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IRB Grand Rounds

Consenting Study Participants in the 21st Century

December 9, 2014

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Outline

I. Background
   - Purpose
   - Technology

II. Application
   - How it works (interactive example)

III. Future of eConsenting
   - Considerations for study teams
   - IRB uptake and regulation

IV. Resources for research teams

Learning Objectives

At the end of this presentation, participants will be able to:

- Understand the benefits of electronic consenting (e-consenting)
- Identify important issues when considering the use of e-consenting
- Describe the potential challenges in e-consenting for both study participants and the research team

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Section 1:

Background

Informed consent & assent in biomedical research

The principle of consent is closely related to the principles of:

I. Autonomy,
II. Self-determination and
III. The affirmation of human rights and respect for human dignity.

Council for International Organization of Medical Sciences. Geneva: CIOMS; 2002.

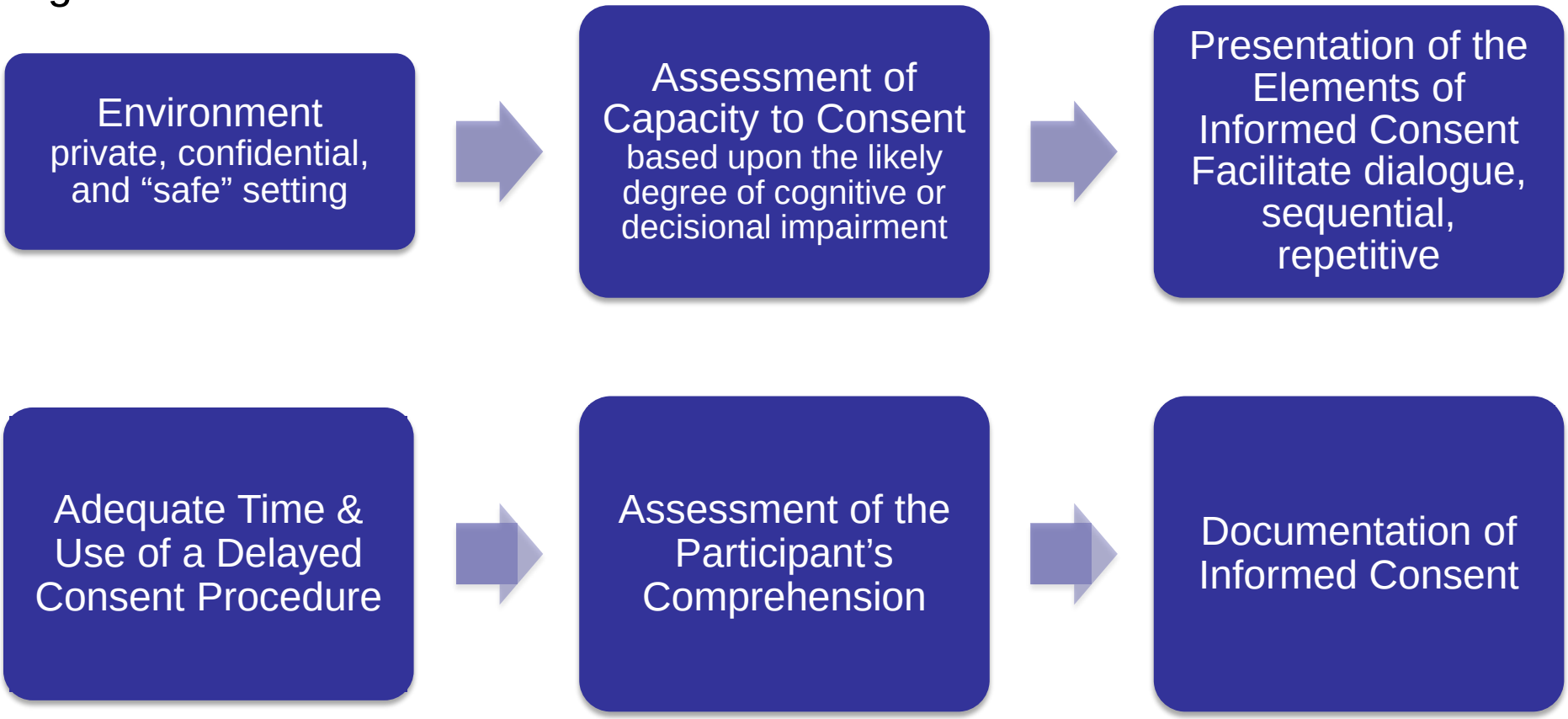
Components of informed consent

Adequate informed consent consists of three required elements: (Appelbaum and Roth 1982; Christensen et al. 1995; Faden & Beauchamp, 1986)

1. Full information;
2. Voluntary participation; and
3. Capacity to make a decision

Traditional consent process (FDA , 1980; HHS, 1991; CIOMS WHO, 2002)

Begins at first contact…



Potential challenges with the Informed Consent Process

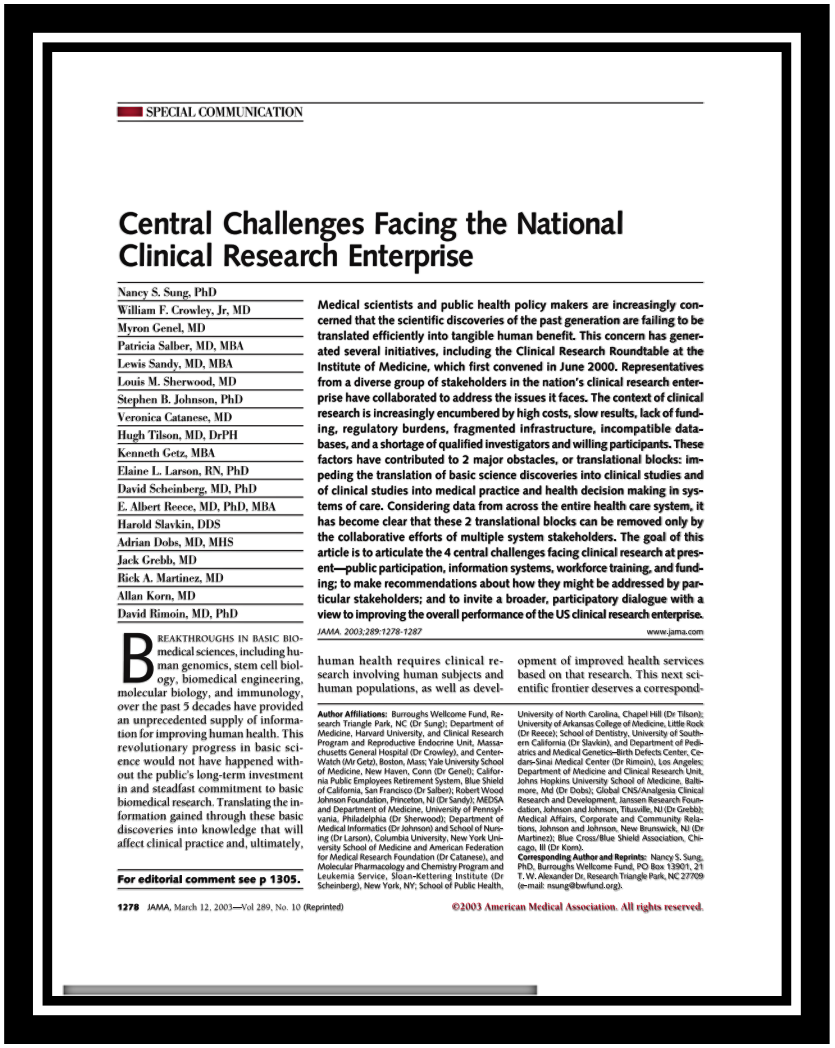
•**Lack of standardization** (Bhutta, 2004; Joffe et al., 2001; Paasche-Orlow, Taylor, & Brancati, 2003; Sieber, Plattner, & Rubin, 2002)

- Pros and cons to standardizing forms and procedures (Lo & Barnes, 2011; Sung et al., 2003)

•**Time-consuming** – May deter individuals from participating in research (participant fatigue; contributes to study team fatigue) (Bhutta, 2004; Sung et al., 2003)

•**Resource intensive** – Study team personnel must be specially trained in order to deliver informed consent (Paris et al., 2010)

•**Communication is at times inadequate/unclear** – Individuals may not understand what they are consenting to do as a potential participant in the study (Sieber, Plattner, & Rubin, 2002; Paris et al., 2010; Joffe et al., 2001)



SPECIAL COMMUNICATION

Central Challenges Facing the National Clinical Research Enterprise

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Patricia Salber, MD, MBA
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Medical scientists and public health policy makers are increasingly concerned that the scientific discoveries of the past generation are failing to be translated efficiently into tangible human benefit. This concern has generated several initiatives, including the Clinical Research Roundtable at the Institute of Medicine, which first convened in June 2000. Representatives from a diverse group of stakeholders in the nation's clinical research enterprise have collaborated to address the issues it faces. The context of clinical research is increasingly encumbered by high costs, slow results, lack of funding, regulatory burdens, fragmented infrastructure, incompatible databases, and a shortage of qualified investigators and willing participants. These factors have contributed to 2 major obstacles, or translational blocks: impeding the translation of basic science discoveries into clinical studies and of clinical studies into medical practice and health decision making in systems of care. Considering data from across the entire health care system, it has become clear that these 2 translational blocks can be removed only by the collaborative efforts of multiple system stakeholders. The goal of this article is to articulate the 4 central challenges facing clinical research at present—public participation, information systems, workforce training, and funding; to make recommendations about how they might be addressed by particular stakeholders; and to invite a broader, participatory dialogue with a view to improving the overall performance of the US clinical research enterprise.

JAMA. 2003;289:1278-1287 www.jama.com

BREAKTHROUGHS IN BASIC BIOmedical sciences, including human genomics, stem cell biology, biomedical engineering, molecular biology, and immunology, over the past 5 decades have provided an unprecedented supply of information for improving human health. This revolutionary progress in basic science would not have happened without the public's long-term investment in and steadfast commitment to basic biomedical research. Translating the information gained through these basic discoveries into knowledge that will affect clinical practice and, ultimately, human health requires clinical research involving human subjects and human populations, as well as development of improved health services based on that research. This next scientific frontier deserves a correspond-

For editorial comment see p 1305.

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"Greater application of standardized electronic record keeping appears to be a logical means to increase efficiency."

Sung, N. S., Crowley Jr, W. F., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., ... & Rimoin, D. (2003). Central challenges facing the national clinical research enterprise. *JAMA*, 289(10), 1278-1287.

Findings from numerous studies and a few meta-analyses confirm that interactive, multimedia-assisted ICFs:

- improve participant understanding,
- reduce literacy-related barriers,
- increase participant & researcher satisfaction with the consent process,
- result in longer recall times of comprehension-related items, and
- simplify the process of declining to continue

Afolabi et al., 2014; Flory & Emmanuel, 2004; Jimison, Sher, Appleyard, & LeVernois, 1998; Mahnke et al., 2014; Nishimura et al., 2013

Electronic (“e”) Consenting Technologies

	Web-based	Computerized	Tablet-based
Electronic record	✓	✓	✓
Response validation	✓	✓	✓
Researcher guided	✓	✓	✓
Standardized delivery	✓	✓	✓
Pictoral explanation	✓	✓	✓
Audio/video enhanced		✓	✓
Literacy independent		✓	✓
Offline		✓	✓
Self-paced; flexible		✓	✓
Interactive (touch screen)			✓
eSignature			✓

CTSA spearheaded an interdisciplinary effort to develop and evaluate eConsent technologies

CTSA Clinical & Translational Science Awards ®

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Comparing eConsents to paper consents

Rowbotham, Astin, Greene, & Cummings (2013) investigated subject comprehension, delayed recall, and ratings of user acceptability of a paper-delivered and iPad-elicited informed consent.

OPEN ACCESS Freely available online

PLOS ONE

Interactive Informed Consent: Randomized Comparison with Paper Consents

Michael C. Rowbotham[1]*, John Astin[1], Kaitlin Greene[1], Steven R. Cummings[1,2]

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Abstract

Informed consent is the cornerstone of human research subject protection. Many subjects sign consent documents without understanding the study purpose, procedures, risks, benefits, and their rights. Proof of comprehension is not required and rarely obtained. Understanding might improve by using an interactive system with multiple options for hearing, viewing and reading about the study and the consent form at the subject's own pace with testing and immediate feedback. This prospective randomized study compared the IRB-approved paper ICF for an actual clinical research study with an interactive presentation of the same study and its associated consent form using an iPad device in two populations: clinical research professionals, and patients drawn from a variety of outpatient practice settings. Of the 90 participants, 69 completed the online test and survey questions the day after the session (maximum 36 hours post-session). Among research professionals ($n = 14$), there was a trend ($p = .07$) in the direction of iPad subjects testing better on the online test (mean correct = 77%) compared with paper subjects (mean correct = 57%). Among patients ($n = 55$), iPad subjects had significantly higher test scores than standard paper consent subjects (mean correct = 75% vs 58%, $p < .001$). For all subjects, the total time spent reviewing the paper consent was 13.2 minutes, significantly less than the average of 22.7 minutes total on the three components to be reviewed using the iPad (introductory video, consent form, interactive quiz). Overall satisfaction and overall enjoyment slightly favored the interactive iPad presentation. This study demonstrates that combining an introductory video, standard consent language, and an interactive quiz on a tablet-based system improves comprehension of research study procedures and risks.

Citation: Rowbotham MC, Astin J, Greene K, Cummings SR (2013) Interactive Informed Consent: Randomized Comparison with Paper Consents. PLoS ONE 8(3): e58603. doi:10.1371/journal.pone.0058603

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Competing Interests: MCR, JA, and KG have no conflict of interest with reference to Mytrus, the maker of the interactive iPad device. The study was funded by departmental funds at CPMCRI under the control of MCR. SRC is a founder and officer of Mytrus but was not involved in any contact with subjects or statistical analysis. JA was responsible for final data analysis. Declaration of competing interests for author SRC because of his relationship to Mytrus. SRC is Chief Scientific Officer and Board Chairman at Mytrus. The study was not funded by Mytrus. No other author has any relationship to Mytrus. No other author has a competing interest to declare. This does not alter the authors' adherence to all the PLOS ONE policies on sharing data and materials.

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Introduction

Informed consent is the cornerstone of human research subject protection

Research studies are growing in complexity and duration. Concerns persist about the adequacy of the consent process, in particular whether subjects are fully informed and actually comprehend the study. The consent form is a detailed – and generally long – description of the protocol, possible benefits and harms, study procedures, and patient rights. Most often, the first step is giving a paper consent form to the potential subject to review. Staff and the study investigator may assist the potential subject in reviewing the consent form and answering questions, but this may be insufficient and is generally not standardized. Many subjects then sign – and thereby provide consent – without understanding the study purpose, procedures, risks, benefits, and their rights. Documentation of comprehension is not required and rarely obtained before a subject is allowed to sign the form. The standard process of informed consent is risky because the subject may have complications that he or she did not realize were inherent in the research or procedure. Misunderstandings can become contentious.

Features of an ideal informed consent process

Understanding may be improved by providing potential subjects with several options to hear, view or read the consent form at their own pace. If done interactively, subjects can be given immediate feedback about their level of understanding of study procedures, risks, and so on, thereby theoretically increasing their overall comprehension. A test can then verify comprehension of key study elements before the subject is allowed to sign the ICF and enter the study.

The need for a comparative study

There has been little study of interactive methods to improve consent. A few studies have tested informed consent on computers – with colorful graphics and multimedia – and compared them with written documents before elective surgeries with mixed results about whether understanding and satisfaction were improved [1]. Furthermore, the consent forms evaluated were for surgery or

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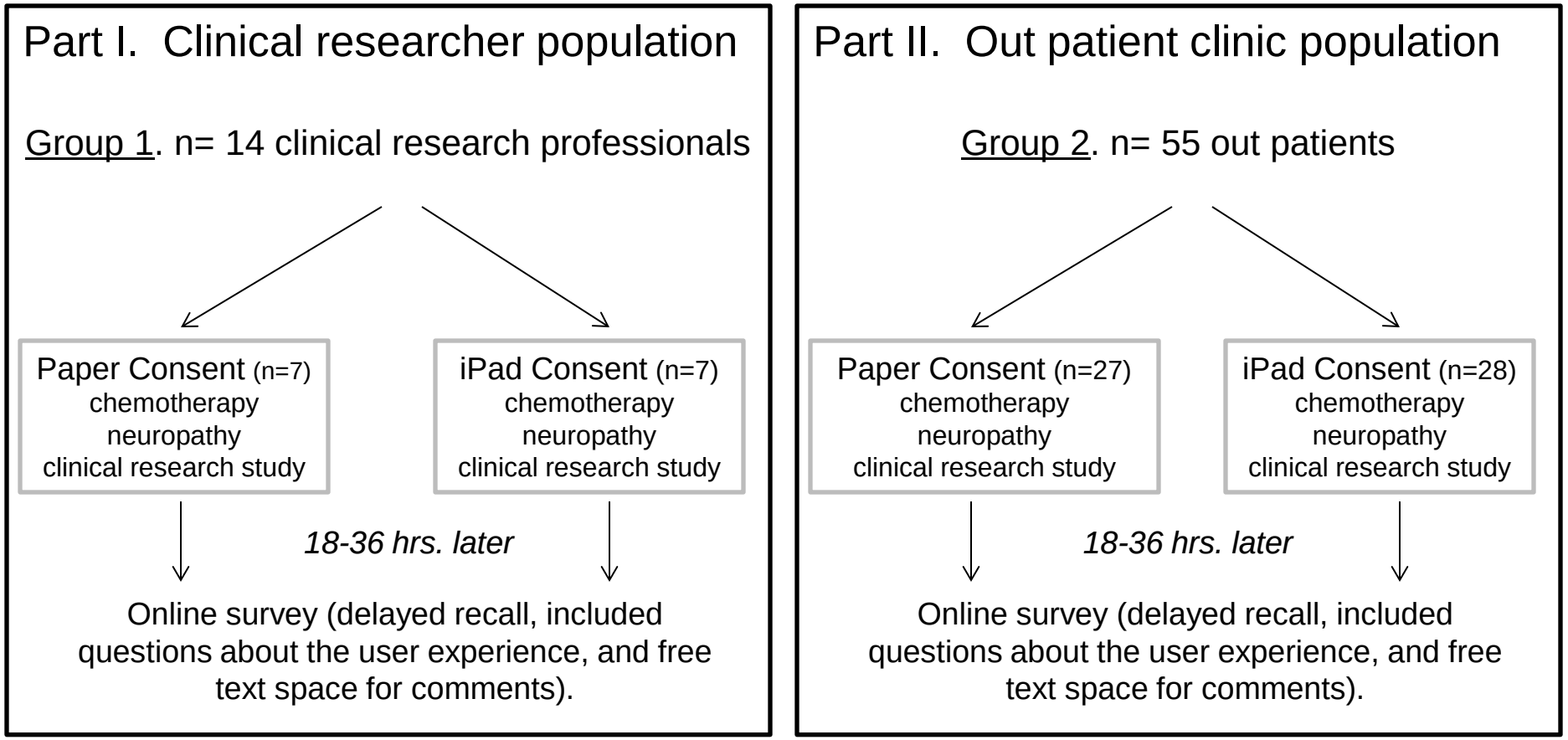
Rowbotham et al. (2013)



Rowbotham et al. (2013)

Table 1. Post-review online survey test question results.

Question	group1 iPad	group 1 Paper	group 2 iPad	group 2 Paper
Q1 (Reason for study) *	88	67	69	72
Q2 (Who to call if injured)	100	83	89	72
Q3 (Who to call if questions)	38	33	15	14
Q4 (Continue with normal treatments) *	75	33	89	62
Q5 (What involved in QST)	50	67	77	55
Q6 (Risks of QST) *	100	50	77	48
Q7 (If you require treatment)	88	67	96	59
Q8 (Amount of compensation) *	100	83	96	76
Q9 (Duration of Study) *	88	33	96	59
Q10 (What involved in study)	75	83	69	72
Q11 (What involved in QST)	38	0	42	21
Q12 (Free to stop participating any time)	88	83	85	86
OVERALL PERCENT CORRECT	77	57	75	58

Rowbotham et al. (2013)

- Among both research professionals and patients, next-day comprehension was better in participants randomized to the interactive iPad consent form.
- The iPad participants spent more time with the device, but the amount of time spent reviewing the actual consent document was actually shorter (13 minutes for paper, 11.4 minutes on the iPad).

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Section 3:

Challenges & Limitations

Considerations for study teams:

Higher up-front cost to develop eConsent;

Time required to develop and test eConsent delivery, storage, and retrieval;

Additional safeguarding may be necessary when using an eConsent with vulnerable populations; and

Training needs of study team members

Regulatory best practices

Regulatory Requirement	Paper-based forms	eConsent forms
Signature validation	Study team member certifies each signature line at the time consent is obtained	Signature line may not be edited; study team member certifies (by signature) content is present and functional
Safe Storage	Forms should be stored under double lock and key; accessible by specially authorized personnel.	AES encryption, using either 128- or 256-bit keys; storage on a secured server; offsite backup for disaster recovery
Participant access to form	Hard copy provided to participant	Hard copy and access to interactive content
Contact information	Instructions enumerated on hard copy provided to participant	Contact information is provided in hard copy and via interactive content
IRB-maintains approved version	IRB maintains record of ICF (e.g. uploaded to database; scanned; etc.)	IRB maintains record of technology used to access form

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Section 4:

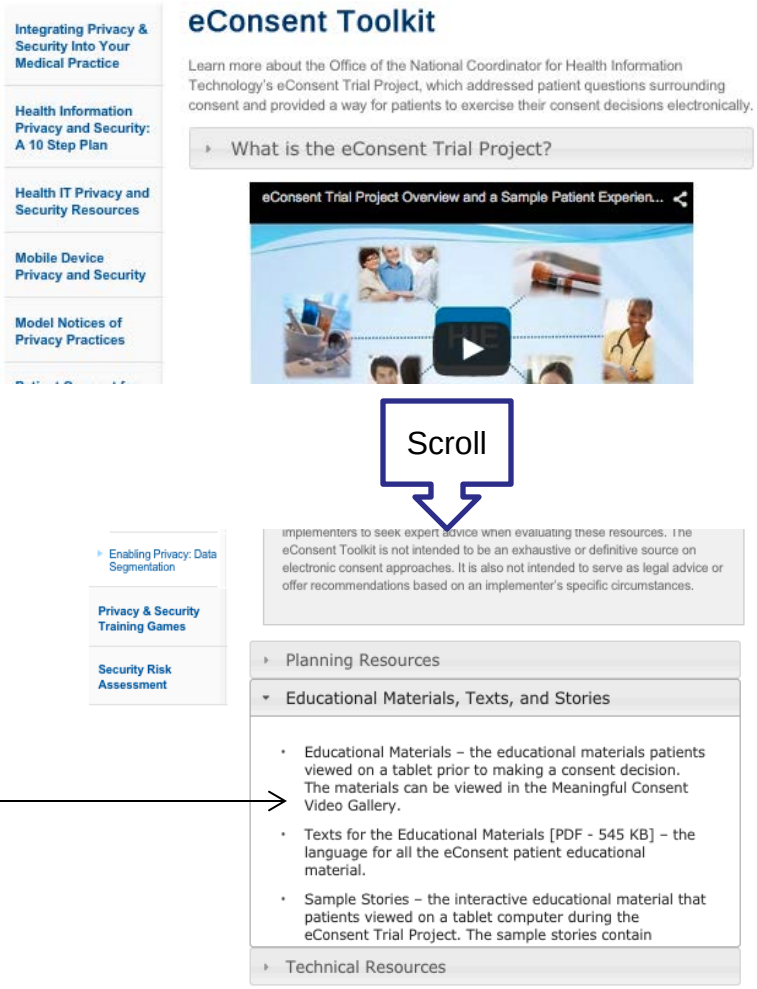
Resources for study teams

Resource	Description
HealthIT.gov	eConsent Toolkit that provides samples of the tools, resources, and educational materials that were used in the Office of the National Coordinator for Health Information Technology's eConsent Trial Project
Survey Gizmo	HIPAA-compliant survey software used to build example
Sample Video Transcript	Fully mapped audio/video transcript for an eConsent used in SBS research - *produced by Duke Clinical Research Institute (DCRI)*
Online Webinar	Addresses electronic technologies for obtaining consent, facilitating consent, storing study data, and monitoring study data – *produced by Quorum*

healthIT.gov eConsent Toolkit

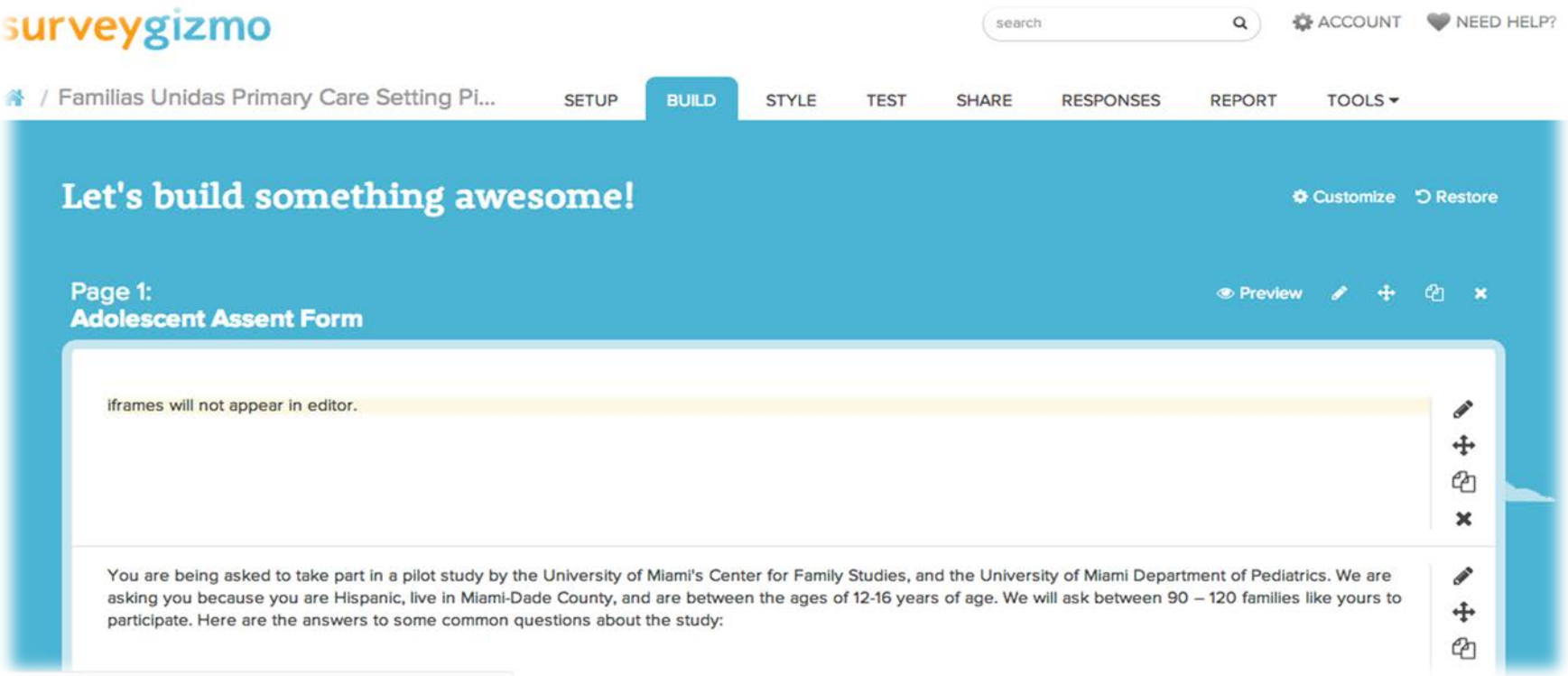
- The eConsent Toolkit provides samples of the tools, resources, and educational materials for national eHIE project.

PDFs are embedded in text



Survey Gizmo

Highly-learnable interface; extensive features; customizable; exports to SPSS



Video Transcript Calerie Study

Multimedia and presenter content is fully scripted

Screen	Audio
Image of a measuring cup with dog food on a kitchen counter The measuring cup pours the dog food into a bowl and a dog eats the food	Dr. William Kraus: The effects of calorie restriction have been studied in animals for years, and this is the only intervention shown to slow the aging process, extend lifespan, and maintain health and vitality.
Text on screen over image of people filling coffee cups at a restaurant: Health Benefits Lower Risk of Diabetes and Cardiovascular Problems	Dr. William Kraus: The specific health benefits have included such things as lower risk of diabetes and cardiovascular problems. It is not known if people will have the same benefits as seen in animals. This is what we want to know.
Images of people walking in a restaurant and a man eating a cookie Images of map with states and cities of centers involved in this study. Text on screen: Pennington Biomedical Research Center Baton Rouge, LA Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University Boston, MA Washington University in St. Louis School of Medicine St. Louis, MO	Dr. William Kraus: Approximately 250 participants will be enrolled in the CALERIE study. Centers involved in this study include Pennington Biomedical Research Center in Baton Rouge, Louisiana; Tufts University in Boston, Massachusetts; and Washington University in St. Louis, Missouri. You must live within a reasonable driving distance to one of the facilities in order to participate.
Dr. William Kraus standing in the produce section of a grocery store	Dr. William Kraus: Choosing to participate in a clinical research study is an important decision. In this video, we hope to answer many of the questions you may have about clinical research and the CALERIE study.

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YouTube link to hour-long webinar provided in table (Slide)

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