



# INFORMED CONSENT

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NIH CLINICAL CENTER

# Disclaimer

- ▶ 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



- ▶ The BASICS
- ▶ CHANGES
- ▶ ENDURING AND EMERGING CHALLENGES

# Consent

- ▶ 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



- ▶ 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 requirement



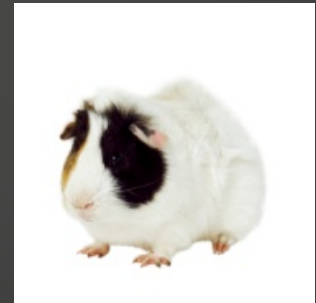
- ▶ Respect for autonomy - an individual's capacity and right to define his/her own goals and make choices consistent with those goals.
- ▶ Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided...[when] informed consent are satisfied. [Belmont Report](#)

**ASSENT**  
— VS —  
**CONSENT**



# Informed consent in clinical research

- ▶ The goal of research is to produce knowledge, not always benefit to 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





# Informed consent in clinical research



- ▶ 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

# Research Informed consent: Regulatory requirements

- ▶ ...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.

# Informed consent

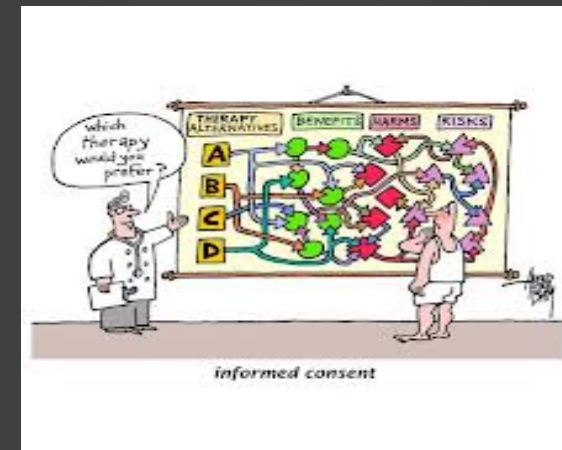
- ▶ “Informed consent involves providing a potential subject with adequate information to allow for an informed decision about participation in the clinical investigation, facilitating the potential subject’s comprehension of the information, providing adequate opportunity for the potential subject to ask questions and to consider whether to participate, obtaining the potential subject’s voluntary agreement to participate, and continuing to provide information as the clinical investigation progresses or as the subject or situation requires.”
- ▶ [US FDA Informed Consent Guidance Sheet, July 2014](#)

# Elements of informed consent

- ▶ (Capacity to consent)
- ▶ Disclosure of information
- ▶ Understanding
- ▶ Voluntariness
- ▶ (Consent authorization)

# Decisions about Disclosure of information

- ▶ What information should be disclosed?
- ▶ How should information be presented?
- ▶ Circumstances and setting?



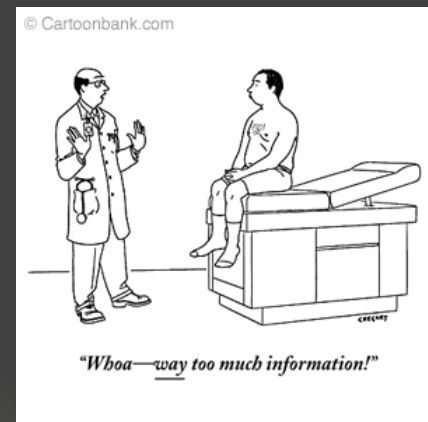
# Disclosure of information



- ▶ Written consent form
  - ▶ Study summary—explanation of what the study is about, the procedures, related risks and possible benefits, alternatives, rights;
  - ▶ Elements required by regulations
- ▶ Advertisements, fliers, brochures
- ▶ (Reviewed and approved by IRB)

# Consent forms

- ▶ Readable, understandable consent forms that explain the study
- ▶ Length, format, reading level, complexity, are all important
- ▶ Using consent forms in discussion



# Health literacy



- ▶ “In ensuring that information is understandable, it should be noted that
  - ▶ more than one-third of U.S. adults, 77 million people, have basic or below basic health literacy,
  - ▶ Limited health literacy affects adults in all racial and ethnic groups,
  - ▶ More than one-half of U.S. adults have basic or below basic quantitative literacy and are challenged by numerical presentations of health, risk, and benefit data.

FDA Informed Consent Guidance Sheet, July 2014



# Easy-to-read informed consent documents

- ▶ Familiar, consistent words, Active voice and personal pronouns
- ▶ Short, simple, direct sentences with limited line length
- ▶ Short paragraphs, one idea per paragraph.
- ▶ Clear, logically sequenced ideas
- ▶ Highlight Important points
- ▶ Avoid acronyms and abbreviations
- ▶ Format (headers, white space, graphics, font, bold)
- ▶ **From NCI Simplification of Informed Consent Documents, Appendix 3.**  
<<http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page1>

# Just one randomly selected example

- ▶ Previous clinical trials have evaluated the xxx vaccine, subcutaneously administered (applied under skin as an injection), in people with advanced cancers. In these trials, there were no side effects considered life threatening or severe due to the administration of the vaccine. Xxxx has not been previously given into the vein (intravenously) to humans. This trial represents a new way of activating different segments of your immune system that may induce additional anticancer effects. This way of administering vaccine is used in other clinical trials using different viral vaccines.

# Length and readability

## ▶ Reading level is high

- ▶ Consent forms and templates usually written at or above the 11<sup>th</sup> grade level [LoVerde et al, 1989](#); [Grossman et al 1994](#); [Paasche-Orlow et al., 2003](#); [Sharp 2004](#)

## ▶ Consent forms are long

- ▶ Consent documents have increased in length over time [Baker and Taub, 1983](#); [LoVerde et al 1989](#); [Tarnowski et al 1990](#); [Beardsley et al 2007](#), [Albala et al. 2010](#)

## ▶ Missing required or relevant elements

- ▶ [Silverman et al. \*Critical Care Medicine\* 2001](#);
- ▶ [Hornig et al, \*NEJM\* 2002](#); [Beardsley et al. \*JCO\* 2007](#); [Abeyseena C et al \*Ind J Med Ethics\* 2012](#)



# Informed consent (revised

Common Rule)

- ▶ §\_\_\_.116 (a)(5)(i) Informed consent *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.

# Challenges



- ▶ “Easy reading is damn hard writing.”  
Nathaniel Hawthorne ~1840
- ▶ Written informed consent protects the institution, sponsor, investigator
- ▶ IRBs often make consent forms longer and more complex

# Prototypical research informed consent

- ▶ Discussion of study information
- ▶ Written consent form
- ▶ Signatures



MEDICAL RECORD	CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
• Adult Patient or • Parent, for Minor Patient	
INSTITUTE:	
STUDY NUMBER:	PRINCIPAL INVESTIGATOR:
STUDY TITLE:	
Initial Review Approved by the IRB on Standard	Date Posted to Web:
<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.	

# Presentation



# Setting





# Elements of informed consent

- ▶ Disclosure of information
- ▶ *Understanding*
- ▶ Voluntariness
- ▶ Consent authorization

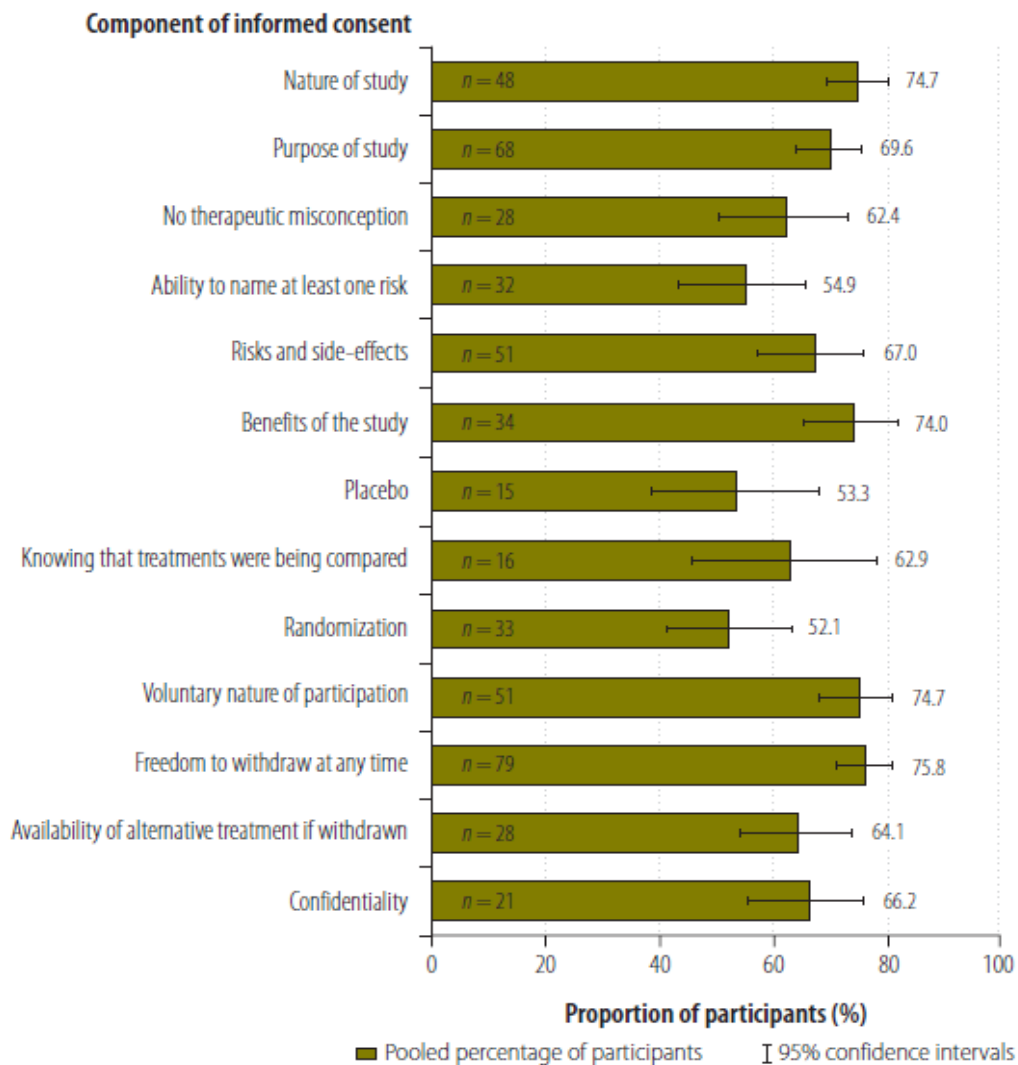


# Participant Understanding



- ▶ Studies continue to show that research participants have variable understanding e.g. Mandava A et al *J Med Ethics* 2012
- ▶ Range of understanding about research purpose and nature (27% -100%) Krosin et al 2006; Joffe et al 2001; Pace et al. 2005; Criscione et al. 2003
- ▶ Range of understanding about research risks (28%-100%) Bergler 1980; Joffe et al. 2001; Leach et al, 1999; Dougherty et al 2000
- ▶ Range of understanding about randomization (21%-42%) Harrison et al 1995; Hietanen 2000; Pace et al. 2005; Howard 1981

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.

# Questions about Understanding



- ▶ What affects understanding? age, education, expectations, disclosure
- ▶ 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

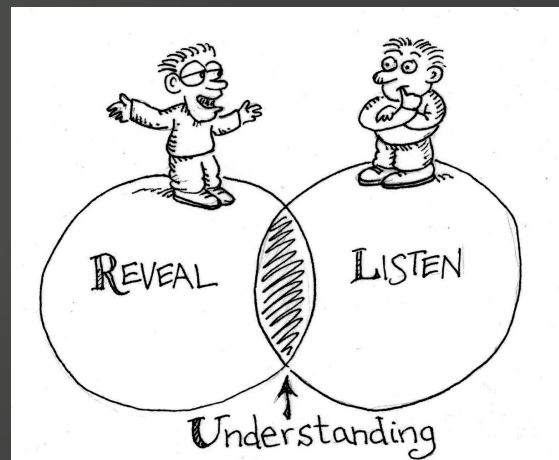
<sup>a</sup>As determined by the institutional review board.

<sup>b</sup>Unless there is reason for concern.

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

# Understanding

- ▶ Knowledge of relevant information
- ▶ Appreciation of how it applies
- ▶ Therapeutic misconception



# Therapeutic Misconception

- ▶ 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 on improving understanding

- ▶ 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)



# Research to improve 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*



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

Leanne Stunkel, Meredith Benson, Louise McLellan, Ninet Sinai, Gabriella Bedarida, Ezekiel Emanuel, and Christine Grady

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ETHICS  
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HUMAN RESEARCH

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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.

Contents lists available at ScienceDirect

Contemporary Clinical Trials

ELSEVIER 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>7</sup>, Julie E. Ledgerwood<sup>8</sup>, Christine Grady<sup>9</sup> and the VRC 306 and 307 Consent Study Teams

Article Info

Article history:

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Received in revised form 22 March 2012

Accepted 14 April 2012

Available online 20 April 2012

Keywords:

Clinical trial

Informed consent

Institutional Review Board

Comprehension

Research subject

Abstract

**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 score higher on further informed.



RESEARCH ARTICLE

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 Smolaki<sup>4</sup>, Shweta Sharma<sup>5</sup>, Abdel G. Babiker<sup>6</sup>, Nicos Pantazis<sup>7</sup>, Jorge Tavel<sup>8</sup>, Eric Florence<sup>9</sup>, Adriana Sanchez<sup>10</sup>, Fleur Hudson<sup>11</sup>, Antonios Papadopoulos<sup>12</sup>, Ezekiel Emanuel<sup>13</sup>, Megan Clewett<sup>14</sup>, David Munroe<sup>15</sup>, Eileen Detnring<sup>16</sup>, the INSIGHT START Informed Consent Substudy Group<sup>17</sup>

OPEN ACCESS

**Citation:** Grady C, Touloumi G, Walker AS, Smolaki M, Sharma S, Babiker AG, et al. (2017) A randomized trial comparing concise and standard consent forms in the START trial. PLoS ONE 12(4): e0172667. <https://doi.org/10.1371/journal.pone.0172667>

**Editor:** Kerry Woolf, University of Liverpool, UNITED KINGDOM

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**Data Availability Statement:** Participant level data are not provided to open access due to ethical and legal obligations to the participants in the clinical trial. Aggregate data will be available to all researchers upon request to the research team.

**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+ 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 usable site consent practices. The option to frame consent process-

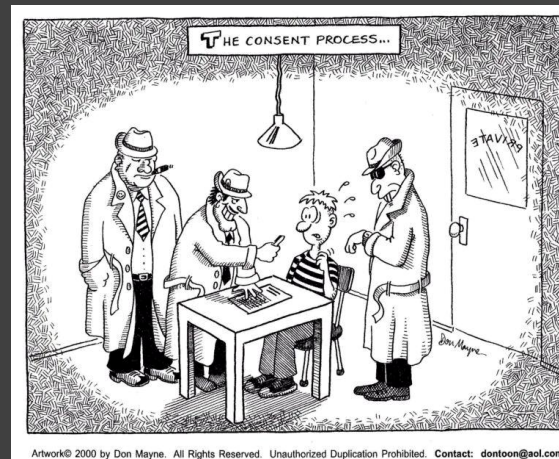
# Understanding Challenges



- ▶ Complex Science
- ▶ Health literacy and capacity
- ▶ Measuring understanding
- ▶ Different kinds of “mis-understanding”
  - ▶ Misconception
  - ▶ Mis-estimation
  - ▶ Optimism *Hornig & Grady IRB 2003*
- ▶ Knowledge v. appreciation

# Voluntariness

- ▶ Able to make a voluntary choice?
- ▶ No deception, coercion, undue influence



# Voluntariness



- ▶ Deception- concealment or distortion of 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

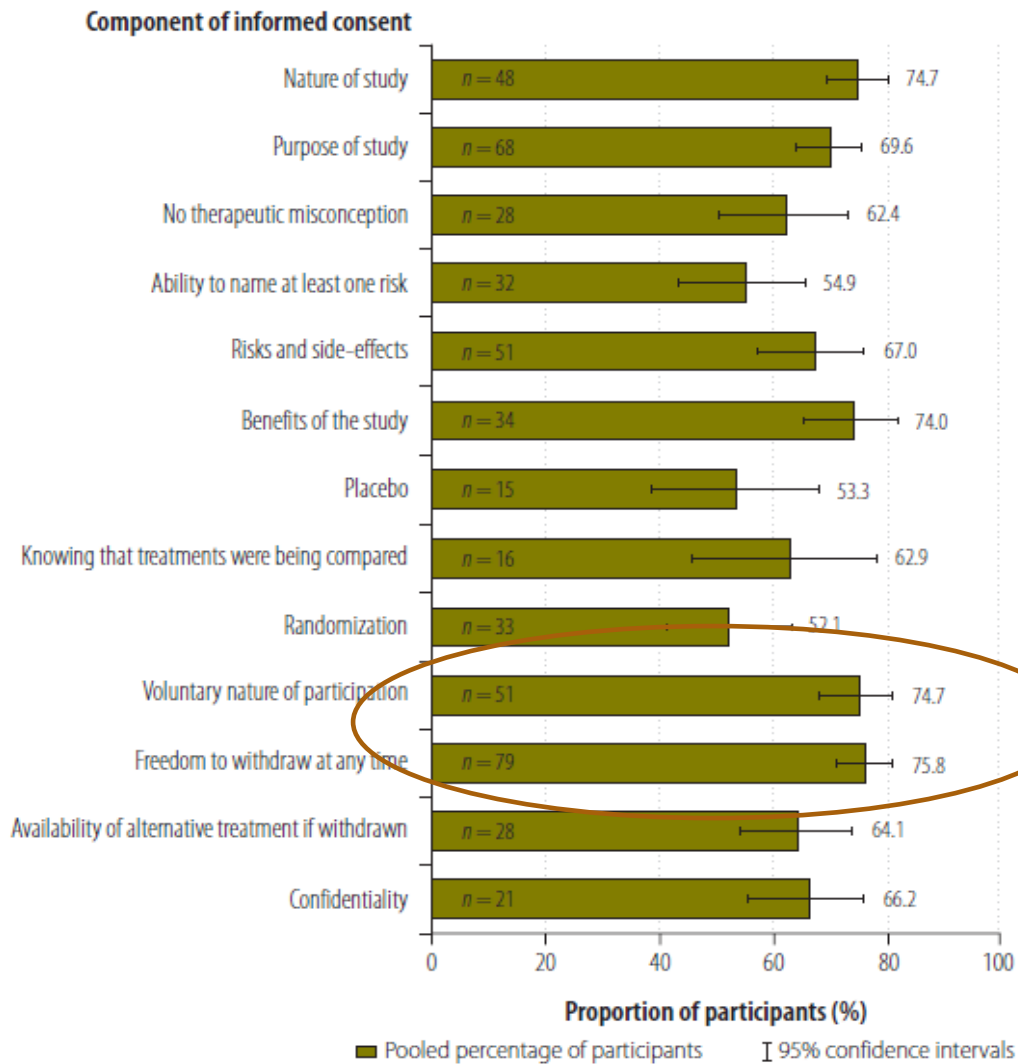


- ▶ Dependent position
- ▶ Power relationship
- ▶ Pressure from others (family, friends)
- ▶ Trust in health care provider
- ▶ Restricted choices?
- ▶ Illness?
- ▶ Incentives?

# Voluntariness

- ▶ 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)
- ▶ 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

▶ The BASICS

▶ *CHANGES*

▶ ENDURING AND EMERGING  
CHALLENGES





# Paradigmatic clinical research



MEDICAL RECORD | CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY  
• Adult Patient or • Parent, for Minor Patient

INSTITUTE: \_\_\_\_\_

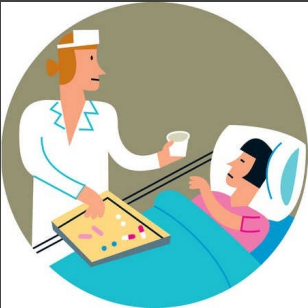
STUDY NUMBER: \_\_\_\_\_ PRINCIPAL INVESTIGATOR: \_\_\_\_\_

STUDY TITLE: \_\_\_\_\_

Initial Review Approved by the IRB on: \_\_\_\_\_ Date Printed to Web: \_\_\_\_\_  
Standard: \_\_\_\_\_

**INTRODUCTION**

We invite you to take part in a research study at the National Institutes of Health (NIH).  
First, we need 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.



Journal Example

Example Author Manuscript Title  
Example Author 1, Example Author 2, Example Author 3

**ARTICLE**

**Abstract**

**Introduction**

**Methods**

**Results**

**Discussion**

**Conclusion**

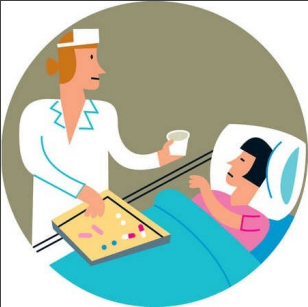
**References**

**Footnote**

**Keywords**

**Copyright**

# Paradigmatic clinical research



# Research with Data and Biospecimens



# Research with Data and Biospecimens



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## No consensus on acceptable consent

	TYPE OF CONSENT	DESCRIPTION
<b>Less Control, Less burden</b>  ↑  <b>More control, more burden</b>	No consent	Do not obtain donor consent
	Blanket	Consent to future research with no limitations
	Broad*	Consent to future research with specified limitations
	Checklist	Donors choose which types of future studies are allowed
	Study specific	Consent for each specific future study

# Pragmatic trials



CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Medical History: \_\_\_\_\_  
Study Number: \_\_\_\_\_  
Principal Investigator: \_\_\_\_\_  
Study Title: \_\_\_\_\_  
Date Approved: \_\_\_\_\_  
Date Published: \_\_\_\_\_

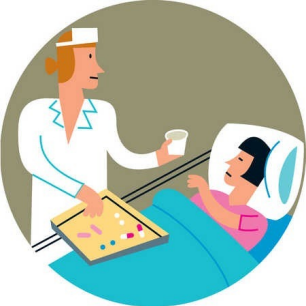
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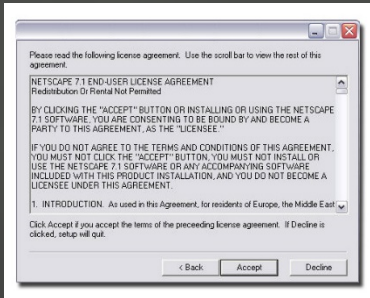
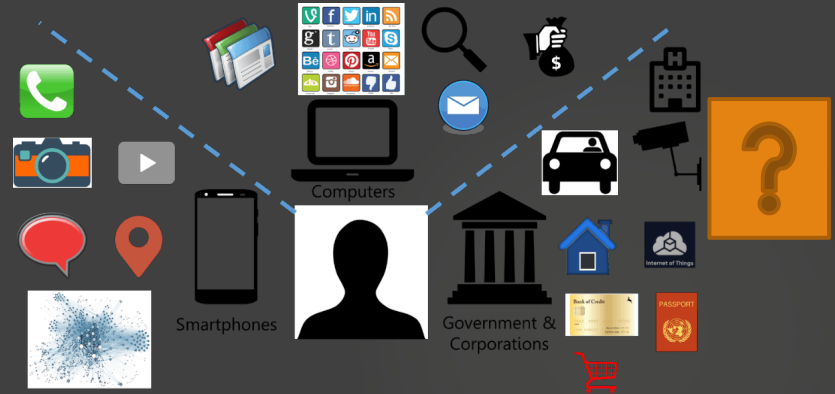
- Taking part in NIH research is entirely voluntary.
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# Pragmatic trials



# Research with big data





# Information technologies



**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 policies on comments to public. (56469, September 2015, [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 **INFORMATION** for written requests for guidance and for electronic 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.”

# Components and Challenges of Informed Consent with Traditional Paper Forms and Electronic Methods.

**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

# Dynamic consent

Interactive technology based platform.  
Not “... locked in time to the beginning of the research process. Depending upon the nature of the research enterprise, participants could consent to a broad range of uses of their samples and data, or opt to be approached on a case-by-case basis, or set different preferences for different types of research. These preferences can be ‘opt ins’ or ‘opt outs’: participants can tailor their profiles to receive no information for specified periods of time or to give a broad consent if they so wish.”

Kaye et al 2015

# Informed consent

- No consent
- Waiver

- Notification
- Simplified disclosure

- Full informed consent
- Full in person informed consent

# Waiver or alteration of informed consent

- ▶ (1) *Waiver*. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) (*general, basic and additional requirements*), provided the IRB satisfies the criteria (paragraph (e))
- ▶ An IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens if a person was asked for broad consent and refused (par d).
- ▶ (2) *Alteration*. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

# The IRB must find and document that:

- ▶ (i) The research involves no more than **minimal risk** to the subjects;
- ▶ (ii) The research could not **practicably** be carried out without the requested waiver or alteration;
- ▶ (iii) If the research involves using **identifiable** private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- ▶ (iv) The waiver or alteration will not adversely affect the **rights and welfare** of the subjects; and
- ▶ (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with **additional pertinent information** after participation.

# Conclusions

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.

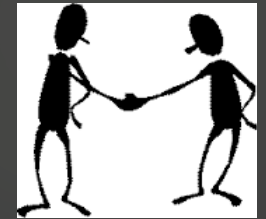
Changes in research methodologies, information technologies, participant engagement, regulations, and our understanding of informed consent offer opportunities for innovative evidence-based strategies for informed consent.





# Informed consent

- ▶ 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