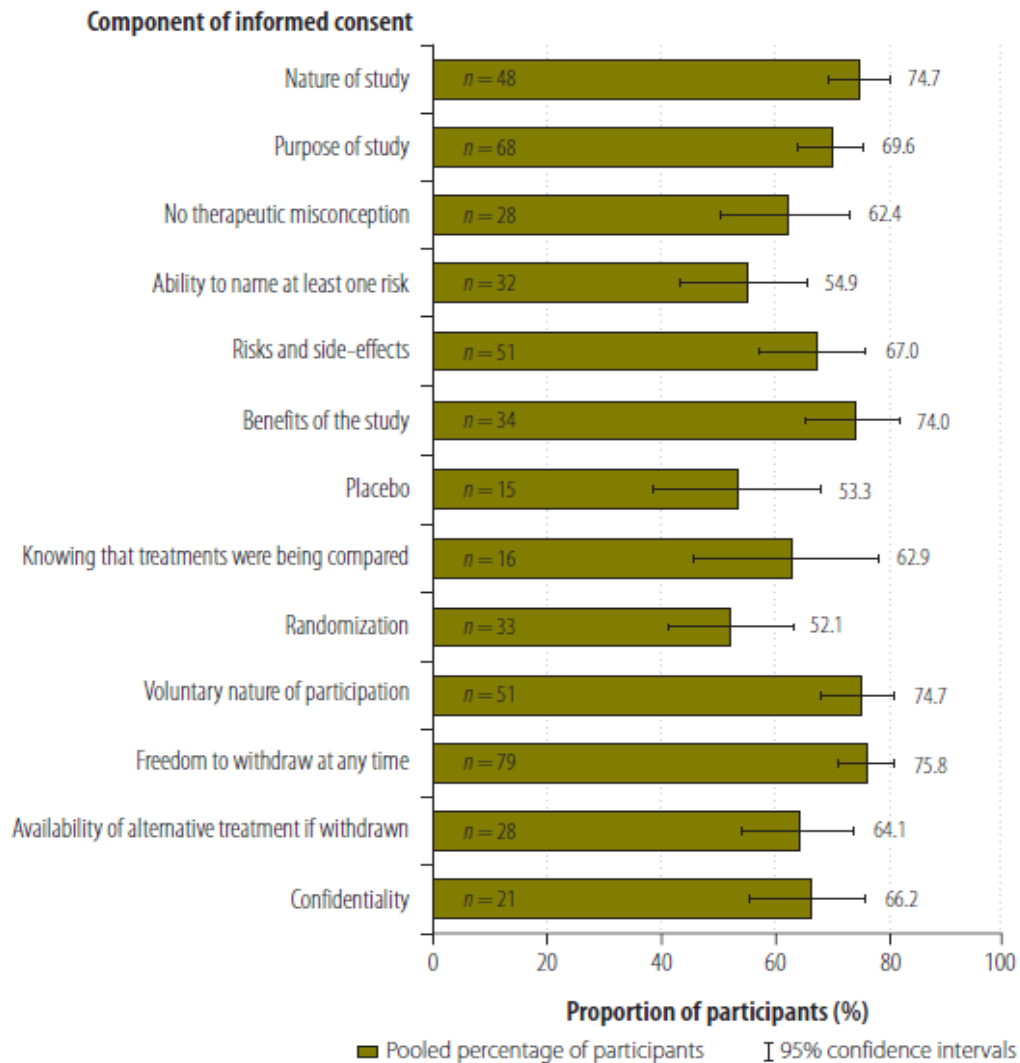
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Research participants have variable understanding e.g. Mandava A et al *J Med Ethics* 2012 ; Tam et al. 2015; Pietrzykowski et al. 2021)

## Range of understanding

- Of research purpose and nature (27% -100%) Krosin et al 2006; Joffe et al 2001; Pace et al. 2005; Criscione et al. 2003; Ponzio et al. 2018)
- Of research risks (28%-100%) Bergler 1980; Joffe et al. 2001; Leach et al, 1999; Dougherty et al 2000; Schumacher et al. 2017)
- Of randomization (10%-80%) Harrison et al 1995; Hietanen 2000; Pace et al. 2005; Chu et al. 2012; Bertoli et al. 2007, Pietrzykowski et al. 2021)

Fig. 2. Participants' understanding of components of informed consent in clinical trials, by meta-analysis<sup>a</sup>



<sup>a</sup> The number of studies included in the evaluation of each component is given.



# What affects understanding?

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“Host” factors- Age, education, pain, cognitive impairment, capacity, literacy

Expectations and familiarity- motivations, trust in providers, cultural views, therapeutic misconception and related misunderstandings

Process related factors- what is disclosed and how and by whom, how (and how well) the participant listens to/reads the information

# Understanding

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How is/should understanding be assessed?

How much should participants understand?

What happens (or should happen) when participants don't understand?

**Table.** Steps for Validating Potential Research Participants' Consent to Research

	Risk/Benefit Profile for Participants <sup>a</sup>		
	Low Risk	Moderate Risk and High Risk/ Potential Benefit	High Risk/ Little or No Potential Benefit
Example	Buccal sampling; few blood draws; standardized surveys	Phase 2 study; research biopsy	Treatment withdrawal for serious condition; challenge studies with high risk
Domains of valid consent			
Competence	Assume <sup>b</sup>	Assume <sup>b</sup>	Consider formal assessment
Understanding	Assume (following explanation of study) <sup>b</sup>	Informal or brief formal assessment	Formal assessment by team or independent party
Voluntariness	Assume <sup>b</sup>	Informal assessment	Formal assessment by team or independent party

<sup>a</sup>As determined by the institutional review board.  
<sup>b</sup>Unless there is reason for concern.

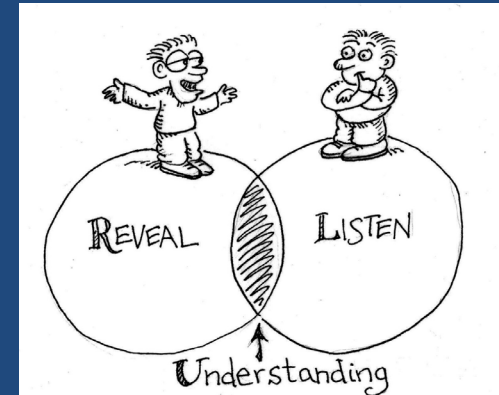
Wendler D How to enroll participants in research ethically. *JAMA* 2011

# Understanding

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## Different kinds of “mis-understanding”

- ▶ Misconception
- ▶ Mis-estimation
- ▶ Optimism (Horng & Grady *IRB* 2003)



Distinction between knowledge of relevant information and appreciation of how it applies

# Therapeutic Misconception

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When a research participant fails to recognize how individualized medical care (i.e. physician obligation to make medical decisions in the patient's best medical interests) may be compromised by research procedures Appelbaum et al. IRB 2004



Failure to recognize the differences between research and ordinary care negates the ability to provide meaningful informed consent. Appelbaum et al. KIE 2006

# Research: improving understanding

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Multimedia (e.g. audiotapes, videotapes, interactive computers)

Enhanced consent form (e.g. modified style, format or length)

Extended discussion ( with team member or neutral educator)

Test/feedback (e.g. quizzes and review)

Mixed and miscellaneous (e.g. online presentations, supplementary vignettes, etc)

Flory and Emanuel *JAMA* 2004; Nishimura A et al. *BMC Medical Ethics* 2013

# Research: improving understanding

## Does a simpler, more concise consent form affect study understanding or satisfaction with consent?

- Randomize actual participants
- Healthy volunteers: Flu vaccine studies, Phase 1 drug development. *Stunkel et al IRB 2010; Enama et al Cont Clin Trial 2012*
- Patient volunteers: Multinational HIV study. *Grady et al PloS One 2017*

Jan-August 2010 • Volume 32, Number 4

### IRB ETHICS & HUMAN RESEARCH

## Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form

BY LEANNE STUNKEL, MEREDITH BENSON, LOUISE McLELLAN, NINET SINAI, GABRIELLA BEDARIDA, EZEKIEL EMANUEL, and CHRISTINE GRADY

Although informed consent is a fundamental ethical requirement for research with humans, many studies indicate that research volunteers often do not understand critical aspects of the research in which they are participating, suggesting that the "informed" part of consent to participate is imperfectly realized.<sup>1</sup> ing, satisfaction with the informed consent process, or both.<sup>2</sup> However, not all studies found improvement.<sup>3</sup> Moreover, these studies have important limitations. Many used consent documents in hypothetical situations rather than in actual research studies.<sup>4</sup> Also, most of the consent studies involved participants who were

Comprehension and Informed Consent: Assessing the Effect of a Short Consent Form  
Leanne Stunkel, Meredith Benson, Louise McEllan, Ninet Sinai, Gabriella Bedarida, Ezekiel Emanuel, and Christine Grady 1

IN THE FIELD  
Assessing the Readability of Non-English-Language Consent Forms: The Case of Kiswahili for Research Conducted in Kenya  
Caroline Kithnj and Nancy E. Kass 10

Contents lists available at ScienceDirect

### Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclint

## Randomization to standard and concise informed consent forms: Development of evidence-based consent practices<sup>1,2</sup>

Mary E. Enama<sup>3,4</sup>, Zonghui Hu<sup>5</sup>, Ingelise Gordon<sup>6</sup>, Pamela Costner<sup>4</sup>, Julie E. Ledgerwood<sup>3</sup>, Christine Grady<sup>6</sup> and the VRC 306 and 307 Consent Study Teams

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<sup>2</sup> Biostatistics Research Branch, Division of Clinical Research, NINDS, NIH, Bethesda, MD 20892, United States  
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ARTICLE INFO ABSTRACT

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**Keywords:**  
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Comprehension  
Research subject

**Background:** Consent to participate in research is an important component of the conduct of ethical clinical trials. Current consent practices are largely policy-driven. This study was conducted to assess comprehension of study information and satisfaction with the consent form between subjects randomized to concise or to standard informed consent forms as one approach to developing evidence-based consent practices.

**Methods:** Participants (N=111) who enrolled into two Phase I investigational influenza vaccine protocols (VRC 306 and VRC 307) at the NIH Clinical Center were randomized to one of two IRB-approved consents; either a standard or concise form. Concise consents had an average of 63% fewer words. All other aspects of the consent process were the same. Questionnaires about the study and the consent process were completed at enrollment and at the last visit in both studies.

**Results:** Subjects using concise consent forms scored as well as those using standard length consents in measures of comprehension (7 versus 7, p=0.79 and 20 versus 21, p=0.13), however the trend was for the concise consent group to report feeling better informed. Both

PLOS ONE

### A randomized trial comparing concise and standard consent forms in the START trial

Christine Grady<sup>1\*</sup>, Giota Touloumi<sup>2</sup>, A. Sarah Walker<sup>3</sup>, Mary Smolckis<sup>4</sup>, Shweta Sharma<sup>5</sup>, Abdel G. Babiker<sup>6</sup>, Nikos Pantazis<sup>7</sup>, Jorge Teve<sup>8</sup>, Eric Florence<sup>9</sup>, Adriana Sanchez<sup>9</sup>, Fleur Hudson<sup>9</sup>, Antonios Papadopoulos<sup>9</sup>, Ezekiel Emanuel<sup>10</sup>, Megan Cvetvet<sup>11</sup>, David Munroe<sup>12</sup>, Eileen Denning<sup>12</sup>, the INSIGHT START Informed Consent Substudy Group<sup>12</sup>

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**Abstract**

**Background**  
Improving the effectiveness and efficiency of research informed consent is a high priority. Some express concern about longer, more complex, written consent forms creating barriers to participant understanding. A recent meta-analysis concluded that randomized comparisons were needed.

**Methods**  
We conducted a cluster-randomized non-inferiority comparison of a standard versus concise consent form within a multinational trial studying the timing of starting antiretroviral therapy in HIV-1 adults (START). Interested sites were randomized to standard or concise consent forms for all individuals signing START consent. Participants completed a survey measuring comprehension of study information and satisfaction with the consent process. Site personnel reported usual site consent practices. The primary outcome was comprehen-

# Research: improving understanding

NS group differences in understanding, but majority favored watching videos, felt better prepared and helped with decision [Hoffner et al. \*Cancer\* 2012](#)

Randomized to 3 formats. Participants exposed to video had better understanding scores and were more satisfied. [Taylor H et al \*Clin Trials\* 2021](#)

Nonrandomized eval of interactive multimedia web-based format vs standard consent among parents/caregivers. Understanding at enrollment similar, retention better at 20 weeks. [Blake K et al. \*JMIR Ped Parent\* 2023](#)

Systematic review- e-consent could improve comprehension and recall. Mixed on enrollment. [Mazzochi A et al \*Trials\* 2023](#)

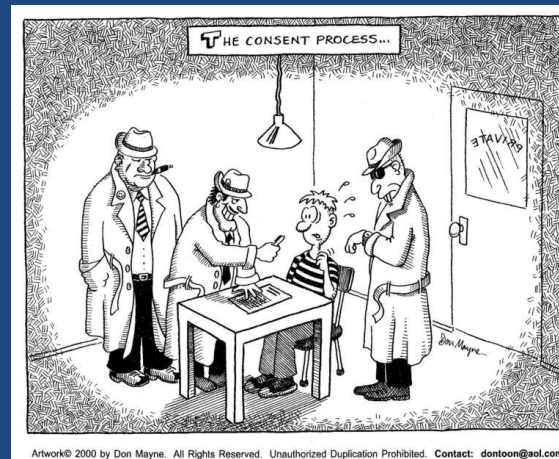
Systematic review showed those using e-consent (vs. paper-based consent) had a better understanding of clinical trial information, greater engagement with content, and rated the process more acceptable and usable. [Cohen E et al \*J Med Internet Research\*](#)



# Voluntariness

Able to make a voluntary choice?

No deception, coercion, undue influence



# Voluntariness

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Deception- concealing or distorting the truth in order to mislead

Coercion- compelling another party to act by force or by threatening to make them worse off

Undue inducement/influence- an offer that distorts judgement or entices someone to participate in research that is contrary to their interests.

# Possible influences on voluntariness

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Dependent position

Restricted choices?

Power relationship

Illness?

Pressure from others  
(family, friends)

Incentives?

Trust in health care  
provider

# Data on Voluntariness

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## Pressure from others

- 2%- 25% (ACHRE 1996, van Stuversten et al 1998, Pace et al 2005)
- 58% from child's disease (Pace et al 2005)

## Knew they could quit

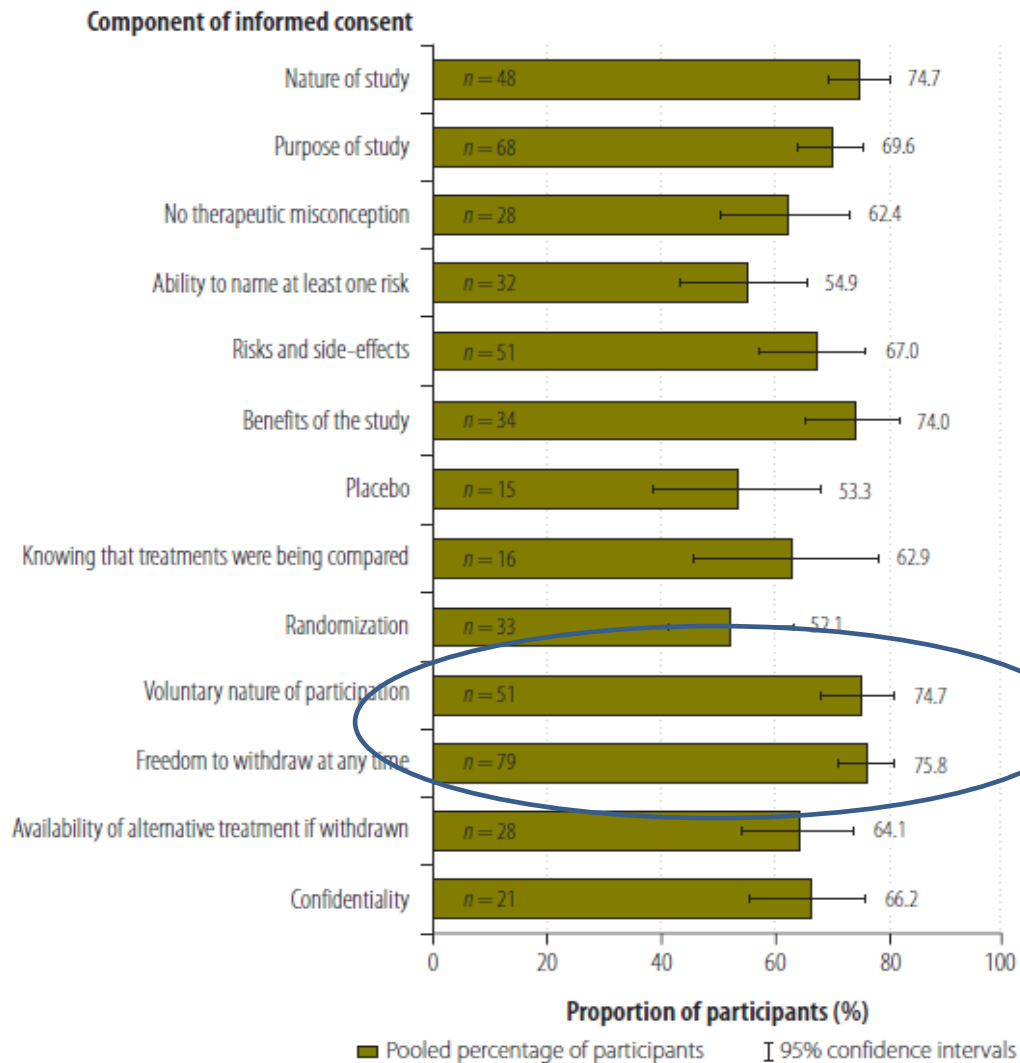
- 44% Swedish women in gyn trial, 88% Thai HIV vaccine participants, 90% US Cancer patients (Lynoe et al 1991 and 2001; Pitisuttithum et al 1997, Joffe et al 2001, Schumacher et al. 2017)

## Decline participation

- Range of actual decliners



Fig. 2. Participants' understanding of components of informed consent in clinical trials, by meta-analysis<sup>a</sup>



<sup>a</sup> The number of studies included in the evaluation of each component is given.

# Informed Consent

**Table 1.** Components and Challenges of Informed Consent with Traditional Paper Forms and Electronic Methods.

Component	Traditional Paper Informed Consent	Electronic and Digital Informed Consent	Challenges and Areas for Research
Disclosure	Information is written, usually on paper Discussion with investigator takes place, usually face to face	Consent can involve electronic information, multimedia information, video graphics, and interactive computer interfaces Investigator can be remote in time or place from participant	All types of disclosure require determining the appropriate content (amount and complexity of information) for disclosure User-friendly disclosure is needed Amount and style of information tailored to electronic platforms need to be determined
Understanding	Investigator and participant discuss information Participant asks questions Investigator assesses understanding, in some cases using questions, structured quizzes, other methods	Interaction can take place during disclosure Questions and assessment of understanding are easily built in Ongoing engagement is enabled Links to additional information can be included	Evidence indicates that people do not read click-through agreements on computers and mobile devices Information should be engaging and user-friendly to promote reading and understanding It may be difficult to assess capacity and understanding Empirical evidence to date indicates that video and multimedia consent strategies have not resulted in consistent advantages or disadvantages with regard to participant understanding <sup>47</sup>
Voluntariness	Investigator asks participant to make a choice in a setting free from coercion and undue influence Research team observes participant's body language and any hesitation	Some electronic systems facilitate participant control Participant can easily sign off or disengage Participant can decline	It may be difficult to assess voluntary choice without the clues of body language and tone It may be difficult to verify the identity of the person consenting Some data collection is passive In some cases, contributing data is a required part of the arrangement
Authorization	Paper consent document is signed Copies of document are kept in records	Options might include clicking agreement or an electronic signature Records of agreement are kept electronically	It may be difficult to verify the identity of the authorizing person

# Informed Consent- complex and imperfect

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- Enduring challenges in disclosure, understanding, voluntary choice
- Informed consent affected by (and by differences in):
  - Motivations and expectations
  - Capacity
  - Experience of and tolerance for inconvenience, burden
  - Differential responses to incentives

# Changes

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## Types of research

- Biobanks and Data Repositories
- Big Data
- Pragmatic trials

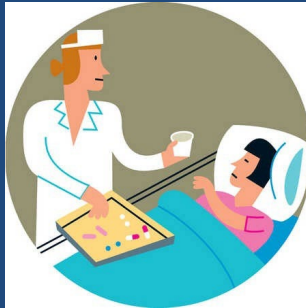
## Types of information exchange

- Electronic consent
- Devices and apps
- Web interfaces
- Telehealth





# Typical clinical research

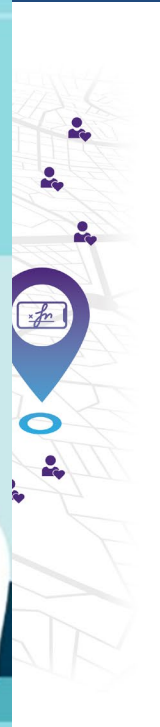
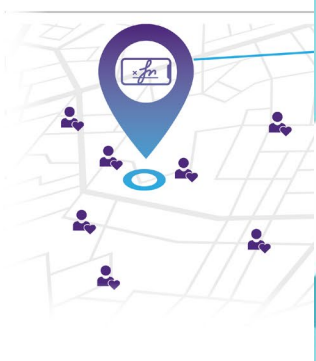


MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
• Adult Patient or • Parent, for Minor Patient	
INSTITUTION:	
STUDY NUMBER:	PRINCIPAL INVESTIGATOR:
STUDY TITLE:	
Initial Review Approved by the IRB on _____ Date Posted to Web: _____	Signature: _____
<b>INTRODUCTION</b>	
We invite you to take part in a research study at the National Institutes of Health (NIH).	
First, we want you to know that:	
Taking part in NIH research is entirely voluntary.	
You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.	



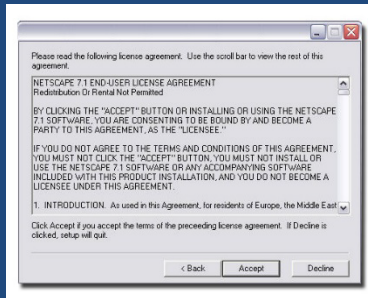
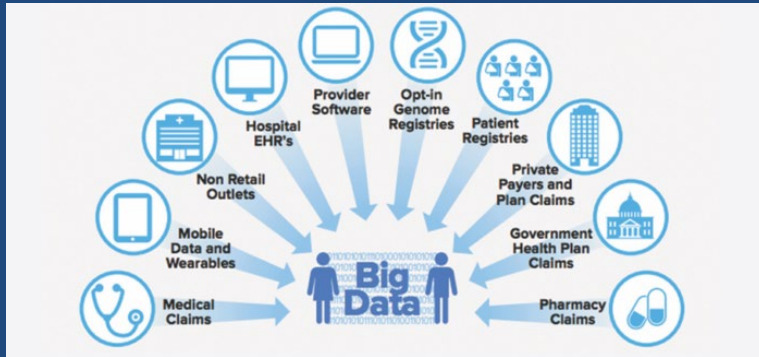
# Decentralized trials

Decentrali



Patient


# Research with big data



# Research with Biospecimens



# Consent for research with data and biospecimens

	TYPE OF CONSENT	DESCRIPTION	Oversight
<p>Less Control, Less burden</p>  <p>More control, more burden?</p>	No consent	No consent from participant	Exempt from review
	Blanket	Consent to future research without limitations	Exempt from review
	Broad	Consent to future research with pre-specified limitations	Limited review
	Checklist/Tiered	Participants choose which types of future studies are allowed	Review
	Study specific	Consent for each specific future study	Review
	Dynamic consent	Personalized, online, on-going consent and communication between participants and researchers custodians of data.	Review

Adapted from Grady et al. *AJOB* 2015

ARTICLE

## Dynamic consent in the twenty-first century research environment

Jane Kaye<sup>\*1</sup>, Edgar

Biomedical research is generating vast amounts of data to be shared on a global scale. Changes in research capabilities and funding mean that consent remain static, particularly for both a specific project and the twenty-first century research environment. Researchers and participants

communication to stimulate a more engaged, motivated and literate participant population where individuals can tailor and manage their own consent preferences. The architecture of DC includes components that can securely encrypt sensitive data and allow participant consent preferences to travel with their data and samples when they are shared with third parties. In addition to improving transparency and public trust, this system benefits researchers by streamlining recruitment and enabling more efficient participant recontact. DC has mainly been developed in biobanking contexts, but it also has potential application in other domains for a variety of purposes.

*European Journal of Human Genetics* (2015) **23**, 141–146; doi:10.1038/ejhg.2014.71; published online 7 May 2014

“Dynamic consent is a personalised, communication interface to enable greater participant engagement in clinical and research activities. It is a participant-centred initiative that places patients and research participants at the centre of decision making, providing an interactive IT interface to engage with participants. This approach is ‘dynamic’ because it allows interactions over time; it enables participants to consent to new projects or to alter their consent choices in real time as their circumstances change and to have confidence that these changed choices will take effect”

# Conclusions

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Informed consent is a process based on respect for persons, that also promotes participant welfare, respects values, offers control, promotes trust, complies with regulations, and helps to ensure integrity.



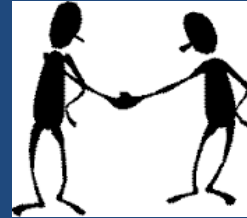
Changes in research methodologies, information technologies, participant engagement, regulations, and our understanding of informed consent offer opportunities for innovative evidence-based strategies for informed consent.



# Informed consent

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As research and technology evolve, maintain clarity about the purpose(s) of informed consent



Quality training of researchers, research teams, clinicians, and IRB members



Creativity and evidence



