Electronic Pathways: HIPAA, Texting, and Emails

Friday, October 6th, 2023

Learning Objectives:

1) Identify the various types of communication used in clinical research.

2) Explain the regulations behind electronic communication

3) Describe how to implement follow-up communication pathways

4) Take away skills to apply within research teams and procedures

Target Audience:

Clinical Research Professionals (CRPs) at UC/H and Cincinnati Children's Hospital Medical Center (CCHMC): including Principal Investigators (PIs), Research Nurses (RNs), Critical Care Unit Nurses (RNs), Pharmacy Technicians and Regulatory Specialists.

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October 2023 Study of the month:

Binge Eating Disorder Study
Are you struggling with overeating?

What
A twelve week study assessing an investigational medication for binge eating disorder.

Who
Adults aged 18-65 years of age with binge eating disorder.

Pay
All study visits, tests, procedures, and medication will be provided at no cost to participants. Eligible participants will be compensated $50 per visit for their time and travel.

Details
For more information, contact us at 513-536-0710 or visit www.LCOH.info to complete a pre-screen questionnaire.

Located at the Lindner Center of HOPE, Mason, Ohio.

UC Health. / UC Health. Lindner Center of HOPE

12-20 IRB # PENDING

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Thursday, October 19th, 2023, 12:00noon - 1:00pm
IN PERSON Presentation
MSB E255

Best Practices: Communication between study teams and clinical care staff

Mary St. John
Jennifer Waters
Kelly Acker
Bethany Fuhrman
UC Health
University of Cincinnati Cancer Center

Today's Presentation:

Electronic Pathways: HIPAA, Texting, and Emails

Join Janelle Allen for the October First Friday Seminar Series to weave through the in's and out's of communication pathways in clinical research. Phone, text, email, newsletter, social media, etc. so many ways to connect with participants... but are we truly connecting, effectively, and through properly regulated and safe pathways. Come to review and collectively dialogue on the dissemination and transfer of information.

Janelle Allen
Professor, Lecturer
University of Cincinnati
College of Medicine

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Technology In Clinical Trial Management & Success:
Electronic Pathways - HIPAA, Texting, and Emails

Janelle Allen, BS, MS, CCRP
Miami University + UC COM EPHS
Professional Consultant + Corporate Trainer
Office of Clinical Research – First Friday Presentation
Friday 6 October 2023

Disclaimers

- No conflicts of interest to note at this time.
- Speaker has completed research across the lifespan within all age ranges and many therapeutic areas.
- This presentation was developed by Janelle Allen and should only be used & reproduced with her written approval & proper citation given.

Agenda

➤ Technology
➤ Systems
➤ Tools
➤ Juxtaposition
➤ HIPAA, Texting, Email

TECHNOLOGY

• Stone
• Bronze
• Iron
• Glass
• Steel
• Aluminum
• Plastic

→ Technology

TECHNOLOGY – USERS

RESEARCH ASSISTANT | RESEARCH COORDINATOR | ADMINISTRATIVE ASSISTANT | REGULATORY COORDINATOR | QUALITY CONTROL | DATA COORDINATOR

GRANTS TEAM | CONTRACTS TEAM | LEGAL TEAM | AUDITORS/ MONITORS | CLINICAL TRIALS DIRECTOR | RESEARCH LEADERSHIP

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SYSTEMS

- IBM Clinical Development
- medidata
- MasterControl
- EXPeRT eClinical
- BioClinica CTMS
- Ofni Clinical
- CANTAB
- OpenClinica
- Clinical Research IO
- LifeSphere CTMS

- Allegro CTMS
- OnCore Enterprise Research
- ActiTrack
- Castor EDC
- Clinical Conductor CTMS
- BSI CTMS
- STARLIMS
- Target Health
- myClin
- Clinical Studio

SUCCESS STORY

TOOLS or TURMOIL

WHEN   WHERE   HOW   WHAT   WHY

TOOLS – SOURCE BASED

- Sponsor
- CRO
- Academic
- Hospital
- Private
- Governmental
- Non-Profit
- Agency
- Independent
- Specific

TOOLS – NEED BASED

- Efficiency
- Communication
- Entry
- Management
- Release
- Sequence
- Plan
- Program
- Organization

Positive Leadership

JUXTAPOSITION

- Assess
- Helpful
- Time
- Need
- Training
- Centralization
- Improvement

JUXTAPOSITION

- If it's not broke don't fix it
- It depends...
- Feedback
- Trial runs
- One system may not fit all
- Demos
- Teamwork
- Just because we can, does not mean we should...

JUXTAPOSITION – WHO IS THIS HELPING...

Will this new technological process or system help...
- Patients, participants, families?
- Coordinators, nurses, CROs?
- Principal investigators, service centers, teams?
- IRB or contract professionals?
- Sponsors or funders?
- You?

...set aside time to truly assess the technological needs of your participants, team & project!

...gather sufficient feedback before making any consistent technological changes!

...efficiency is a buzz word ... is it really helpful or not?

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10/11/2023

HIPAA, Texting, Email

- Federal Communications Commission - Telephone Consumer Protection Act 47 U.S.C. § 227 (TCPA)
- HHS Regulations, 45 CFR Part 46
- FDA 21 Code of Federal Regulations (CFR) Part 11
- Annex 11 | FDA 21 CFR Part 11 European equivalent
- GCP Ethical Principles: persons, beneficence, justice
- IRB Approval
- Clinical Trial Consent/Assent
- Preferred Communication Pathways
- Third-party program encryption with 3DES, AES, or similar algorithms for body of email + any/all attachments
- Participant approval documented in study file
- No direct patient identifiers nor PHI otherwise

Text | Email | Phone – Etiquette / Netiquette

- Reasonable Safeguards
- Confidentiality + Integrity
- Three Email Rule
- Twelve Second Rule
- Five Golden Rules
- Risk Assessment + Monitoring
- Restricted Access + Accountability
- Protect PHI from unauthorized access during whatever platform of transit
- GCP Pillars: data, flexibility, people, security

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RECAP...
A Technological Transformation

- What is technology... why do we use technology in research?
- What are basic versus complex technological improvements?
- How can we, as research employees, create value through use of technology?
- What kind of systems truly transform a complex process?
- Why is communication always key? How is feedback gathering paramount?
- Why is it so important to not change something that is working?
- When do we feel technological support? How do we feel it?
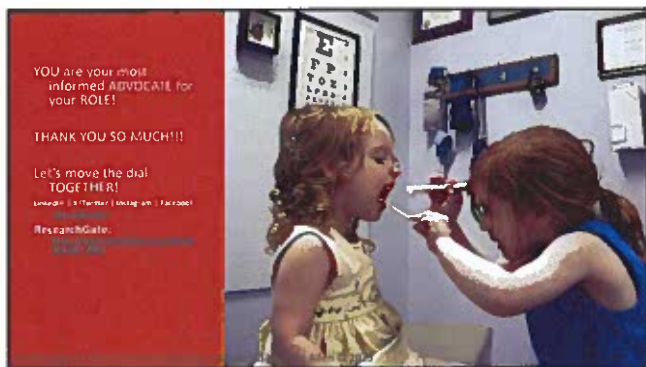- Future tech... the new frontier!

YOU are your most informed ADVOCATE for your ROLE!

THANK YOU SO MUCH!!!

Let's move the dial TOGETHER!

ResearchGate:

Thank You!
Questions?
Thoughts?
Sharing!
Caring!
Collaboration!

Contact Me:
Janelle Allen, BS, MS, CCRP
@janellerallen
janelle.rallen@gmail.com
1-513-313-2196