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INSTITUTE *for* CLINICAL & TRANSLATIONAL RESEARCH

ICTR Clinical Research Professionals Lecture Series

Monday August 29th 2022

WELCOME

Clinical Research Professionals Lecture Series

- New Lecture Series geared to bring innovative and new topics to Clinical Research Professionals at Johns Hopkins
- https://ictr.johnshopkins.edu/events/clinical-research-professionals-lecture-series/
- Topics are based on questions received from Clinical Research Professionals throughout Hopkins
- Welcome topic suggestions: sswords1@jhmi.edu
- Welcome speakers!

Agenda

Remote & eConsent:

- Liz Martinez – Research Participant Advocate
- Suzanna Roettger - Associate Director Compliance Monitoring
- Lauren Swedberg - Sr. Consent Form Specialist
- Questions and Discussion

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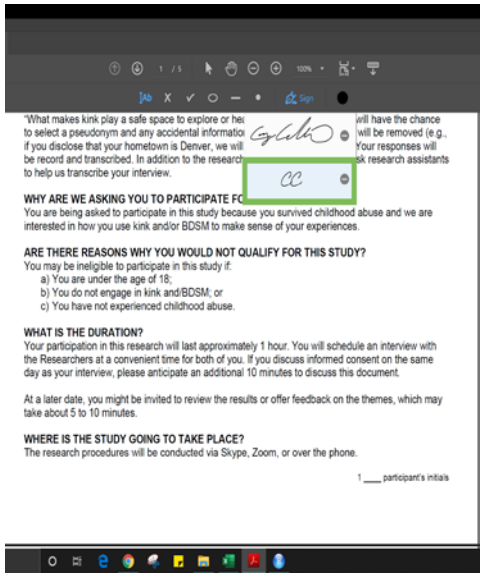
Remote Consent and eConsent

Both remote consent and eConsent were in limited use pre-pandemic.

Not surprisingly, there was an increase in their use during the Covid-19 pandemic.

Will there be continued or increasing use of these modalities in the consent process moving forward?



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Remote Consent

Remote consent is a consent process that allows the person conducting the consent and the potential participant to engage in the informed **consent process** in a way that is similar to what would be conducted in-person under normal circumstances **without being in the same physical location**.

eConsent

eConsent is an **electronic** media/format that can be used to *supplement* or *replace* paper-based informed consent forms **to provide information** to a potential research participant. It can also be used to **obtain documentation** of consent (e-signatures.)

eConsent can be conducted both in person or remotely.

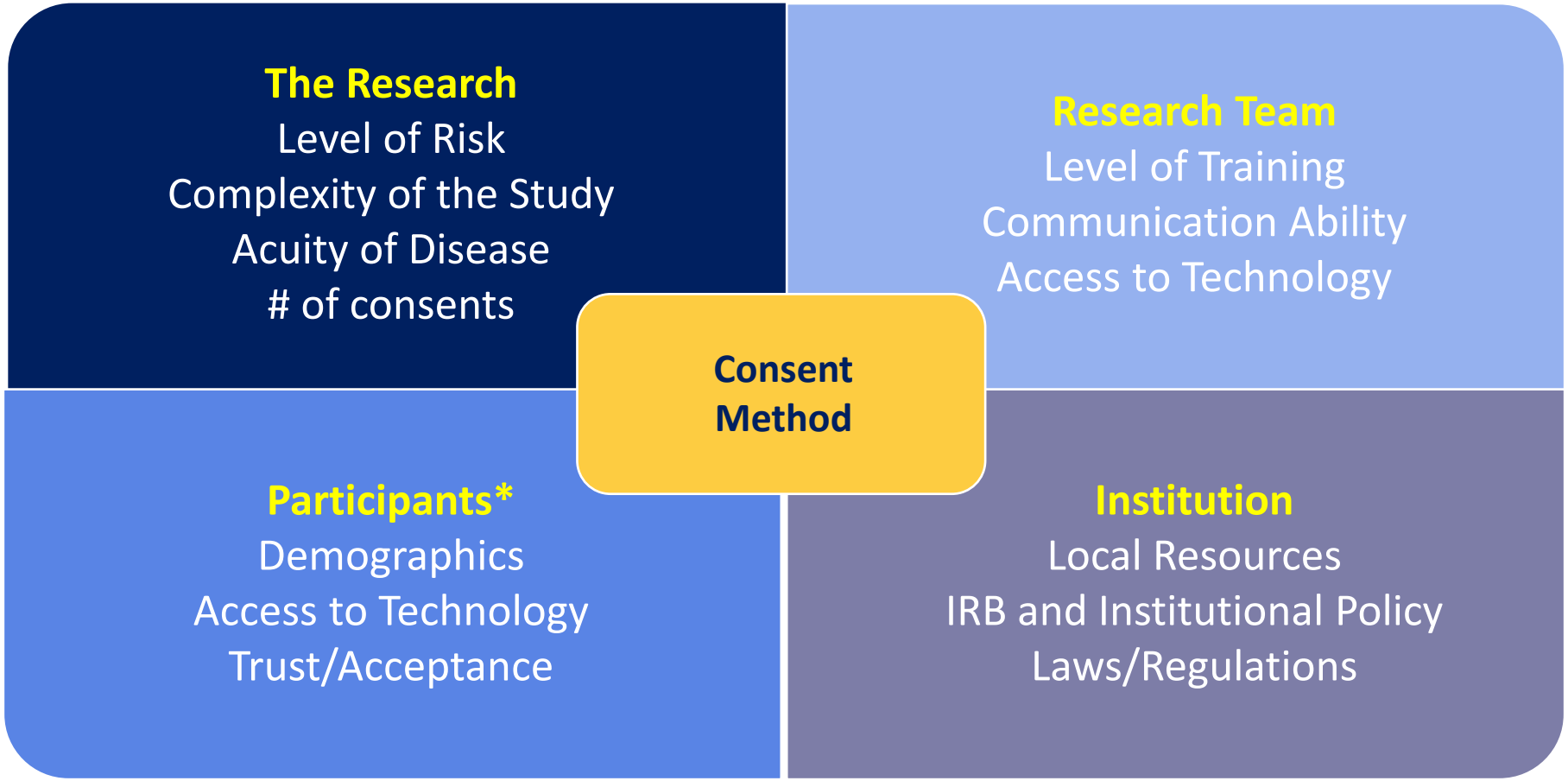
Remote and eConsent

Combinations of remote, e-consent, and or e-signatures can be used together to accomplish the Informed Consent Process.

How these modalities are implemented should take into consideration the qualities of the research study, the type of participants, regulations, institutional policies and the research team itself.

There is no single "best way" to execute these consent modalities for *all* research.

Use of Remote and eConsent



*See Resource: Chen C, Replacing Paper Informed Consent with Electronic Informed Consent for Research in Academic Medical Centers: A Scoping Review. (2020)

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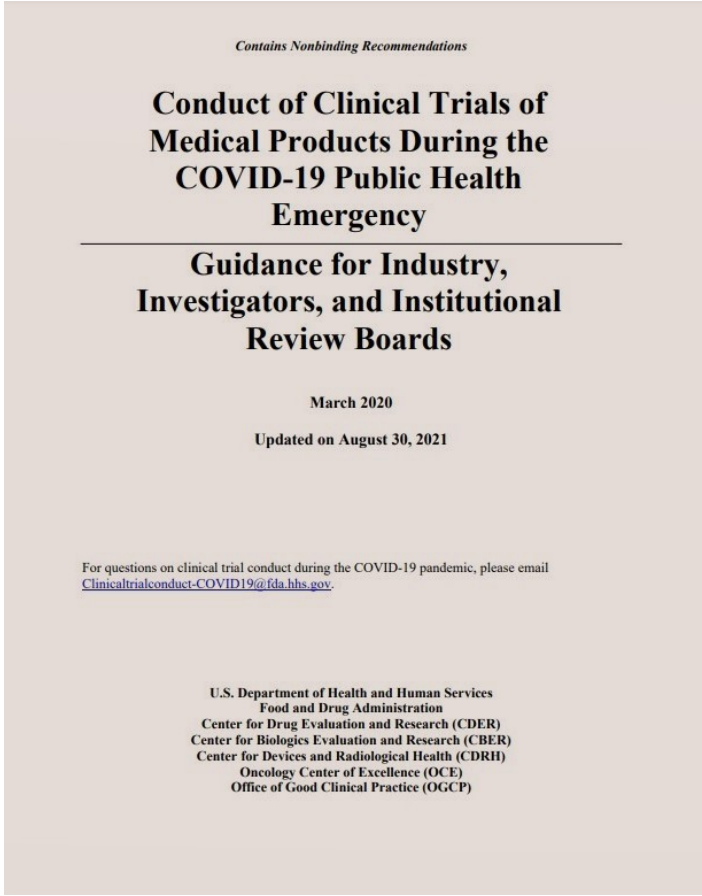
Remote Consent Best Practices

FDA Guidance provided during the Covid pandemic provided detailed considerations for conducting remote consent processes.

We can use this material to guide practices for appropriate conduct of remote consent processes.



Contains Nonbinding Recommendations

Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency

Guidance for Industry, Investigators, and Institutional Review Boards

March 2020

Updated on August 30, 2021

For questions on clinical trial conduct during the COVID-19 pandemic, please email Clinicaltrialconduct-COVID19@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Oncology Center of Excellence (OCE)
Office of Good Clinical Practice (OGCP)

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Remote Consent Best Practices

The person providing consent **must** have a copy of the consent form


eConsent (to be discussed later in presentation)


email (secure release)


mail


text


provided “in-person” at a visit

Best Practice:

- **Provide the consent form for review prior to discussion.**
- **Ask the potential participant to write out their questions.**

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Remote Consent Best Practices

phone

videocall

telemedicine

Best Practice: landline

Best Practice: secure platform

Best Practice: when available

Best Practice:

- Elements of the study described in the form will be presented
- Conversation about these elements will occur
- The participants questions will be answered
- The participants understanding will be evaluated

Remote Consent Best Practices

Remote signatures must include a method to ensure that the signer of the consent form is the person who plans to enroll as a participant or is authorized to sign for the participant

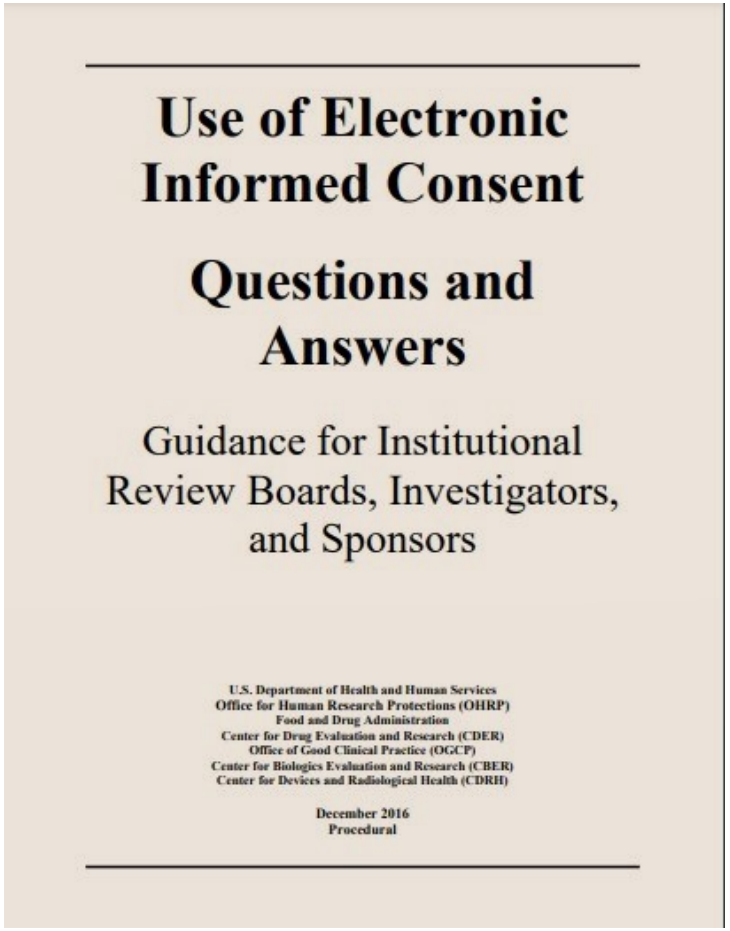
Best Practice:
The person obtaining consent must verify the appropriate person physically signed the consent document :

- view via video conference or,
- obtain a photo of the signed consent document or,
- obtain verbal confirmation that they signed the consent form or agreed to participate electronically.

A **signed consent document must be in possession of the study team** before any study related procedures are initiated.

eConsent Best Practices

FDA Guidance document published in 2016 provides considerations for the use of electronic consent processes in research.



Use of Electronic Informed Consent

Questions and Answers

Guidance for Institutional Review Boards, Investigators, and Sponsors

U.S. Department of Health and Human Services
Office for Human Research Protections (OHRP)
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Good Clinical Practice (OGCP)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

December 2016
Procedural

eConsent Best Practices

"Whether part or all of the eIC process takes place on-site or remotely, the responsibility for obtaining informed consent remains with the investigator and the study personnel to which responsibility has been appropriately delegated. **The investigator cannot delegate the authority to obtain consent to the electronic system.**" FDA Guidance "Use of Electronic Consent" (2016)

Best Practice:
As with in person consent using paper forms:

- Present the elements described in the form
- Converse about these elements
- Answer the participants questions
- Evaluate the participants understanding

eConsent Best Practices

eSignatures are an important part of eConsent

Best Practice US:

FDA regulated Investigations:

- In-person eSignatures -personnel may verify the persons identity
- Remote eSignature -must comply with 21 CFR part 11 (user name password combinations, computer readable ID cards, biometrics, or digital signatures.)

OHRP/Research under 45 CFR part 46: Risk based identity verification which for minimal risk could mean no verification or waiver of documentation of consent.

Johns Hopkins DocuSign

Johns Hopkins Instituted DocuSign as eSignature tool in 2020

Choice based on:

- **21 CFR part 11 compliance**
- **Quick set up**
- **Study team ability to add forms**

Attention:
DocuSign Costs may eventually be the responsibility of the study

Best Practice JH:

- Used for FDA and non FDA regulated research* (*if requested by study)
- IRB approved consent document uploaded as a pdf into DocuSign for use.
- JH developed and provided training which is required for all users.

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DocuSign Continued

- To use DocuSign you will need to fill out a form from the DocuSign team at researchdocusign@lists.johnshopkins.edu
- Study must be approved by DocuSign team before submission to the IRB
- All signatures will be required as they would for any written consent form

Johns Hopkins DocuSign Experience

Top Perceived Issues in use of DocuSign at JH:

- **Participant problems logging in and/or accessing the consent in DocuSign**
- **Pediatric consents when child has to sign are not feasible**
- **Non-English consent problems**
- **Set up effort too significant for low enrolling studies**

Johns Hopkins REDCap

REDCap for eConsent and eSignature
Research not requiring 21 CFR part 11 compliance

- **System Readily available at JH**
- **Support on site**
- **Study team able to add forms**

REDCap

- Can be used without modifications if the study is minimal risk and has been IRB-approved for a waiver of documentation of consent
- Modification is required to be used to obtain legally effective signatures (greater than minimal risk studies)
  - Subject's identity can be verified with a code or authenticator
  - There is a place for the subject to enter name or click to agree to participate
  - Study team responsible for modifying REDCap
- IRB approved consent language added into RedCap by trained team member.

Johns Hopkins REDCap Experience

RedCap eConsent/eSignature Experience

- **RedCap eConsent and eSignature in use pre pandemic**
- **Roughly 110 studies currently using RedCap for research requiring a signature**
- **More using it for research not requiring a signature**

Top perceived issues with use of RedCap eConsent and eSignature at JH:

- In order to use RedCap for research requiring part 11 compliance there is a complex certification process that the site must execute (JH currently not part 11 compliant).
- Version control concerns with IC documents.

Remote and eConsent Best Practices

Remote/eConsent consent methods need to be accurately documented

- **When using remote consent/DocuSign a PDF copy (fully signed and dated by all necessary parties) of the consent should be uploaded to Epic with a research note indicating that remote/ eConsent was conducted.**

- **Utilize a consent checklist to document the informed consent process to confirm consent process completeness and compliance.**
  - **A note to file or note on the consent checklist detailing specific dates when form was sent, when the conversation took place, who was there, explanation of differing signature dates, etc.**

- **Assure the participant has a copy of the consent form for their records (signed is preferred).**

REDCap versus DocuSign

REDCap	DocuSign
Platform for presenting consent information electronically	Platform for obtaining electronic consent signatures
May included interactive elements: images, videos, narration or quizzes to aid and evaluate understanding	Uses standard pdf image of the consent document.
May not be used for FDA regulated research unless upgraded to Part 11 compliant	May be used for FDA regulated studies (and others.)
Signatures may not be legally valid (authentication and attestation needed)	Signatures legally valid

DocuSign versus REDCap cont.

		Common E-Consent Systems		
		DocuSign	Standard JHU REDCap	Modified REDCap*
Is it 21 CFR Part 11 Compliant?		✓	✗	✗
Can it be used for greater than minimal risk research?	FDA regulated	✓	✗	✗
	Non-FDA regulated	✓	✗	✓
Can it be used for minimal risk research where documented consent is required?	FDA regulated	✓	✗	✗
	Non-FDA regulated	✓	✗	✓
Can it be used for research that qualifies for waiver of documentation of consent?	FDA regulated	✓	✓	✓
	Non-FDA regulated	✓	✓	✓

*Modified REDCap refers to REDCap that has been modified to include all features necessary to obtain legally effective documented consent.

IRB Approval

These Consent processes must be IRB approved prior to implementation.

Best Practice:
Provide information to the IRB as to how you will satisfy each of the items discussed in the previous slides with your remote/eConsent process.

When outlining your remote/eConsent plan for the IRB, include **alternative options** of obtaining consent from participants who cannot engage in a remote/eConsent process (*if this will be an option for your particular research.)

Submitting Remote/eConsent Requests to IRB

How to request IRB approval for remote/eConsent

- Any consent method needs to be IRB approved before use
- Currently the eIRB system does not have a separate section for remote/eConsent
- Where you will include information and forms depends on whether the consent method is considered ‘documentation of consent’ or ‘waiver of documentation of consent’

Submitting Remote/eConsent Requests to IRB

Documentation of Consent	Waiver of Documentation of Consent
eIRB Section 15: "Written Consent"	eIRB Section 16: "Waiver of Documentation of Consent"
For documented consent methods:	For non-documented consent methods:
• In-person consent with wet signature	• Oral consent script
• REDCap with ID verification	• Standard JHU REDCap
• Other eConsent where participant's identity is verified	• Other eConsent where participant's identity is **not** verified
• DocuSign	

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What to submit to the IRB: Remote/eConsent

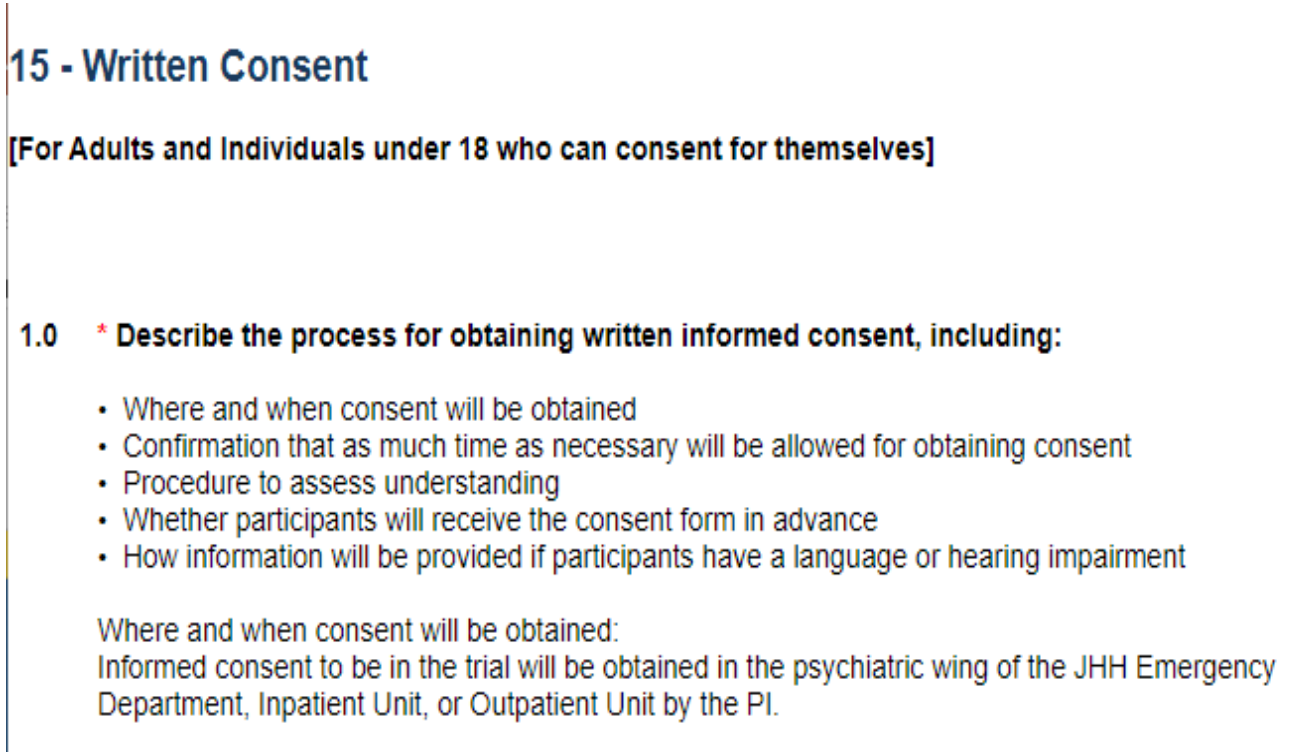
eIRB Section 15

DocuSign:

- Add language provided by the DocuSign team

Remote consent:

- Add language from [IRB website]



15 - Written Consent

[For Adults and Individuals under 18 who can consent for themselves]

1.0 * **Describe the process for obtaining written informed consent, including:**

- Where and when consent will be obtained
- Confirmation that as much time as necessary will be allowed for obtaining consent
- Procedure to assess understanding
- Whether participants will receive the consent form in advance
- How information will be provided if participants have a language or hearing impairment

Where and when consent will be obtained:
Informed consent to be in the trial will be obtained in the psychiatric wing of the JHH Emergency Department, Inpatient Unit, or Outpatient Unit by the PI.

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What to submit to the IRB: Other eConsent

eIRB Section 15/16

Other eConsent Systems:

—Explain the process for obtaining eConsent

—State what system you will use

—Explain that system is Part 11 compliant (if needed)

—Explain that system is able to document and authenticate consent (if needed)

—Confirm whether the electronic version includes all of the same information as non-electronic or explain differences

- Ex: graphics in electronic version

What to submit to the IRB: Remote/eConsent

Consent Forms

Remote consent using wet signature:

—No changes needed to the consent form

DocuSign:

—Written consent form signature lines need extra space for DocuSign signature overlay

—PDF of written consent is used in DocuSign system

What to submit to the IRB: Other eConsent

Consent Forms

If you will *only* use eConsent

—Upload the eConsent form as a Word document

—Include the signature/'agree to participate' page from the eConsent system in the Word document for the IRB to review

—You will receive a stamped PDF of the eConsent form

eConsent Script with REDCap 'Agree to Participate' Page

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONTACT INFORMATION:
If you have any questions about this study, please feel free to contact the Principal Investigator Dr. John Hopkins at 410-955-9555.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

To continue, please provide some information about yourself. This information is used to verify your participation in this research study.

First Name

Last Name

Date of Birth (mm/dd/yyyy)

Best phone number:

Date of remote oral consent

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What to submit to the IRB: eConsent

Consent Forms

<u>If you will use eConsent *and* non-electronic consent</u>

—Only upload the non-electronic version

- Having 2 versions of the same form – greater chance of errors

—The format and content of the consent in the eConsent system should be as similar as possible to the non-electronic version.

- If there are differences between the non-electronic and electronic versions, explain in eIRB or upload the electronic version in a Word document for review

What to submit to the IRB: eConsent

Consent Forms

If you will use eConsent *and* non-electronic consent

—Upload the eConsent 'agree to participate'/signature page by itself in the eIRB consent section if:

- The signatures will be considered legally effective documented consent
- The page differs from the non-electronic version (e.g. if you will be collecting DOB or phone number in the eConsent system)

—This page will be reviewed but not stamped

Sponsor/Other eConsent Systems

- Sponsor or other institutions' eConsent systems may be used if they can be modified to include state law and Hopkins institutional requirements:
  - —Physician consent page
  - —Financial Information Sheet signature line

- Example: can add the physician consent as a separate "survey" in REDCap

- Sometimes these systems cannot accommodate Hopkins requirements and the study teams are not able to use eConsent

eConsents

Consent Forms

Reminder: Whenever edits to the consent form are IRB approved, don’t forget to update the consent in the eConsent system

What to submit to the IRB: Outside eConsent Systems

eIRB Section 20.2

21 CFR Part 11

If using a Part 11 compliant eConsent system, upload any of the following:

- A letter/email from the system "owner" verifying that the system is Part 11 compliant
- An official product descriptor of the eConsent system (i.e. from the eConsent system's official website) verifying it is Part 11 compliant
- An email from an IT professional at the host institution verifying the system is Part 11 compliant
- Documentation from the sponsor that the system is Part 11 compliant.

What a Monitor Expects

- Per FDA, HHS, and JHU requirements, consent documentation, regardless of the modality, must be obtained prior to the initiation of study procedures.
- The presence of fully signed and dated consent forms, in their original modality, either in hard-copy or electronic.
- Additional signatures must be obtained for internal options, Financial Information, and MD/APP, if applicable.
- That the methods employed are approved by the eIRB in 15.1/16.1 and specify the use of eConsent and/or remote consent

Remote/eConsent Questions?

Review the Remote/Electronic Consent FAQ on the IRB website

https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/remote_consent_and_eletronic_consent.html

Reach out to IRB staff with questions about remote or eConsent options

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Questions?

Contact Information:

Stephanie Swords: sswords1@jhmi.edu
Liz Martinez: liz@jhmi.edu
Suzanna Roettger: sroettg1@jhmi.edu
Lauren Swedberg: lswedbe1@jhmi.edu

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Reference

- Rothwell, E., Brassil, D., Barton-Baxter, M., Brownley, K., Dickert, N., Ford, D., Wilfond, B. (2021). Informed consent: Old and new challenges in the context of the COVID-19 pandemic. *Journal of Clinical and Translational Science, 5*(1), E105. doi:10.1017/cts.2021.401

Resources

- Chen C, Lee PI, Pain KJ, Delgado D, Cole CL, Campion TR Jr. Replacing Paper Informed Consent with Electronic Informed Consent for Research in Academic Medical Centers: A Scoping Review. AMIA Jt Summits Transl Sci Proc. 2020 May 30;2020:80-88. PMID: 32477626; PMCID: PMC7233043.

- "Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards March 2020 Updated on August 30, 2021" https://www.fda.gov/media/136238/download

- "Use of Electronic Informed Consent Questions and Answers Guidance for Institutional Review Boards, Investigators, and Sponsors" December 2016 https://www.fda.gov/media/116850/download

- Vanderbilt Institute for Clinical and Translational Research RedCap eConsent Website https://victr.vumc.org/econsent_basics/

Learning as we go

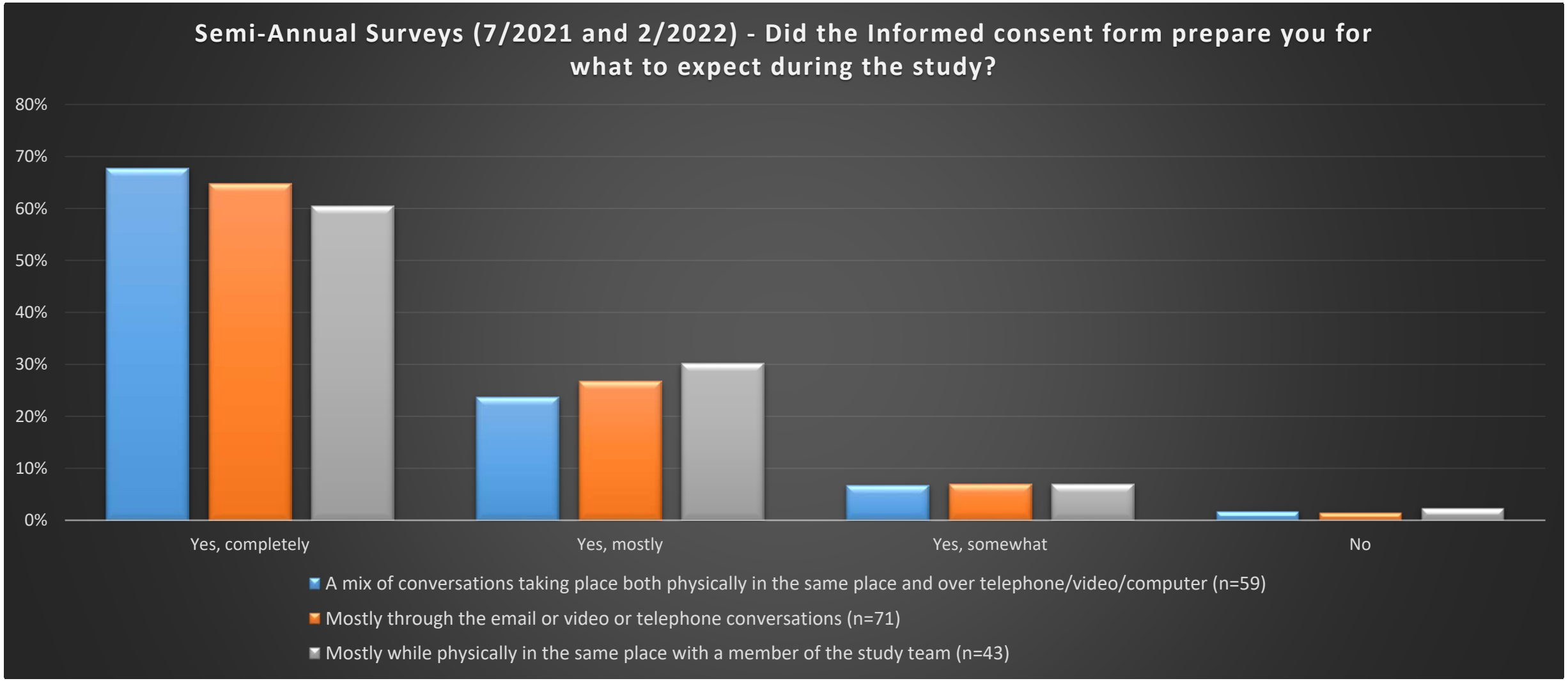
"The pandemic spurred innovation and demonstrated the feasibility of different approaches to informed consent. Most concretely, e-consent and other remote consent methods were rapidly implemented in order to facilitate important research in a situation where traditional methods could not be used. Moving forward, more tools are now available to research teams, but important questions remain regarding how to use these tools most effectively in order to advance key goals of consent. It is especially important that novel platforms be harnessed to address, and not exacerbate, well-known problems with traditional informed consent."

Rothwell, E (2021) *Journal of Clinical and Translational Science.*

“Quick Look Data” at JH

- The RPSS (Research Participant Satisfaction Survey)
- For 5 years we have been asking questions about how well the consent and consent discussions prepared participants for what to expect during the study
- During the pandemic we added a couple of questions about how consent was conducted
- Surveys completed July 2021 and February 2022

“Quick Look Data” at JH



“Quick Look Data” at JH