

Session I: Presentation of the Literature Review and Expert Interviews

Zachary Hallinan, Center for Information and Study on Clinical Research Participation (CISCRP)

March 10, 2015



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Session I Objectives

- ▀ Present and discuss findings and conclusions from the project
 - literature reviews
 - expert interviews series

Informed Consent Literature Review

Zachary Hallinan, Center for Information and Study on Clinical
Research Participation (CISCRP)

10 March 2015

Washington, D.C.

*Prepared by CISCRP and the CTTI Informed Consent Literature Review
Workgroup*



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Literature Review Work Group

- Annick Anderson (CISCRP)
- Fred Bloom (CDC)
- Annemarie Forrest (CTTI)
- Zach Hallinan (CISCRP)
- Kevin Hudziak (Eli Lilly)
- Hallie Kassan (North Shore – LIJ Health System)
- Ross McKinney (Duke University)
- Linda Morgan (Patient Advocate)
- Jane Perlmutter (Patient Advocate)

Agenda

➤ Introduction

- Summary Findings of Previous Reviews
- Primary Literature Review: Questions, Methods and Limitations

➤ Findings of the Primary Literature Review

- Operational barriers to improving consent
- Patient satisfaction with consent process
- Instruments for measuring aspects of consent
- Impact of consent process on trial enrollment, retention and adherence

➤ *Q&A following Expert Interviews presentation*

Premise of the Literature Review

- Two primary purposes of informed consent in clinical research:

Informed consent honors autonomy by requesting permission to proceed after a balanced discussion

And...

Informed consent meets a variety of legal and regulatory needs

- To improve the consent process, we need to unpack these two purposes and be aware of how they may be contradictory

45 Prior Literature Reviews Tell Us...

- **Informed Consent process needs to be improved**
 - Current length of Informed Consent document burdens patients
 - Complexity of information communicated during the informed consent process raises concerns that participant has made an informed decision
- **Not clear what improvements would be best or even how to measure 'best'**
 - No single intervention has been shown to be most effective in improving understanding
 - 23 of 45 (51%) reviews noted limited ability to draw meaningful conclusions given variability in studies (variation in instruments, methodology, and populations; small sample sizes).
- **Barriers to understanding are wide ranging:** process variability, unrealistic expectations, emotional state, financial state, trust in the relationship between patient/doctor, insurance benefits available, age, education, and physical ability to refuse/agree
- **Literacy and health literacy are both critical in giving consent**

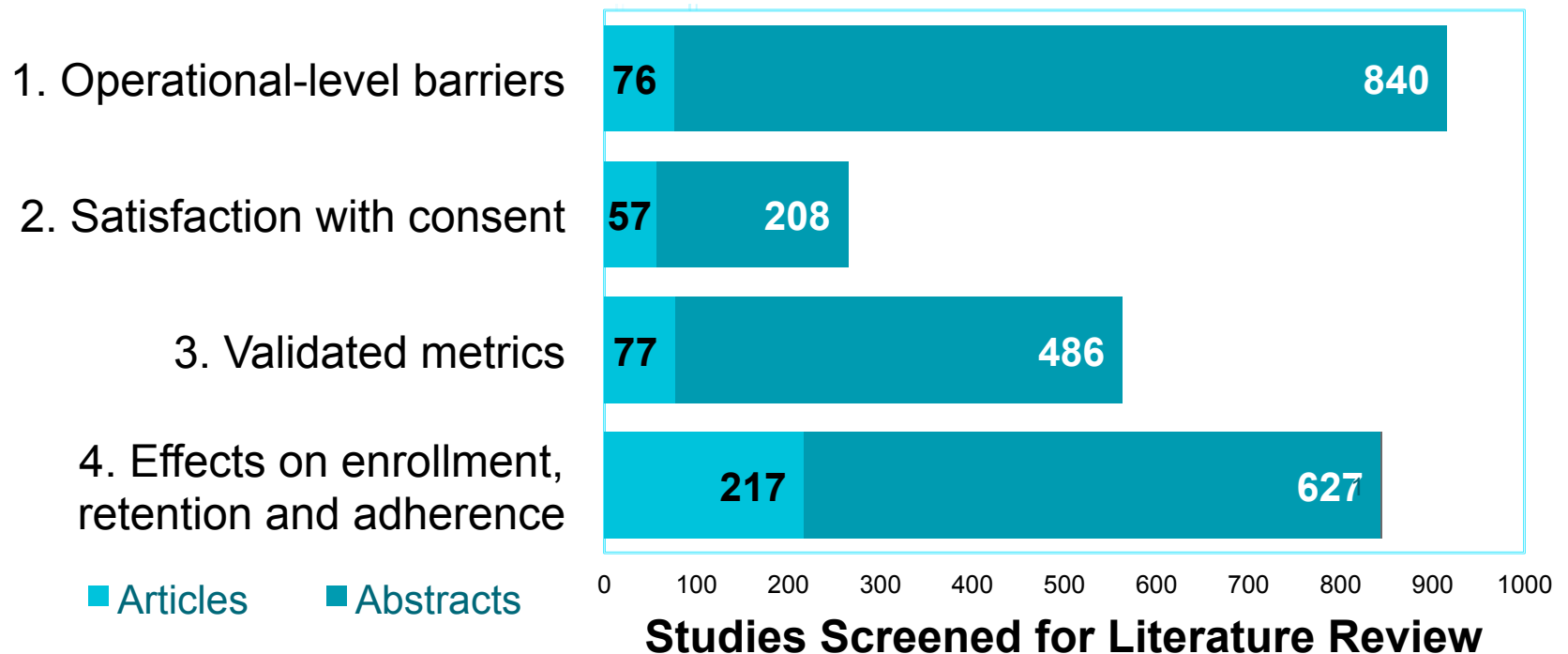
Four Primary Literature Review Questions

- ① How might the operational-level policies and procedures within clinical research sponsors/IRBs/investigative sites pose a barrier to implementing better informed consent processes?
- ② What factors are associated with greater or lower patient satisfaction with the informed consent process?
- ③ What formal assessments have been done of tools and methods for measuring or evaluating informed consent in clinical trials?
- ④ In what ways does informed consent increase or reduce enrollment, retention or protocol adherence of participants or prospective participants in clinical trials?

General Inclusion Criteria:

- Electronically-indexed primary literature
- Published in English between 2000-2014
- Focused on informed consent in drug or device trials with competent adults

Primary Literature Review Methods

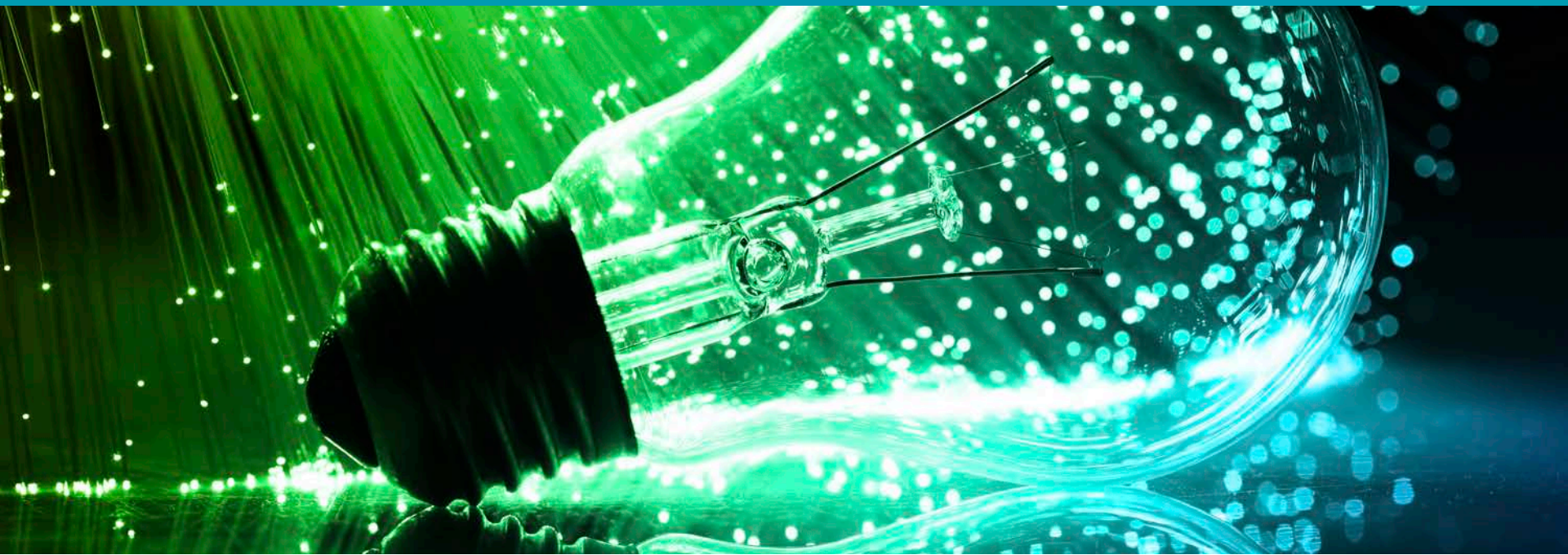


Systematic Review Process

- Searches conducted May – June 2014. Filters for language and publication date.
- Databases: MEDLINE/PubMed, Cochrane Library, CINAHL, ScienceDirect, EMBASE.
- Minimum 2 reviewers assessing each identified article for relevance.
- Data extraction via standardized forms evaluated for >0.80 inter-rater reliability.

Common Limitations

- **Oncology most common therapeutic-area focus (e.g., 76% of reviewed studies for Question 2).**
 - PubMed search suggests ~22% of published studies on informed consent in clinical trials have oncology focus.
- **Respondents to qualitative and quantitative studies typically 80-90% Caucasian.**
 - Apparent bias toward middle-age and middle-class respondents.
 - Limited data on people who chose not to enroll
 - Generally good gender representation.
- **Limited data on informed consent for clinical trials of medical devices.**
- **Literature intentionally included on United States *and other Western/developed nations.***



Q1 Summary Findings

How might the operational-level policies and procedures within clinical research sponsors, IRBs and investigative sites pose a barrier to implementing better informed consent processes?

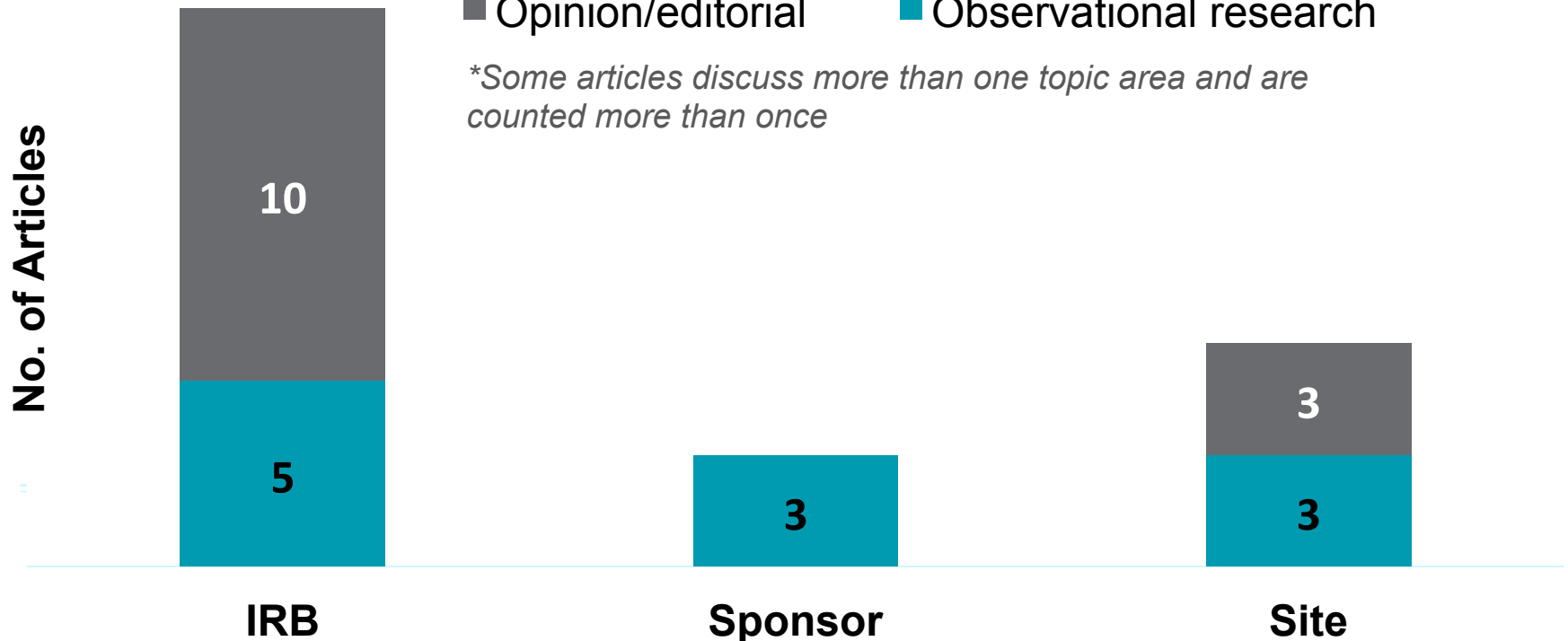
Q1: Operational Barriers

19 Relevant Articles

Identified Articles by Topic Area*

■ Opinion/editorial ■ Observational research

**Some articles discuss more than one topic area and are counted more than once*



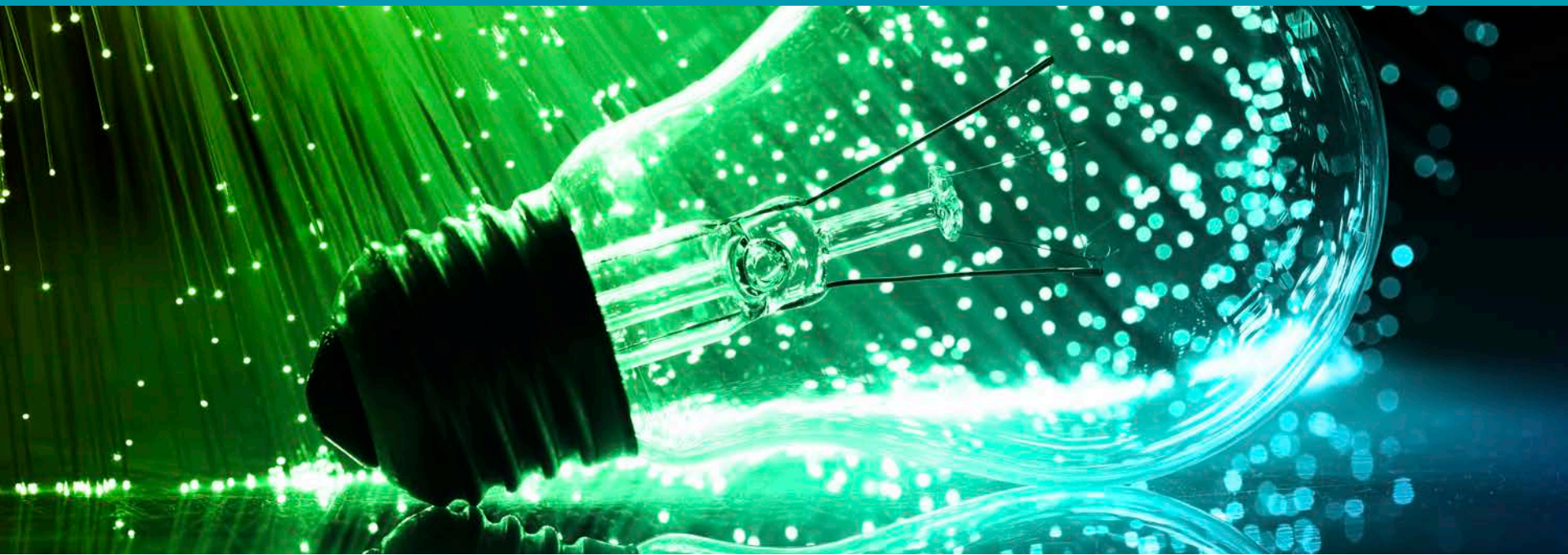
- Primarily opinion/editorial studies (12 of 19 studies)
- Primarily US (14 of 19 studies)
- No strong therapeutic area focus/bias (6 of 19 studies did not focus on any therapeutic area)

Operational-level Barriers Identified

Barrier (sorted by # of articles that mention barrier)	Topic Area	# articles mentioning	% opinion
1. Local IRB reviews for multi-site trials	IRB	8	63%
2. Focus on inclusion of all legal/regulatory requirements	IRB/ SPONSOR	5	60%
3. Local IRB review for multi-national trials	IRB	3	67%
4. Variability in expertise and attendance of IRB members	IRB	2	100%
5. Pressure to meet study enrollment deadlines	SITE	2	0%
6. No staff training on Informed Consent	SITE	1	100%
7. Focus on using appropriate lay language	IRB	1	100%
8. Role conflict as clinician/investigator	SITE	1	100%
9. Creation and approval of consent documents ignores the complexity faced by study nurses in actual practice	SITE	1	0%
10. Required to give too much information about possible side effects	SITE	1	0%
11. Absence of knowledge of consent process realities at site-level	SPONSOR	1	0%

Author Proposals to Address Barriers

- **Refocus Informed Consent process on primary goal of educating and informing research participants** about trial, risks & benefits so they can make an informed decision
- **Revise IRB policies and procedures**
 - Centralized review for multi-site trials structured with options for local review
 - Focus local review on appropriateness of language and other cultural/socio-economic issues.
 - More guidance from OHRP to reduce variability in interpretations of federal regulations.
- **Improve collaboration between IRBs and sites**
 - Have IRBs stress key elements of process to site staff, then follow up with site to ensure implementation
 - Better understand and integrate realities of consent process into prospective review
- **Use plain language**
 - Need for accepted readability standards
 - Train IRB staff on using simplified language and performing readability analysis



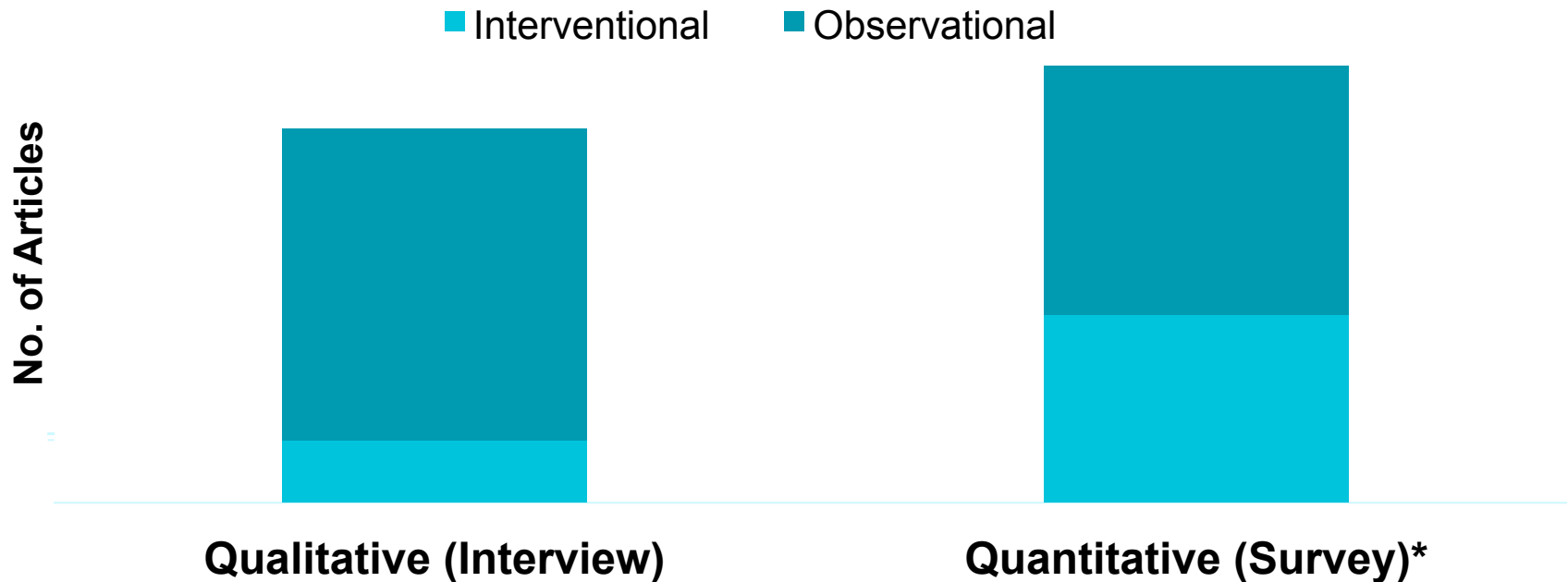
Q2 Summary Findings

What factors are associated with greater or lower patient satisfaction with the informed consent process?

Q2: Patient Satisfaction

13 Relevant Articles

Identified Studies by Research Type



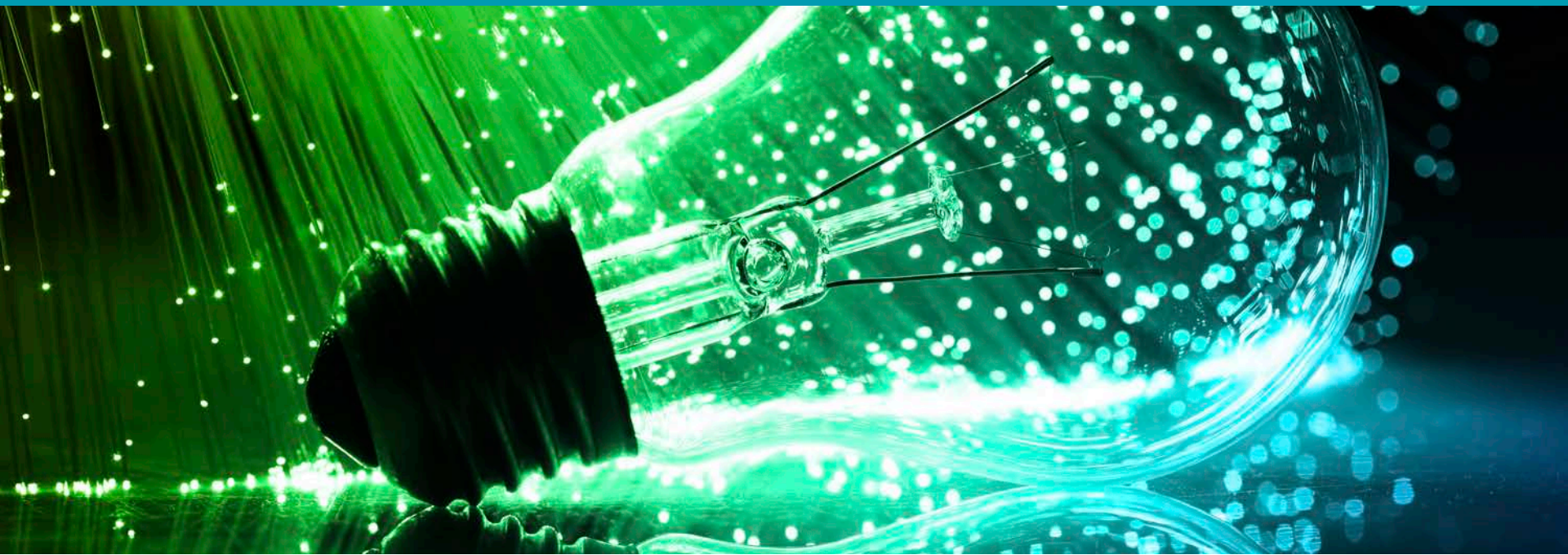
- Primarily oncology trials (10 of 13 studies)
- Primarily drug trials (13 of 13 studies) and 1 study that included device trials
- Primarily OUS (10 of 13 studies) and wealthy/developed nations (13 of 13)
- Over 90% Caucasian patients where specified (5 studies)

Summary Qualitative Study Findings

Factors affecting satisfaction with informed consent vs. # of studies mentioning		Increased Satisfaction	No Effect	Decreased Satisfaction
General Situation / Environment	Limited time to deliberate / feeling rushed			3
	Feeling overwhelmed by diagnosis			1
	Being asked to give written consent			2
	Feeling involuntarily responsible for choice of treatment			2
Informed Consent Discussion	Physician's language and structure of the consultation			1
	Trial information presented in positive language	1		
	Trial physician friendly and dedicated	1		
	Physician encouraged questions	1		
	Significant others, relatives or nurses present	1		
Informed Consent Forms	Reviewing ICF independently			1
	Not enough detail in ICF			2
	Too much detail in ICF			1
	Reduction of non-treatment-related info in ICF		1	

Key Findings: Qualitative and Quantitative

- **No standard metrics** for quantitative evaluation of informed consent/decision-making from the patient perspective
- **Satisfaction seems to derive more from the discussion than the document**
 - Two studies found patients perceiving the ICF as primarily a legal document
 - Some patients find the ICF helpful as a reference, but do not consider it a substitute for verbal interaction
- **Satisfaction can be high even when understanding is low**
- **Information needs vary, and should be catered to in both the ICF and discussion**
 - *"This is not to say that full information should be withheld, but rather that we could offer people a menu of different levels or layers of information and let them choose how deeply they wish to investigate."*
- **Patients do not always want to be responsible for their decision**



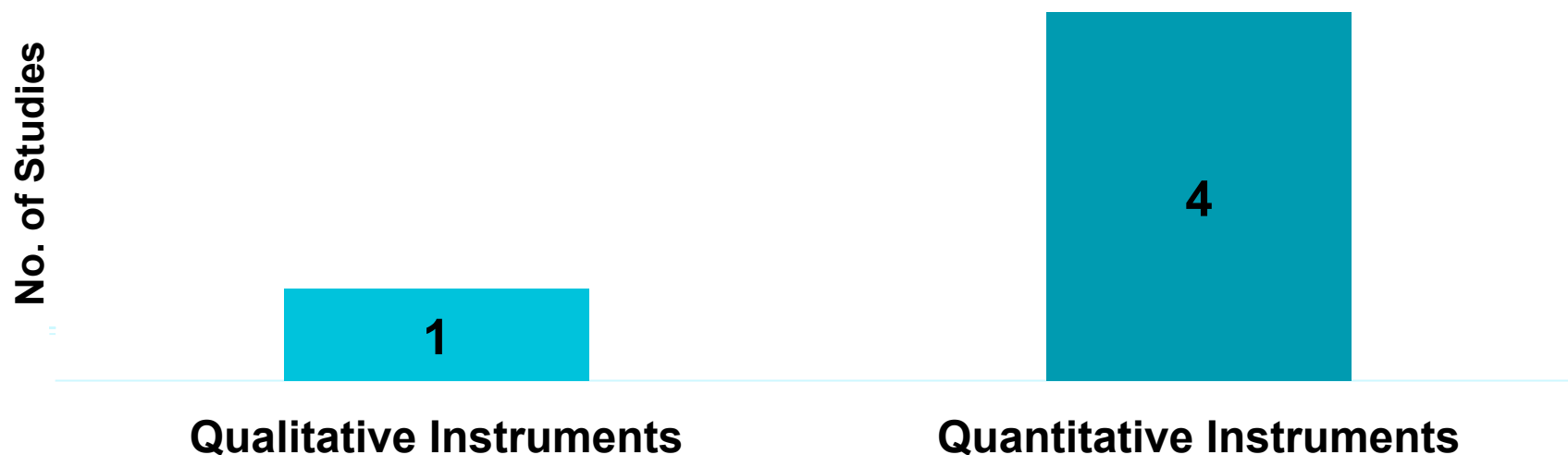
Q3 Summary Findings

What formal assessments have been done of tools and methods for measuring or evaluating informed consent in clinical trials?

Q3: Validated Metrics

Summary of 5 Relevant Articles

Identified Studies by Research Type*



- Primarily among white/Caucasian (3 of 5 studies where ethnicity specified indicate 77%+ white/Caucasian study population)
- No validation among prospective participants who declined enrollment.

** 3 additional studies described instruments validated outside of drug or device trials; identification of such instruments was not the primary goal of this review, and potentially incomplete.*

Psychometric Validation of 5 Instruments

Instrument	TAs	N	Content Validity	Construct Validity	Internal consistency ¹	Test-retest ²	Pub. Date	Later Uses
Therapeutic Misconception questionnaire	Psychiatry oncology neurology	189	Yes	Factor Analysis, Criterion	0.90	-	2012	0
Quality of Informed Consent (QuIC)	Oncology	207	Yes	-	-	0.66 – 0.77	2001	7
BICEP (Brief Informed Consent Evaluation Protocol)	6 TAs, most NOT drug/device	632	Yes	-	-	-	2005	0
Patient Understanding of Research	Oncology	26	Yes	Discriminative	0.77	-	2007	1
Therapeutic Misunderstanding Scale ³	Not specified	37	Yes	Factor Analysis, Criterion	0.92	0.49	2012	0

¹Standard is 0.7 – 0.9

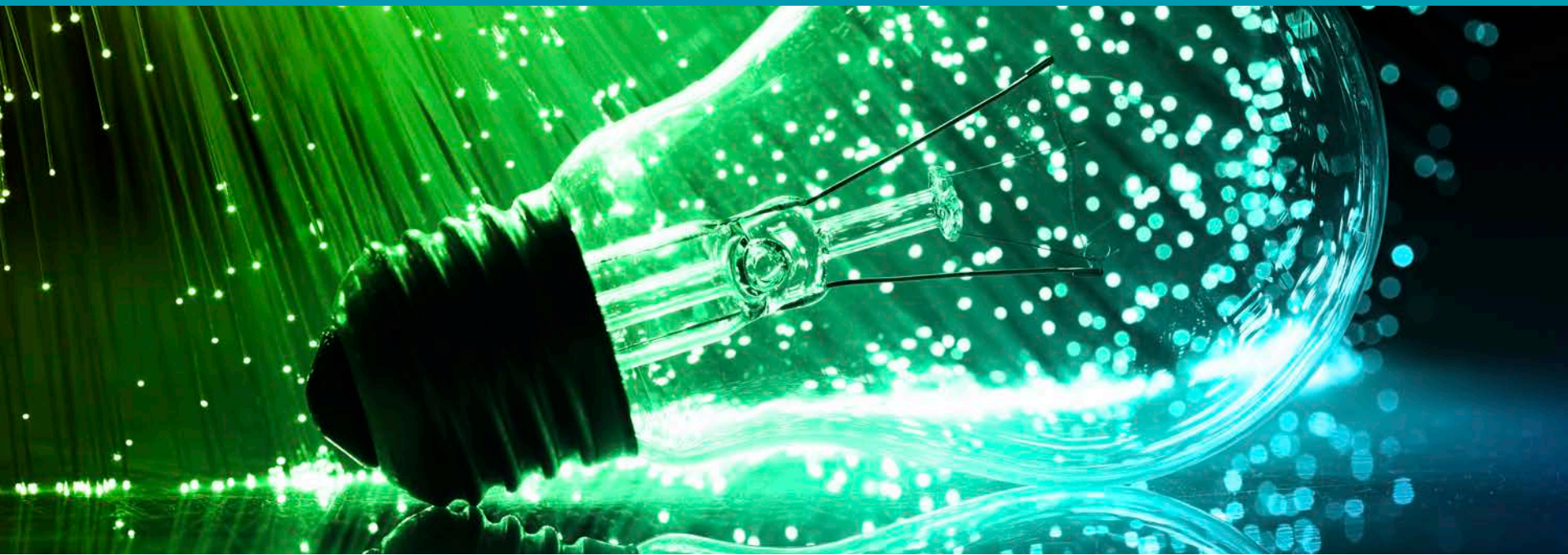
²Standard is 0.7 – 0.8

³Factor analysis presented for study with general population, not patients

Key Findings

- **Focus on objective or subjective understanding** of required and general elements of consent
 - There are also 'satisfaction' instruments with at least minimal validation: Satisfaction With Decision-Making, Decisional Regret, Consent Anxiety.
- **Testing and implementation of instruments both appear feasible**
 - QuIC, BICEP and Patient Understanding of Research reported average questionnaire completion times; in each case, <10 minutes.
- Author recommendations for use:
 - **Screening for participants who need additional support/education**
 - **Ethics committees can monitor informed consent** process and establish eligibility for enrollment or referral to further education
 - **Assessing the effectiveness of interventions** designed to improve the consent process

“As attention is appropriately focused on ensuring that the rights and interests of those enrolled in clinical research are protected, it is essential to inform these conceptual and policy efforts with relevant empirical data.”



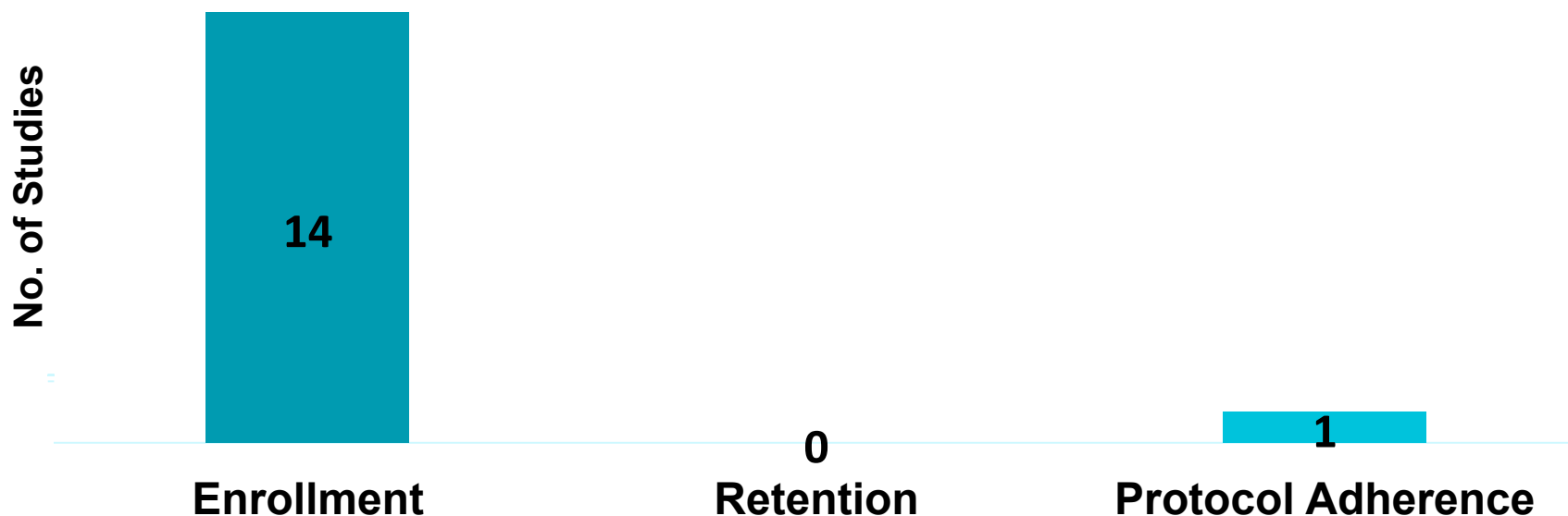
Q4 Summary Findings

In what ways does informed consent increase or reduce enrollment, retention or protocol adherence of participants or prospective participants in clinical trials?

Q4: Enrollment, Retention & Adherence

Summary of 15 Relevant Studies

Identified Studies by Topic



- Primarily oncology trials (10 of 15 studies)
- Primarily drug trials (14 of 15 studies)
- Primarily among white/Caucasian (8 of 10 studies where ethnicity specified indicate 80% + white/Caucasian study population)

Effect of Consent Discussion on Enrollment

Informed consent factors impacting ENROLLMENT vs. # studies measuring*		Increased Enrollment	No Effect	Decreased Enrollment	Metrics
Informed Consent Discussion	Presentation of complex information in limited amount of time			1*	Patient self-report
	Physician poor communicator and less friendly			1	Patient self-report
	Physician friendly and easy to maintain conversation with	1			Patient self-report
	Perception that clinical research personnel trustworthy	2*			Patient self-report
	Use of positive language/framing of information (ethical issue)	1			Patient self-report
	In-home consent visit by nurse (as part of comprehensive recruitment approach)	1			Trial enrollment data
	Decision to enroll already made in advance of Informed Consent discussion		3*		Patient self-report

*All studies quantitative, unless otherwise designated with asterisk to indicate inclusion of qualitative studies

Summary Findings

➤ Enrollment

- Positive interactions with clinical research staff may increase enrollment (though not always appropriately)
- Informed Consent Document generally has no effect (even if 'improved')
- Some patients making decision without reference to informed consent process

➤ **Adherence:** Just 1 study, no evidence of effect

➤ **Retention:** No published literature at time of review, but...

Retention Findings from Recent CISC RP Survey

Survey respondents who have participated in a clinical trial reported...	Overall	Dropped Out (n=260)	Completed (n=1326)
It was 'Somewhat/Very Difficult' to understand the ICF*	19%	35%	16%
After reading ICF, the purpose of the study was 'Not Very/Not At All Clear'*	5%	14%	2%
'Not Very/Not At All Satisfied' questions were answered during IC review*	4%	12%	1%
I still did not understand parts of the study after IC review*	12%	22%	11%

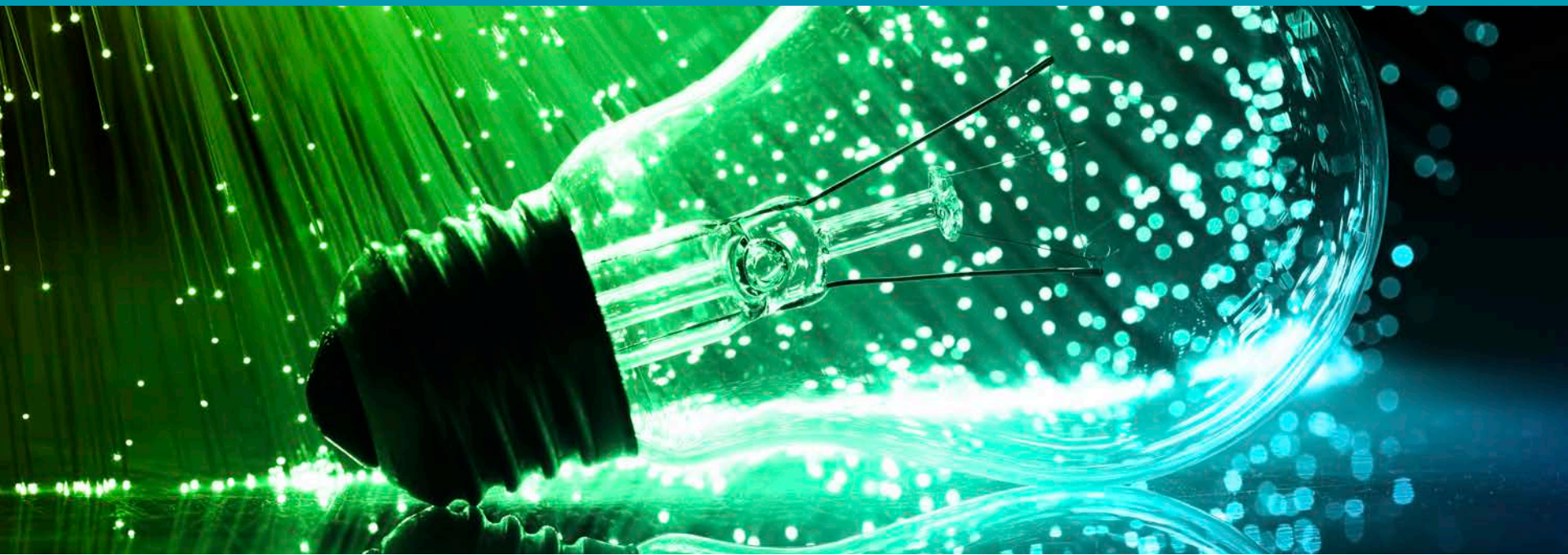
**Dropped Out vs. Completed significantly different at $P < 0.05$*

Overall Sample: n=5,701

58% Female / 42% Male

75% North America / 5% South America / 15% Europe / 5% Asia Pacific

39% have participated in a trial at any time in the past



Summary Findings Across the Literature Review

Summary Knowledge Gaps and Findings

Lit. Review Topic	Critical Findings	Critical Gaps
1. Operational barriers (sponsor, site, IRB)	Greater use of Central IRBs may resolve several important barriers to improving informed consent	Limited study of how Sponsor and Site policies / procedures affect informed consent
2. Patient satisfaction with consent	Patients have widely varying information needs – there is no apparent ‘one size fits all’ approach	No ‘gold standard’ metrics for evaluating adequacy of informed consent from patient perspective
3. Validated metrics	Testing and implementation appears feasible; need consensus on what to measure.	No ‘gold standard’ metrics for evaluating understanding prior to enrollment
4. Enrollment, retention, adherence	Informed consent may be a driver of trial feasibility and success	Limited study of informed consent as driver of patient behaviors during the trial

Recurring Observations Across the Literature

- ① We have lost sight of the primary goal of informed consent:
To help research participants make an informed choice
- ② The informed consent discussion is more important than the informed consent document (but both matter)
- ③ Improving informed consent requires agreement on standards and how to measure 'success', potentially including:
 - Objective understanding, satisfaction with understanding, and satisfaction with decision-making
 - Accrual, retention, and/or adherence

Expert Interview Findings

Beverly Lorell, King & Spalding

Steve Mikita, Patient Advocate

March 10, 2015



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Work Group Members

- ▶ Beverly Lorell (King & Spalding) (co-chair)
- ▶ Steve Mikita (Patient Advocate) (co-chair)
- ▶ Annick Anderson (CISCRP)
- ▶ Zach Hallinan (CISCRP)
- ▶ Kathy Kopnisky (NIH)
- ▶ Jennifer Lentz (Eli Lilly)
- ▶ Seth Schulman (Pfizer)
- ▶ Mary Smolskis (NIH/NIAID)

Presentation Overview

Project Objectives & Methodology

Key Findings:

- State of the current Informed Consent process
- Barriers to improving Informed Consent
- Transforming the research participant's understanding of Informed Consent:
 - Transforming the Informed Consent process
 - Transforming the Informed Consent document
 - Actionable changes to Informed Consent

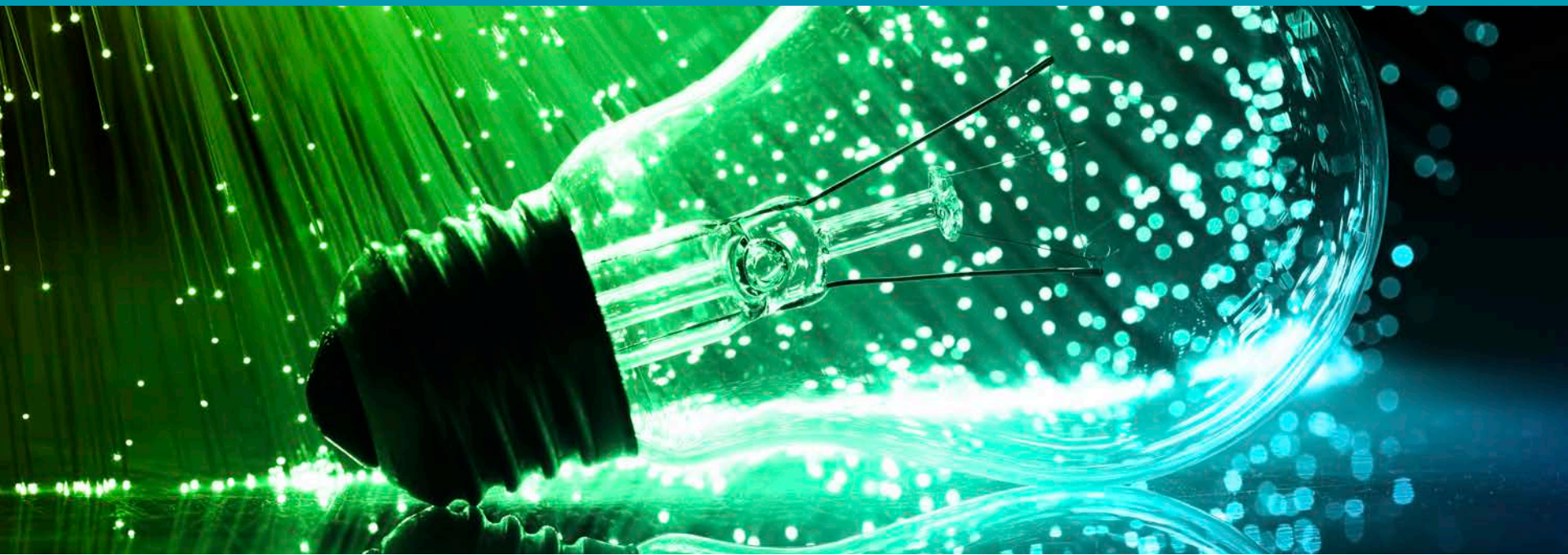
Q&A / Discussion

Project Objectives

- Gather opinions and perspectives on the state of the current Informed Consent process
- Capture recommendations on how to transform the existing process into one that enhances research participant understanding of a clinical trial
- Link learning from expert interviews to primary literature review to create comprehensive picture of the Informed Consent process in key topic areas

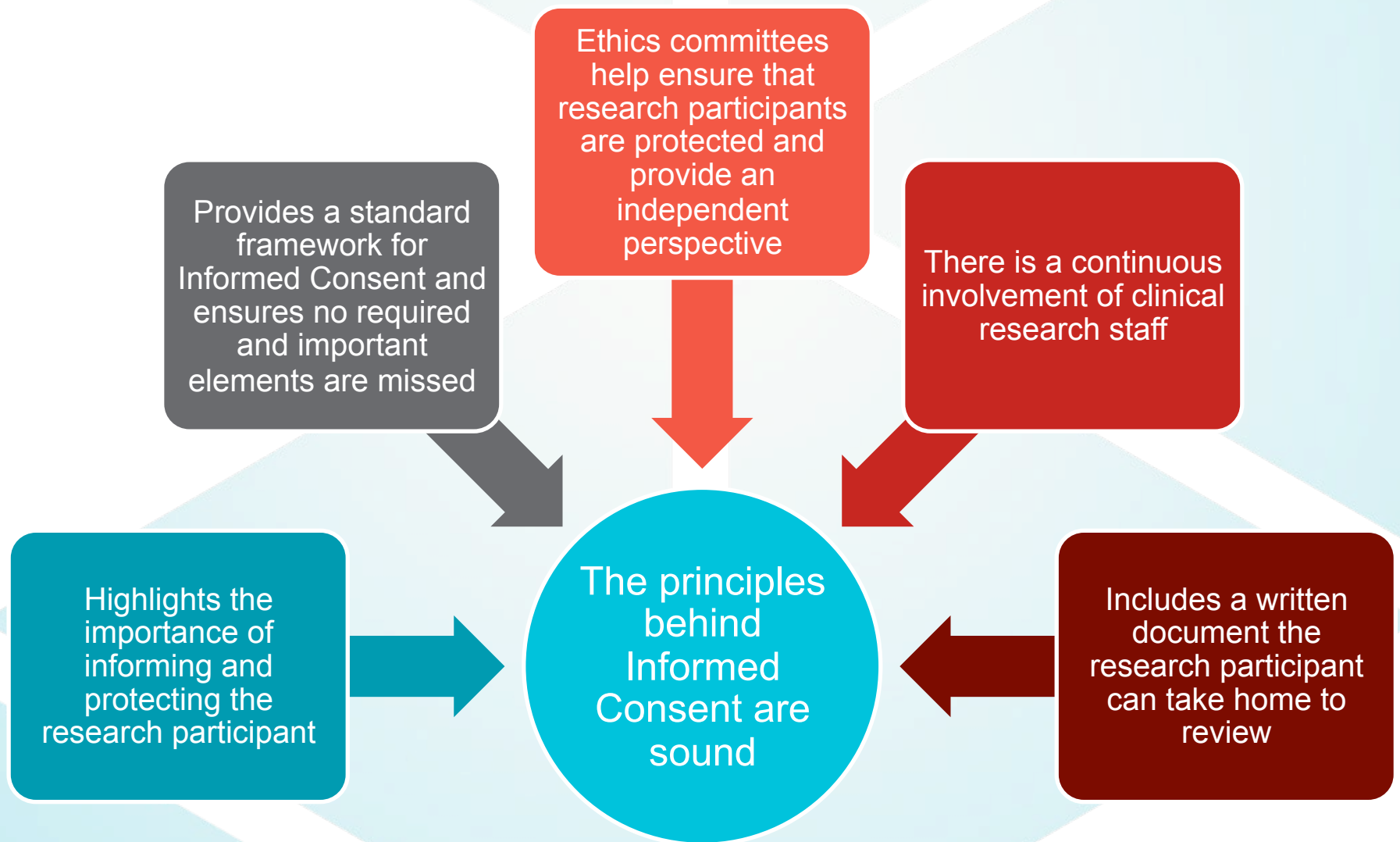
Methodology

Interview Guide Design:	The CTTI Informed Consent Expert Interview Workgroup drafted the initial set of interview questions. The interview guide was subsequently finalized through a collaborative effort between the CTTI Informed Consent Expert Interview Workgroup and CISCRP. The final guide was reviewed by an IRB.
Sample Selection:	Experts interviewed from a variety of sectors (FDA/NIH/IRB/ pharma/academic/patient advocates/etc.). Interviews were subsequently scheduled among interested participants. Participants did not receive any compensation or other incentive for their participation.
Interview Method:	In-Depth Interview (IDI). One hour telephone interview.
Interview Timeframe:	Interviews were conducted April through June 2014.
Total Number of Interviews Conducted:	25
Data Analysis Methodology	Thematic analysis approach.



State of the Current Informed Consent Process

Expert Interviews



Implementation of Informed Consent in Practice is Problematic

- Providing prospective participants with information they require to make an informed decision has evolved into a “rigid” and cumbersome process
- Lack of formal training for clinical research staff contributes to an ineffective process

“Too often, the process,...has...sort of gone completely out of control in some respects, is again driven more by concerns around meeting the regulatory requirements and protecting institutions and others from liability than it is toward achieving the real goal of... participation in research.”

“There’s really no training and there’s really no accountability around the informed consent process. It’s no surprise that both the process of a conversation and the consent forms are really pretty poor.”

Primary Concerns with the Process

- Single, standard approach to Informed Consent
- Variability in Informed Consent procedures across institutions
- Clinical research staff time constraints
- No evidence or tool to demonstrate that a research participant truly understands trial
- Not constructed around the research participant decision-making process
- **Lack of general public knowledge on clinical research**

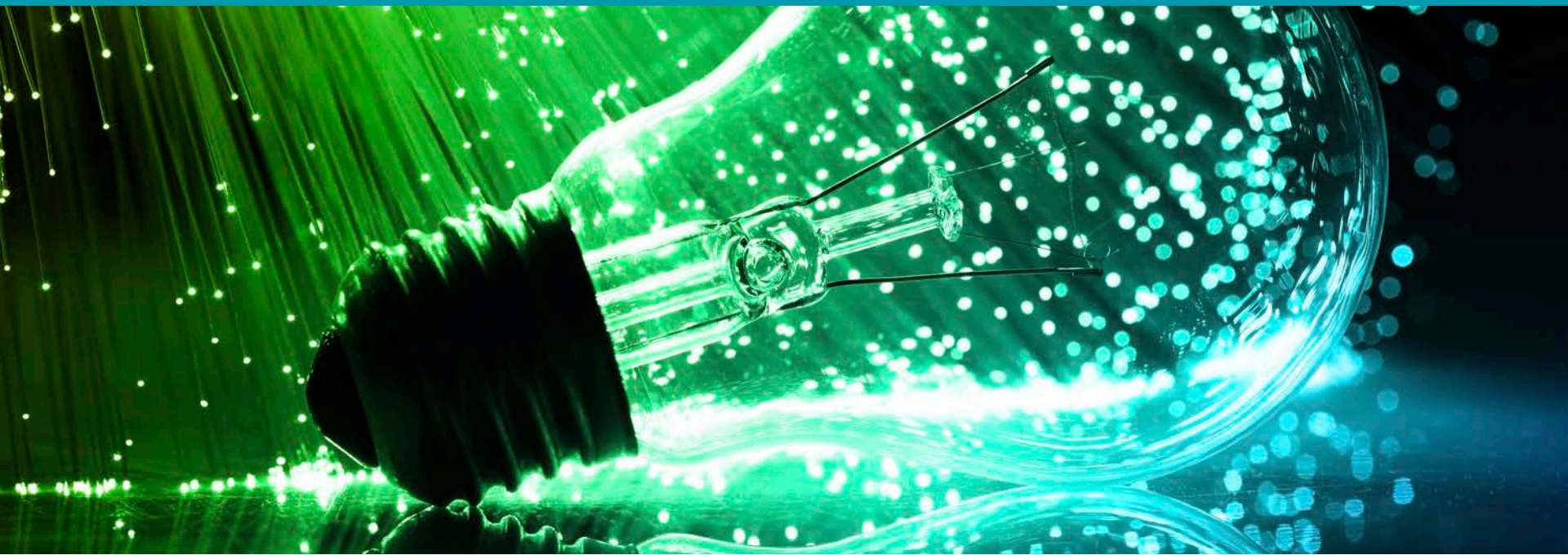
Primary Concerns with the Document

- Too lengthy and overly detailed
- Not written at the appropriate reading level
- Too much legalese
- Laundry list of risks frightens research participants

Conversation with research staff during the Informed Consent process influences participation

- Mixed opinions on the impact of the Informed Consent Document on participation:
 - ½ mentioned that ICD neither encourages nor discourages participation.
 - ½ perceive ICD tends to be a deterrent to participation.
- However, conversation with clinical research staff is more likely to influence decisions to participate.

I think the informed consent as a document would neither persuade nor deter a person, necessarily, from participating. I think it's written in a way – or at least it's supposed to be written in a way that's pretty neutral. It's not supposed to bias a patient one way or another. I think the determinant or persuasion really comes in from someone that's talking to them and how they're able to explain to that patient what it really means for them.”



Barriers to Improving Informed Consent

RESULTS OF Expert Interviews

The impetus for change is lacking

- There is a general lack of will to make a change. Research stakeholders are accustomed to working within the guidelines and are focused on going through the routine development process.

“It's trying to achieve a passing score, and no one has said, 'Actually we want you to do better than a passing score'.”

- Combined with a lack of a regulatory, national push for change. There is a belief among some experts that change needs to be initiated at a higher level (OHRP/FDA), however, change has not occurred due to a perceived lack of strong leadership at OHRP/FDA and the fear of potential repercussions associated with relaxing the standards.

Lack of understanding around the research participant decision-making process

Clinical research staff are inadequately trained on how to properly perform the Informed Consent discussion.

Too many parties are involved in the development and review of the Informed Consent document.

Current Infrastructure does not support an Informed Consent Process that is conducive to promoting participant understanding

IRBs may pose a barrier to improving Informed Consent

- ▶ IRBs are valued for providing independent perspective and helping researchers adopt lay language in their documents – particularly where the researcher is inexperienced.
- ▶ Including all required legal/regulatory elements may preclude IRBs from allowing Informed Consent documents to be more understandable for research participants. Result: Add unnecessary complexity and length to Informed Consent documents.
- ▶ IRBs allocate too much time to “wordsmithing” documents.

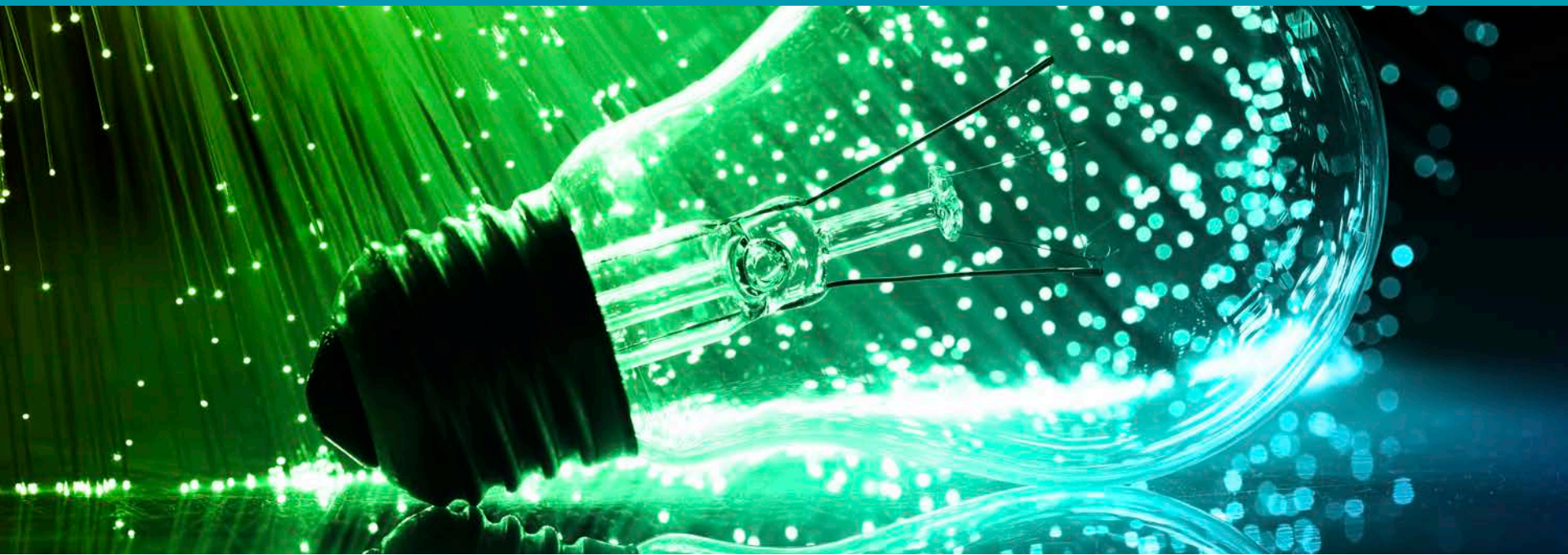
“IRBs are actually resistant to making consent forms more readable. And some of that is, they're worried about not including everything that needs to be included, from a regulatory slash legal framework, risk management, whatever. All of the details. And so, sometimes the IRBs themselves will take a consent form that might be otherwise adequate, and make it longer. Or more complicated.”

Local IRB reviews for multi-site trials are also perceived as inefficient

- ▶ Local IRB reviews for multi-site trials may contribute to an inefficient process, as the feedback of multiple IRBs results in too many variations of the same document across sites.

“If you have 50 centers in your clinical trial, 50 different IRBs making 50 different changes, each of their own customized change in a consent form, and the contracting process, which is not part of our discussion, it’s a – unfortunately it adds to a lot of delay in getting trials started, getting sites up and going.”

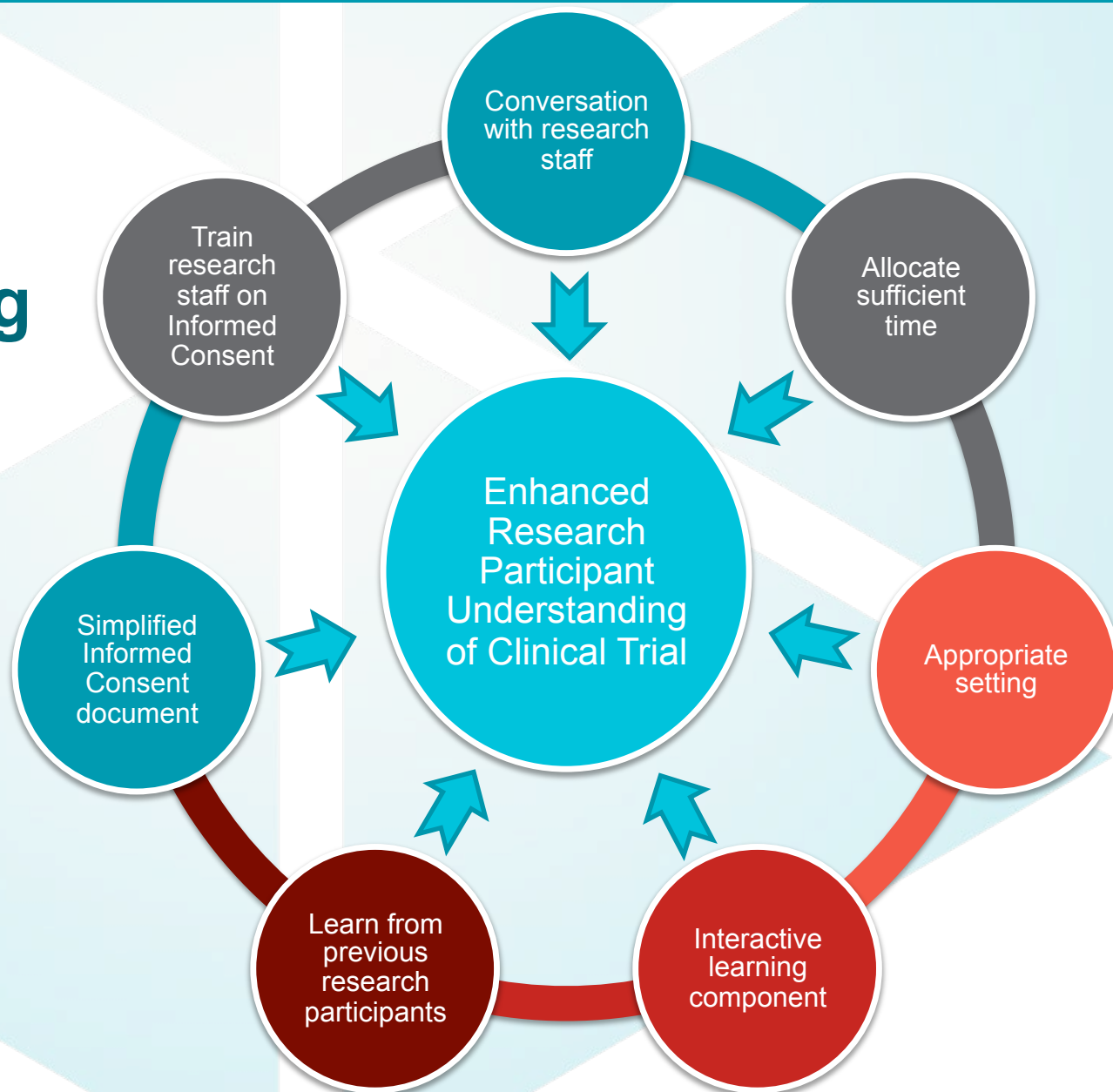
“We don’t need to have every institution writing their own version of the same informed consent document.”



Transforming the Research Participant's Understanding of Informed Consent

Expert Interviews

Transforming the Research Participant's Understanding



Conversation with research staff

Ensure the Informed Consent process is a discussion

- Ensure the Informed Consent discussion is a conversation between the research participant and the clinical research staff, as opposed to a process where loads of detailed information are “dumped” on the research participant.

“Spending more direct time talking to the person who's making a decision. And not as much as possible. That's not realistic. But more direct one on one attention, with somebody who knows something about the study. With a knowledgeable person.”

“Make it a conversation like doctors do with any new information they are giving the patient. Don't move from that format that they use on the clinical side. When you have surgery, the guy doesn't bring out the Consent form for surgery and read it to you.”

Allocate
sufficient
time

Allocate sufficient time to the Informed Consent process

- ▶ Sufficient time should also be allocated to the process to ensure that the research participant has an opportunity to ask questions and has time to carefully consider his/her decision to participate.

“Make it clear that we’re not rushed about doing this, though sometimes we are rushed, but as much as we can, make it clear that we want them to make a good decision and if they need to take time and ask questions, they should feel free. If they go home and have questions, have ways to contact the team to ask those questions so they can be addressed.”

Appropriate setting

Create the appropriate environment for the Informed Consent discussion

- ▶ Ensure the setting for the Informed Consent discussion is comfortable for the research participant and is conducive to holding confidential conversations.
 - The Informed Consent discussion should not be held while the research participant is in his/her hospital gown in the exam room or immediately before a procedure when a research participant may be nervous or may not have eaten.
 - A private setting is also important.

“People feel a lot more comfortable if they don't have their clothes off and have IVs in, and feel vulnerable and [think] ‘I just have to sign this and get it out of the way.’ They're not going to pay any attention to it.”

Interactive
learning
component

Transform the discussion into a more engaging process for the research participant

- ▶ Including an interactive learning component during the Informed Consent discussion enables the process to be more engaging, therefore potentially increasing research participant understanding of the clinical trial.

“Also add other procedures to reinforce and to help understanding, like verbal feedback groups where we ask people at important points in understanding a consent form. We ask them to tell us what they thought it said. And if they can't do that, then we do what's called a teach back...until they understand it.”

Learn from
previous
research
participants

Learning from previous trial participants

- Offering prospective research participants the opportunity to speak with previous clinical trial participants was frequently mentioned as a way to help someone gain a better understanding of what participating in a clinical trial would be like.

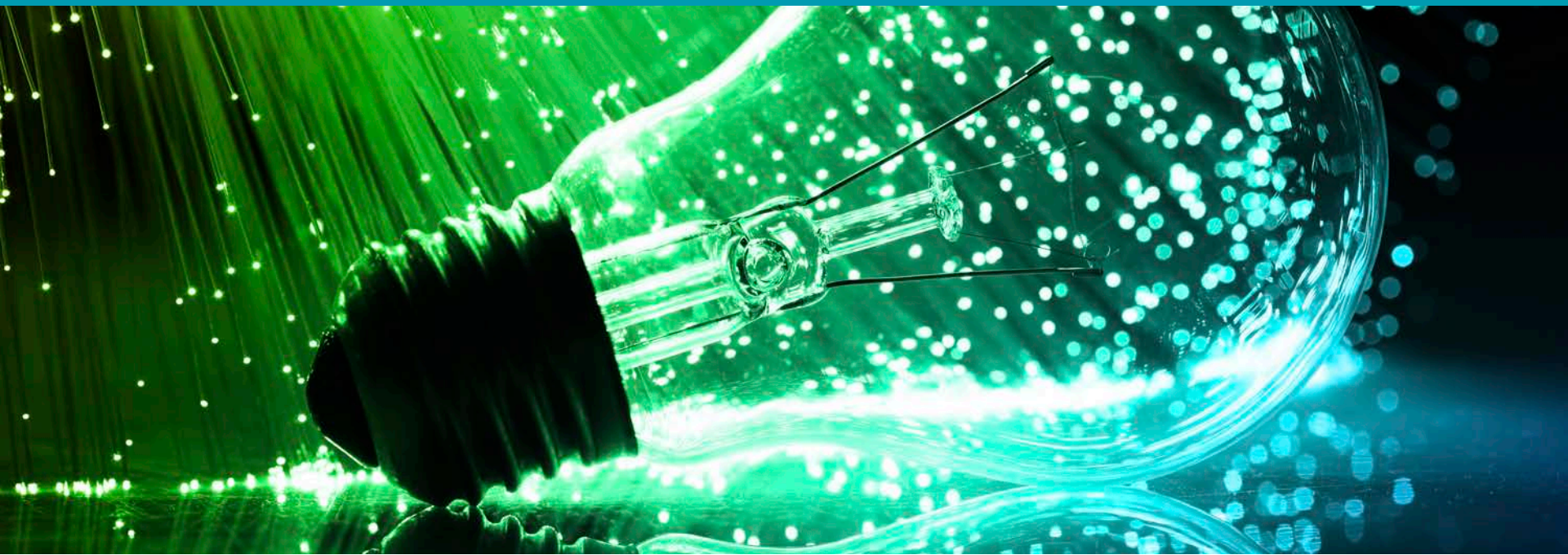
“...coming from another patient who's done the process, who's gone in and said, “It was a good experience. This is what happened.” Even those that have a bad experience, why was it a bad experience, and talk about some of the experiences, and what it's like to do different kinds of clinical trials, because no two clinical trials, typically, are the same.”

Train clinical research staff on how to conduct an effective Informed Consent discussion

➤ Train clinical research staff on how to properly and thoroughly conduct an informed consent discussion with a prospective research participant.

- Use appropriate communication methods
- Allocate sufficient staff time with the research participant to answer questions
- Being aware of special circumstances

“The biggest impact that we can have is really making sure that the people that are talking to our patients are truly knowledgeable not just about that particular clinical trial and the procedures, but what it means for them [research participants]. How long do procedures take? Who’s going to help them get in there or not help them? Who they’re going to talk to, where are they going to go, how many times are they really going to come, how long are they going to wait?”



Transforming the Informed Consent *Document*

Expert Interviews

Expert POV: Research Participant Perceptions of the Informed Consent Document



“I think they think of it as a contract. We’re all given these forms and contracts and people don’t really read them.”

“I can’t read this, it’s too long and it’s too complicated. Just tell me where to sign it.... If we believe in informed consent as a way for people to make decisions, we don’t want that to be the norm for research decisions.”

“You present a patient with a 30-page document that they’re then supposed to review and digest and go through, it’s overwhelming.”

The risks section is too lengthy

► The risks section is perceived as too lengthy; and frequently presented in formats that are difficult for a research participant to comprehend.

- *“And I think long lists – endless lists of risks without any context, probably don't give people much information at all. So, thoughtful presentations about the kinds of things that they might expect, how often they might expect – the frequency, severity, reversibility, what gets done with certain things, and not a laundry list, I think would help.”*

SUGGESTED IMPROVEMENTS

- Provide context around numbers/percentages
- Incorporate graphics
- Provide comparison to standard of care
- Shorten the list of risks (serious/common)
- Physician/CRC assists research participant in interpreting risks

The procedures section is too detailed and long

➤ The procedures section was also frequently mentioned as too detailed and not presented in a format that allows the research participant to fully understand the commitment that is required or the impact on his/her life.

- *“Having 6 pages of: Day One this will happen - Day Two this will happen - Day Seven this will happen. Page after page of that, depending on the protocol. I don't think is very useful.”*

SUGGESTED IMPROVEMENTS

- Presenting the information in a visual manner – such as a calendar
- Highlight information that is most relevant to research participant

“It might be nice for them to see kind of the schedule. ‘In the first three visits, these are the things that’ll be done. In the last three visits, these are the things that’ll be done. And in between, we’ll just call you on the phone.’ That way they get a bigger picture. That’s how people usually think. They don’t kind of think at the micro level.”

The benefits section needs to be simple and straightforward

- ▶ The benefits section needs to be a short and simple communication that clearly explains that the intervention may or may not work.

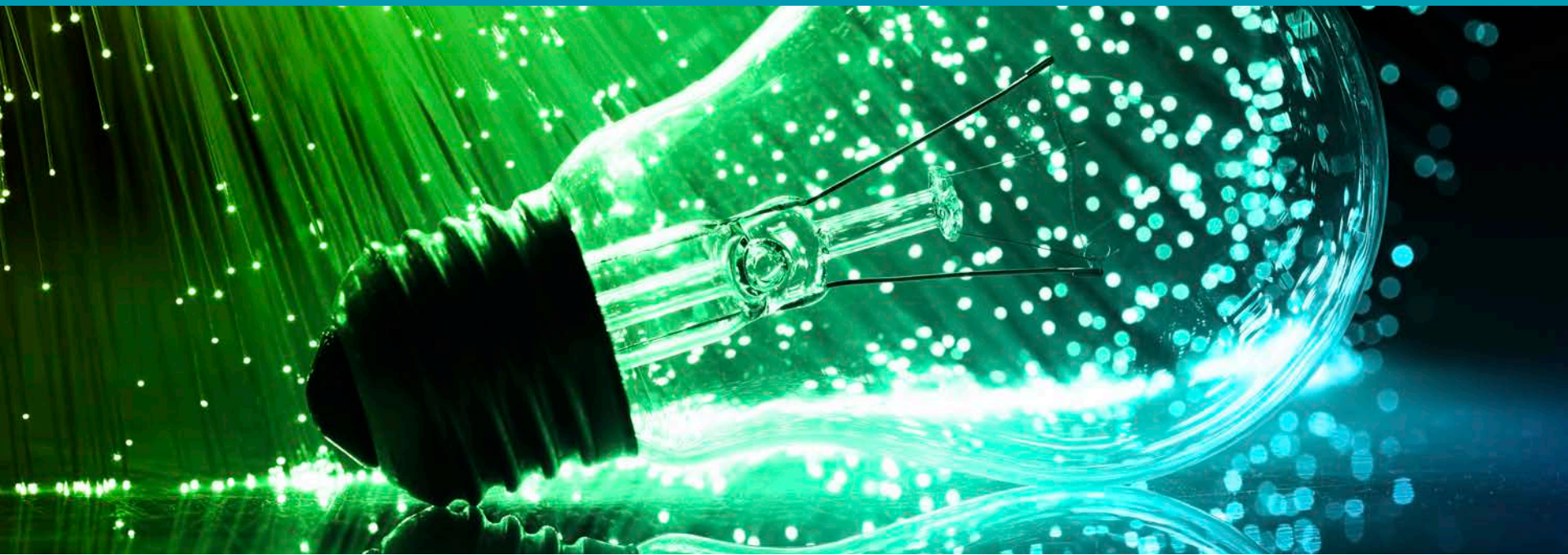
“I think we could be much clearer about benefits, in most cases. And so, what I would hope that we do is not try to hedge on benefits, but say, we don't expect any benefit. Or, there is no benefit to you. But it may be benefit to other people, or something very direct and clear about the benefit language. I also think that's an area where we could do a lot more research to try to understand what people care about – what the people who are volunteering care about.”

Summary: Sections in Need of Improvement

	# of Mentions
Risks section too long/complex/overall document too long	11/25
Procedures section too detailed/too much information on visits	10/25
Compensation from injury/reimbursement language too legalistic/ too much emphasis on legal rights or protecting institution	5/25
Language too high level overall	5/25
HIPAA section too long/no one reads	4/25
All sections need improvement	4/25
Introduction too general	3/25
Benefits oversold/"may or not benefit" says nothing	2/25
Additional studies/future research not explained well as separate study from main protocol	1/25
Too much variability in privacy section from one institution to another	1/25

Summary: Recommendations

	# of Mentions
Comparison to standard of care risks/put risks in context/shorten to most frequent and most serious/less serious-common in addendum	12/25
Include visual calendar/diagrams/charts/visuals/bullets	10/25
Use simpler language/terms patients would use	9/25
Simpler procedures section (general terms/group together)	5/25
Explain how benefit future patients more/explain clinical research more/explain more what development phase intervention is at and what learned to date	4/25
Present only what is relevant to participation decision	3/25
Take out HIPAA/place in addendum	2/25
Have patient test out/read ICD to see if they can understand	2/25
Structure document so most important material in front	2/25
Public education on clinical research	2/25



***Actionable* Changes to Informed Consent**

Expert Interviews

Actionable Changes

➤ Shorter, simpler Informed Consent document.

- Implement training programs so research teams can learn how to write the document in simpler terms.
- Have IRBs develop rules and guidelines to follow.
- Or use professional consent writers required to meet certain standards, with OHRP/FDA oversight to ensure standards are followed.

“Take the consent form itself and let it be, you know, certainly no longer than two pages, incorporate much of the information that will be covered in the consent process, not into the form, but rather into, you know, an informative appendix that people can in fact read, where you could go through it with people if they needed to, but to dissociate, or separate those two in some way so that again, there’s less focus on the form and more focus on the content of the discussion and the interaction that goes on.”

Actionable Changes

➤ Transform Informed Consent into a more dynamic, interactive, and understandable process to help research participants comprehend what they are signing up for.

- Replace or supplement the written document with a video/animation or other multi-media approach that engages the prospective participant and allows him/her to select and review the sections that are personally relevant and discuss those with the research staff.

“Imagine how simple this would be if you had this thing on a computer or app where you would layer the information. Here are the three most important bullets about the risks you might have in this trial and you can expand all of these to learn more detail. And you can track how people go through those. You can track that they have actually spend at least 30 seconds on each page, whatever. You can set certain matrices by which people must read and evaluate. There are a lot of decision making tools that help people weigh their preferences against each other. Technology is here and it does require a culture shift for a move in that direction.”

Actionable Changes

- Train research staff thoroughly and uniformly on how to conduct an effective Informed Consent process through the implementation of training programs and a demonstration of competency in this area.
- Continue to educate the public about the basic elements of clinical research, and make this information readily available (i.e. pamphlets in doctors' offices).
- Continue to seek feedback from the research participant – the voice of the research participant should continue to be incorporated in any transformational efforts of Informed Consent.

“We have to listen to the participants. Listen to them in terms of what they want to know, what's useful for their decision making, and how can we make them more comfortable in terms of asking questions and making choices.”

Summary: Single Actionable Change to Informed Consent

	# of Mentions
Make the content of the document more effective for research participants (shorter/simpler)	9/25
Change Informed Consent to a more engaging/interactive/multi-media process/ include teach-back	5/25
Educate public about clinical research	3/25
Train research staff on Informed Consent	3/25
Focus on the process more, not the form	3/25
Professional consent form writers/establish standards/have health literacy expert sign off on ICD	2/25
Push for change at the regulatory level (get everyone together for change)	2/25
Monitor Informed Consent discussion/accountability/formal check of research participant understanding	2/25
Seek research participant feedback to test out new ICDs	2/25
Determine what information is most relevant to patients and incorporate in process to facilitate their decision	1/25
Create a single "group" charged solely with reviewing consent forms	1/25
Mandate use of central IRBs for multisite trials	1/25

THANK YOU

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Discussion

Break 11:00 – 11:15am