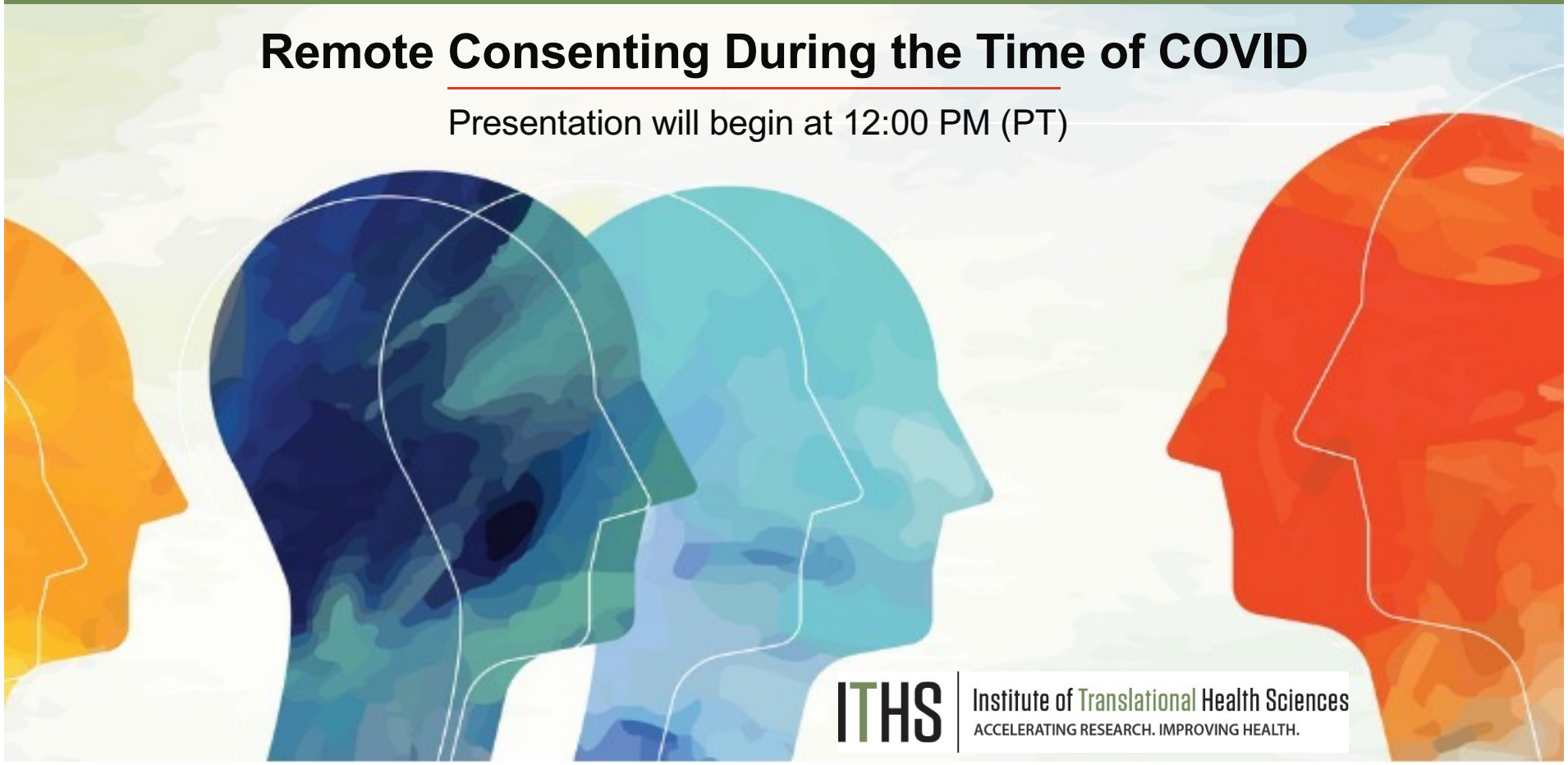
Career Development Series 2021

Remote Consenting During the Time of COVID

Presentation will begin at 12:00 PM (PT)



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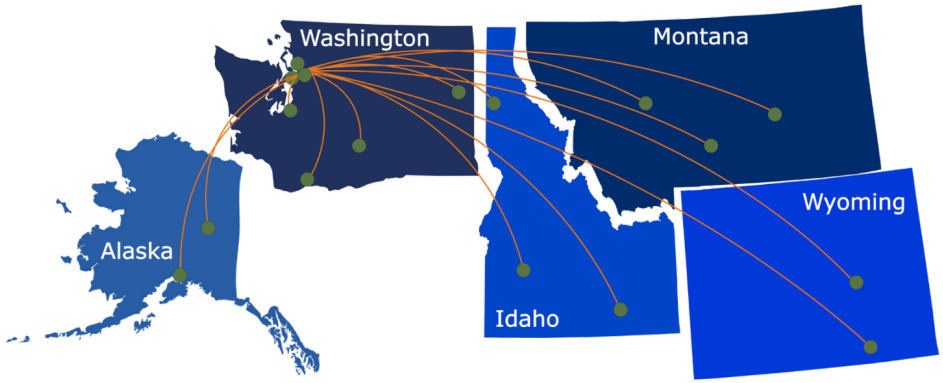

What We Offer:

1. **Research Support Services:** Members gain access to the different research services, resources, and tools offered by ITHS, including the ITHS Research Navigator.

2. **Community Engagement:** Members can connect with regional and community based practice networks

3. **Education & Training:** Members can access a variety of workforce development and mentoring programs and apply for formal training programs.

4. **Funding:** Members can apply for local and national pilot grants and other funding opportunities. ITHS also offers letters of support for grant submissions.

Contact our Director of Research Development

- **Project Consultation**
- **Strategic Direction**
- **Resources and Networking**

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Feedback

At the end of the seminar, a link to the feedback survey will be sent to the email address you used to register.

Career Development Series 2021

Remote Consenting During the Time of COVID

Presented by:
Claudia Z. Flores

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Learning Objectives

1. Be able to list three advantages to remote consent
2. Be able to describe two of the barriers to remote consent
3. Be able to explain how REDCap can be used for remote eConsent

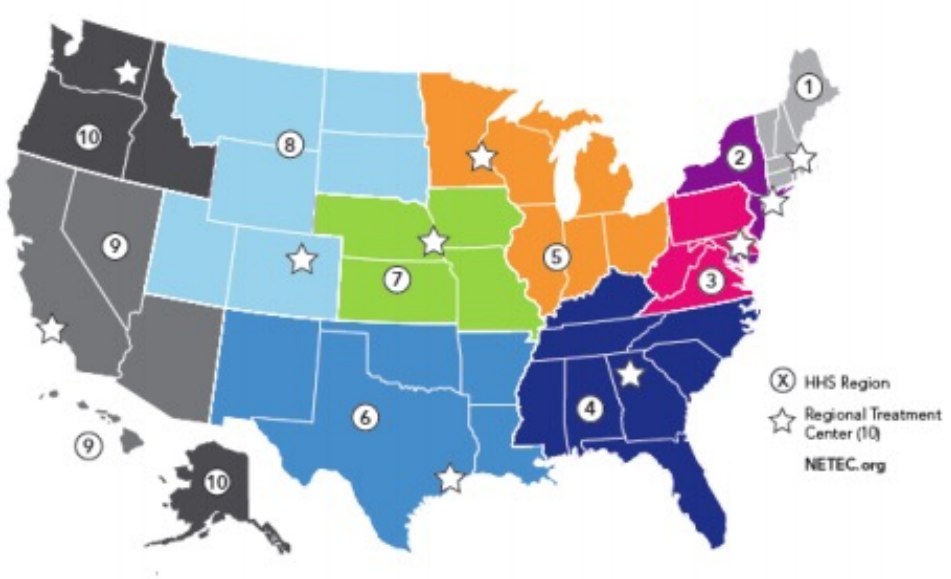
Poll

What is your research role?

- Research Investigator
- Research Coordinator
- Regulatory Specialist
- Data Manager
- IRB Member
- Project Manager
- Administrative Staff
- Other

Regional Ebola and Other Special Pathogens Treatment Centers (RESPCT)

1. Massachusetts General Hospital
2. NYC Health & Hospitals Bellevue
3. Johns Hopkins
4. Emory University Hospital
5. University of Minnesota Medical Center
6. University of Texas Medical Galveston
7. University of Nebraska Medical Center
8. Denver Health
9. Cedar-Sinai
10. Providence Sacred Heart Medical Center

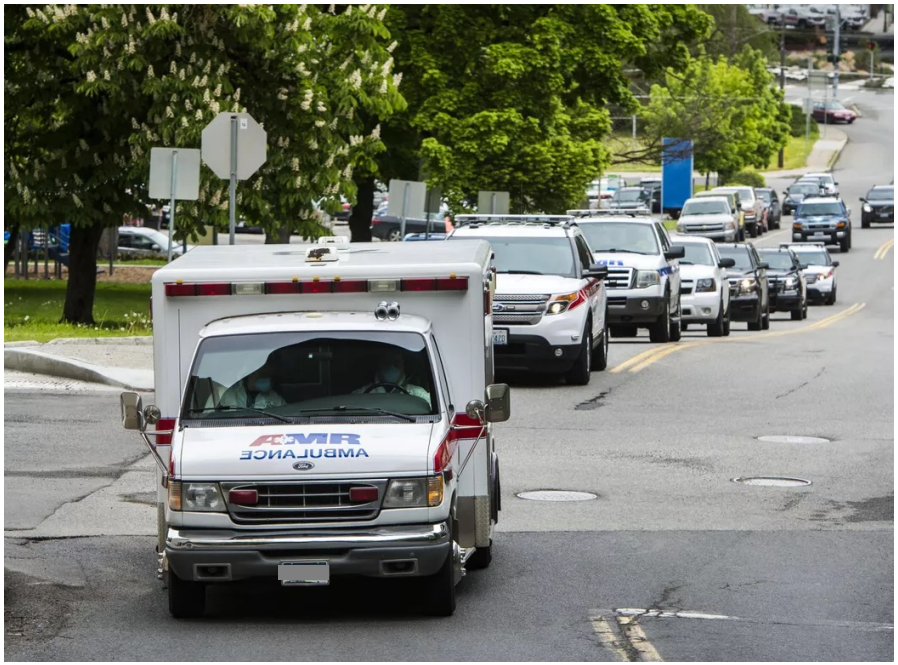


Research Protocols | Research Preparedness

- Universal Protocol
  - Data & biobanking
  - Any special pathogen outbreak
- Ebola treatment trial

- Research education development
- Research processes drilled hand-in-hand with clinical preparedness drills

May 17, 2017 - Spokane



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August 5, 2014 - Atlanta

April 2018 – Spokane Participates in Federal Exercise

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Challenges & Solutions

Anticipated challenges

- Face-to-face discussion is limited
  - People are very ill
  - Language barriers
  - Family quarantined
- What goes in the room stays in the room
  - How long does virus survive on paper?
  - Is it enough of a transmission risk?

Plans

- Use traditional paper consent form
- Investigator dons & conducts discussion and get signature
- Photograph consent form through the unit's video equipment, making sure signatures, version & IRB stamp clearly captured
- Leave the original consent form in the room
- Mail a copy to the participant's home

February 24, 2020 - Spokane's first COVID-19 patients arrive

New Challenges

- Treatment trials were prioritized
- Patients were admitted to every hospital unit
- Pandemic impacted all studies and caregivers

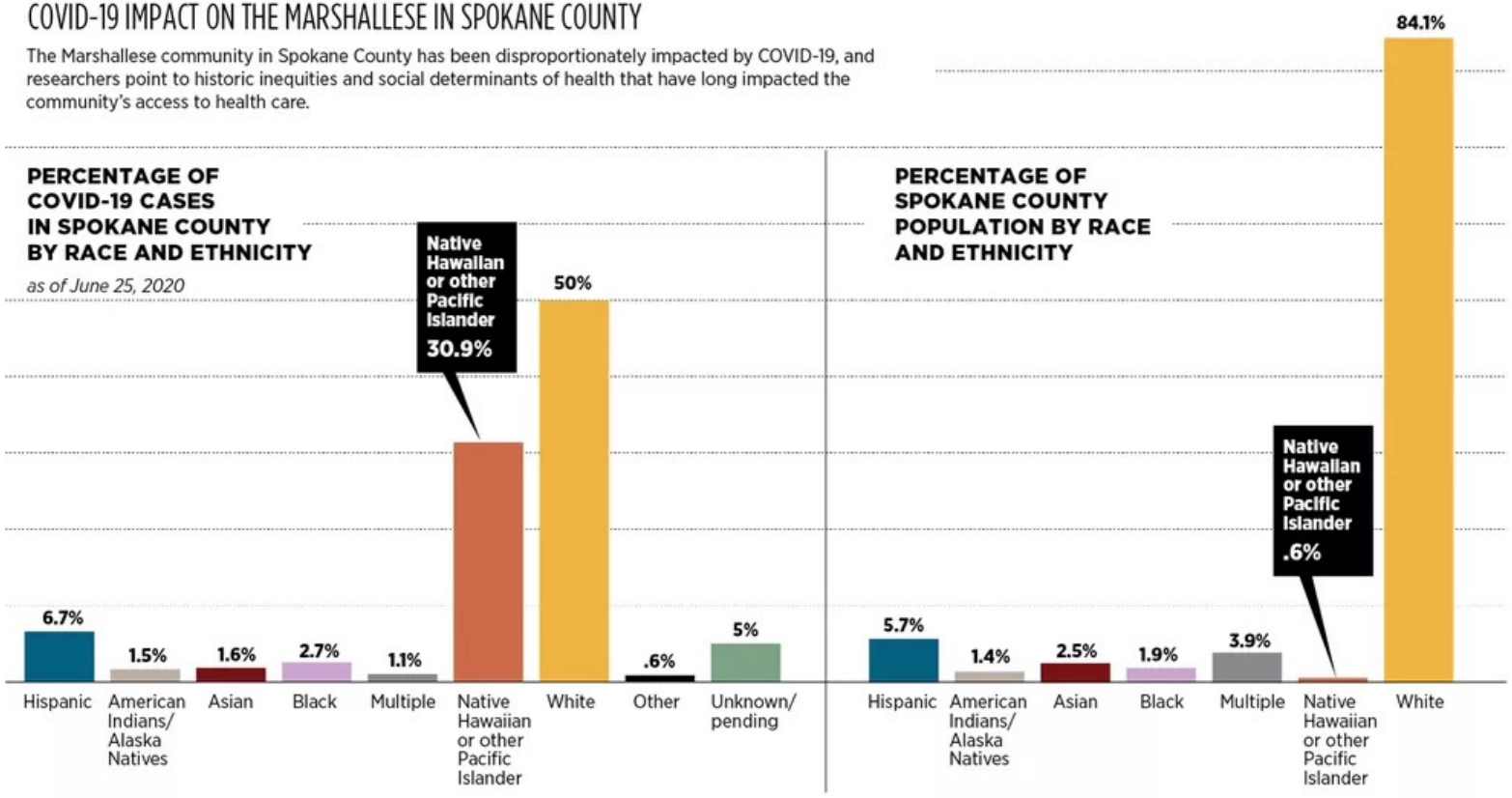
Polling Question

In 2020, what percentage of your study participants were non-English speaking?

- **0-10%**
- **Between 10-50%**
- **Over 50%**

COVID-19 IMPACT ON THE MARSHALLESE IN SPOKANE COUNTY

The Marshallese community in Spokane County has been disproportionately impacted by COVID-19, and researchers point to historic inequities and social determinants of health that have long impacted the community's access to health care.



Sources: Spokane Regional Health District, U.S. Census Bureau

MOLLY QUINN/THE SPOKESMAN-REVIEW

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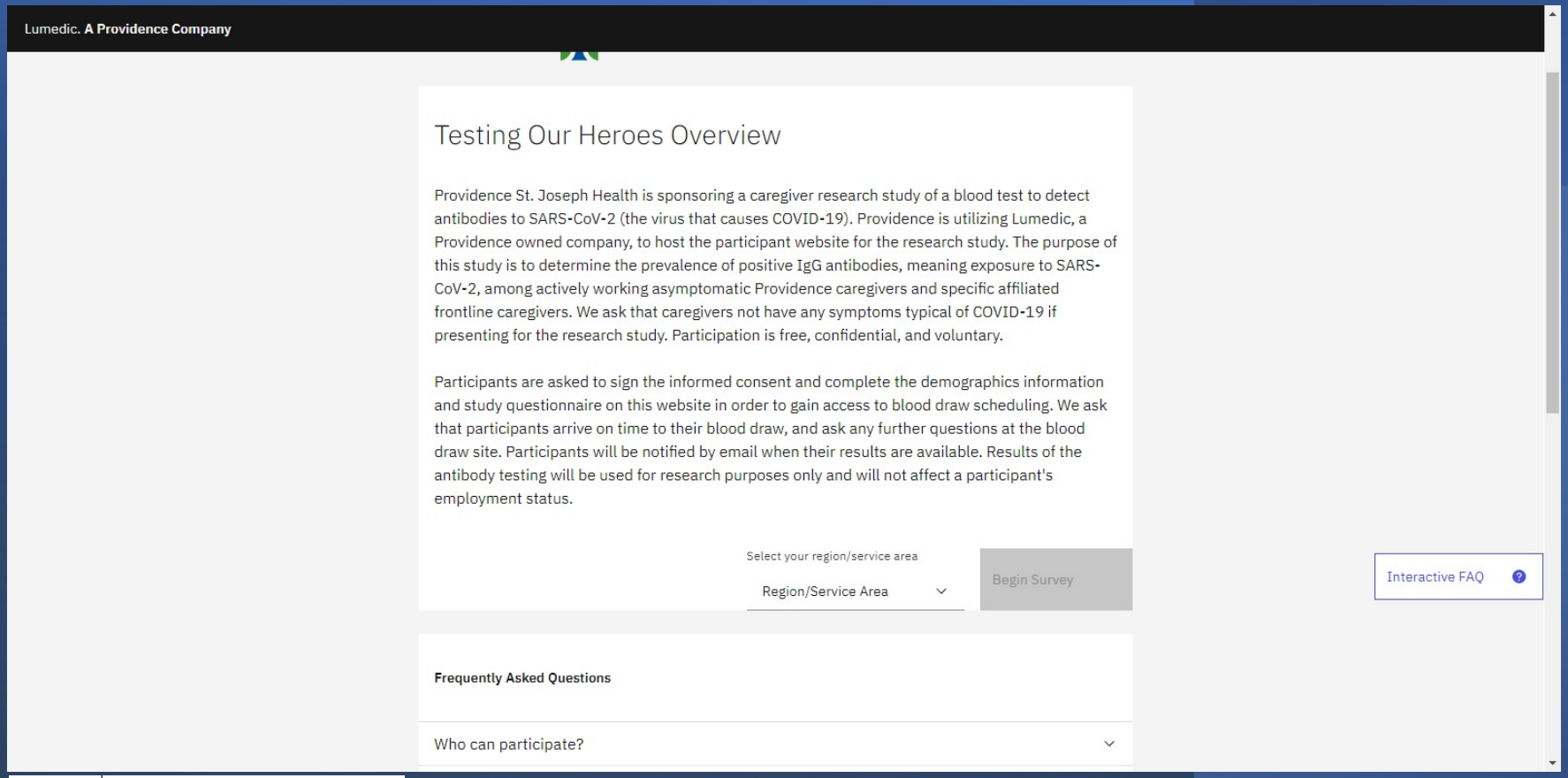
New Opportunities

- Consent by telephone / video conferencing / live chat
- Added enhancements: links to FAQ, chat bot
- Reach people who can't easily travel or are quarantined
- Facilitate non-English presentations while maintaining social distance
- Streamline documentation of the signatures
- Automate processes like providing a copy and filing



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Key Components of Consent Process

- Enough information to decide
- Processes to facilitate comprehension
- Required elements
- Time and opportunity to think and ask questions
- Documentation
- IRB approval
- Sponsor approval

Electronic Consent

- Include all general required elements & HIPAA authorization
- Include specific elements – risks/benefits specific to the study
- Easily retrievable for monitors and auditors - links that work for the duration of the study record retention period
- Provide a copy: electronic and paper option at no cost
- Document a valid signature
  - Federal law: Electronic Signatures in Global and National Commerce (e-sign) Act; Uniform Electronic Transactions Act (UETA), 21 CFR Part 11 for FDA regulated research
  - State law: WA Laws of 2020, Ch 7
  - Verification of ID

FDA Regulated Research – CFR Part 11 Compliance

- Appropriate controls / audit trails
- System privacy/security provisions
- Record retention/ retrieval for inspection
- Valid electronic signatures
  - Clearly indicate printed name date and time and meaning/significance
  - confirm the identity of the person signing
  - linked to the record directly (not a copy and paste)
  - designed to prevent alteration
- Biometrics are accepted – subject to the same controls,
  - designed to ensure the genuine owner and
  - performed according to government agency standards (National Institute of Standards and Technology)

Look at your policies / Consult your IRB

Policies are not the same. Here are some examples:

- Remote consent approved only during the public emergency
- Allowed only for minimal risk trials /Remote consent for screening only in more than minimal risk trial
- Specific about the consent form being provided prior to discussion
- Differences in witness requirements
- Contact via a secure mail system
- Zoom platform HIPAA compliant
- Make sure Alexa is deactivated

Polling Question /Challenge

A potential study candidate is in the ICU, intubated. Spouse is quarantined at home with no computer or cell phone.

What would you do?

- Not enroll this person
- Facilitate an emergency /compassionate use authorization
- Drive to the spouse's home and take a photo through the window
- Have the spouse sign a blank piece of paper and mail it to you

From the FDA guidance document:

- "Verbal confirmation by the participant or LAR that they signed and dated a blank piece of paper with a written statement that they voluntarily agree to participate in the protocol, noting both the protocol NUMBER and brief protocol title"… the newly created document can be returned by mail or at a later visit and appended to a copy of the consent document
- A recording of the conversation is allowable if in manner consistent with law and policy: WA State RCW 9.73.030 requires you to get a person's consent to record, with no option for a waiver
- Get a family member to help

REDCap: Research Electronic Data Capture

- Licensed from Vanderbilt University
- Secure, HIPAA and Part 11 Compliant
- Customizable
- Self Service training modules
- Web-based application: any browser

Thank You!

Open for Questions

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Feedback Survey

A link to the feedback survey has been sent to the email address you used to register.

Please get out your device, find that email, and spend a few moments completing that survey before you leave today.

Tip: If on a mobile device, shift view to landscape view (sideways) for better user experience.