



# Office of Clinical Research First Friday

## Health Literacy for Clinical Research

Friday, August 5<sup>th</sup>, 2022

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# **Learning Objectives:**

- 1) Describe the role of health literacy in clinical research**
- 2) Describe the importance of relationship centered communications**
- 3) Identify best practices for planning and developing clinical research related communications**

## **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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### Off-Label Disclosure Statement:

Faculty members are required to inform the audience when they are discussing off-label, unapproved uses of devices and drugs. Physicians should consult full prescribing information before using any product mentioned during this educational activity.

### Learner Assurance Statement

The University of Cincinnati is committed to mitigating all conflicts of interest issues that could arise as a result of prospective faculty members' relationships with ineligible companies. The University of Cincinnati is committed to retaining only those speakers with financial interests that can be mitigated as they relate to the goals and educational integrity of the CME activity.

### Accreditation Statement for Directly Sponsored Activity

The University of Cincinnati is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The University of Cincinnati designates this live activity for a maximum of 1 *AMA PRA Category 1 Credit*<sup>™</sup>. Participants should claim only the credit commensurate with the extent of their participation in the activity.

\*\*CRPs, NPs, PAs, and RNs can count activities certified for *AMA PRA Category 1 credit*<sup>™</sup> for professional credit reporting purposes. Other healthcare professionals should inquire with their certifying or licensing boards.\*\*

### Disclaimer Statement

The opinions expressed during the live activity are those of the faculty and do not necessarily represent the views of the University of Cincinnati. The information is presented for the purpose of advancing the attendees' professional development.

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## **Speaker Disclosure:**

In accordance with the ACCME Standards for Integrity and Independence and the University of Cincinnati policy, all faculty, planning committee members, and other individuals, who are in a position to control content, are required to disclose all relationships with ineligible companies (commercial interest) within the last 24-months. All educational materials are reviewed for fair balance, scientific objectivity, and levels of evidence. The ACCME requires us to disqualify individuals who refuse to provide this information from involvement in the planning and implementation of accredited continuing education. The following disclosures were made:

## **Planning Committee Members:**

- Maria Stivers, MS, CIP; Course Director – No Relevant Relationships
- Nathaniel L. Harris, BS, Course Coordinator – No Relevant Relationships
- Zachary Johnson, BS – No Relevant Relationships
- Heather Muskopf, CME Program Manager – No Relevant Relationships

## **Speaker:**

**Angela Braggs-Brown, MA, CIP, RAC**

Sr. Director

UC Human Research Protection Program

*No Relevant Relationships*

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# August 2022 Study of the Month #1

## NMDAR Autoimmune Encephalitis Study

NN111 ExTINGUISH Research Study

### What

A research study to evaluate the safety and effectiveness of Inebilizumab for NMDAR Encephalitis. Inebilizumab is an FDA approved medication for a related autoimmune disorder. Currently there are no approved medications for NMDAR Encephalitis.

### Who

Adults 18 and older who have been diagnosed with NMDAR Encephalitis and are willing to forego other immunomodulatory therapies.

### Pay

Eligible participants will receive \$50 per completed visit.

### Details

For more information, please contact Tiffany Rupert at (513) 558-0269 or rupertts@ucmail.uc.edu or Angela Molloy at (513) 558-7118 or angela.molloy@uc.edu.



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# August 2022 Study of the Month #2

## Do you have PTSD?

Post-Traumatic Stress Disorder (PTSD) Study

### What

The purpose of this study is to determine the safety and effectiveness of an investigational drug in treating adults with PTSD.

### Who

Adults, 18 to 65 years of age, who have been diagnosed with PTSD or are suspected of having PTSD.

### Pay

Participants may be reimbursed for study-related travel.

### Details

For more information, please contact Heather Williamson at (513) 558-6612 or [Heather.Williamson@uc.edu](mailto:Heather.Williamson@uc.edu).



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# New Resource: UC Regulatory Channel:

This chat channel was created with the goal of unifying the regulatory communities and specialists at UC/UCH. There are many ways of handling regulatory duties, and this chat is designed to create an open community where any question, suggestion, or inquiry is welcomed. This channel will can provide the following to all who join:

- Aid or advice to new regulatory staff members at UC/UCH
- Potential demo/training opportunities of new systems, regulatory procedures, or submissions
- Discussion or feedback relating to regulatory submissions/approval processes for studies using UC IRB, CIRBs, or external IRBs
- Sharing of regulatory guidance documents and knowledge as it relates to FDA/ICH guidelines or OCR/IRB SOPs and Policies
- A way for regulatory staff to unify and share ideas or create innovative workflows aiding the regulatory processes

For anyone interested in joining this chat channel, please send an email to Kalen Butcher ([butchekn@ucmail.uc.edu](mailto:butchekn@ucmail.uc.edu)) to be added or have your team members added.

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# **UC / UC Health Clinical Research Orientation and Training (CRO&T)**

**Thursday, September 8<sup>th</sup>, 2022**  
**9:00 am - 3:00 pm**  
**Virtual presentation**

**The last day of registration is**  
**Friday, September 2<sup>nd</sup>, 2022**

**Register [Here](#)**

**Please reach out to Nate Harris,  
[nate.harris@uchealth.com](mailto:nate.harris@uchealth.com) for any questions**

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# Clinical/Laboratory Research Professional Award

**Nominations due: August 22, 2022 (by 5pm)**

To recognize the service of UC College of Medicine staff, the CoM Office of Research is soliciting nominations for the **Clinical Research Professional Award** and the **Laboratory Research Professional Award**.

A single award will be presented to each a clinical and a laboratory research employee who shows outstanding commitment to advancing the CoM research mission. Award recipients will be honored with a \$1,000 award!

All nominations and submission information can be found at:

**<https://www.med.uc.edu/research/recognition/professional-award>**

These are two separate and distinct awards. Applicants should further review the **Clinical Research Professional RFA** or the **Laboratory Research Professional RFA** for specific information unique to each award.

Nominations should be submitted electronically through the **submission portal**.

Questions should be sent to **Brienne Sheehan**.

Please consider donating to the CoM Research Professional Award Fund so that we may continue to honor our research professionals. **Give today!**

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**Thursday, August 18<sup>th</sup>, 2022, 12:00noon - 1:00pm**  
**Virtual Presentation**

## **Education and Career Development: Formal Education at UC**

Attendees will learn how to access educational opportunities at UC. Topics include how to activate tuition remission for UC employees, degrees and certifications of interest to CRPs, and addressing challenges to completing formal educational requirements.

**Elizabeth J. Kopras**  
**Pulmonary Clinical Research Unit**

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## Today's Presentation:

# Health Literacy for Clinical Research

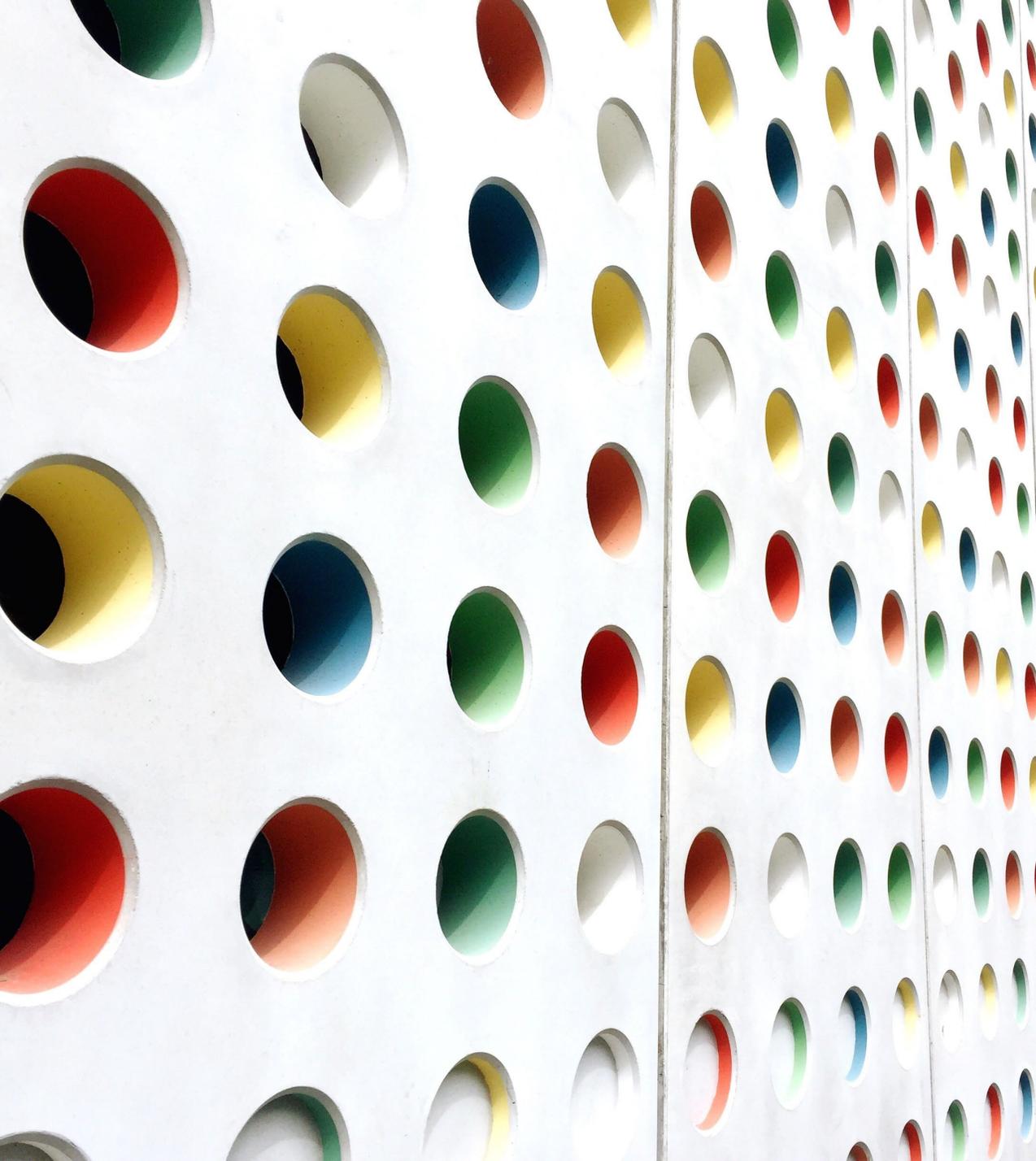
Health literacy is the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions. Low health literacy is more prevalent among: Older adults, minority populations, and those who have low socioeconomic status. This presentation will address the importance of relationship centered communications in health literacy for clinical research.

**Angela Braggs-Brown, MA, CIP, RAC**

Senior Director

UC Human Research Protection Program

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# Health Literacy for Clinical Research

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8/5/2022

# What Is Health Literacy?

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The Centers for Disease Control and Prevention uses two definitions:

- Personal health literacy – the degree to which individuals have the ability to find, understand and use information and services to inform health-related decisions and actions for themselves and others
- Organizational health literacy – the degree to which organizations equitably enable individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves

These definitions were revised in 2020 to:

- Emphasize “use” rather than only understanding
- Focus on “well-informed” rather than “appropriate decision making
- Acknowledge the responsibility of organizations in addressing health literacy
- Acknowledge the interconnectedness of health literacy and health equity through the use of a public health perspective

# Connecting to Clinical Research

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We can use these definitions as a springboard to ask relevant questions about clinical research programs:

- To what degree do individuals have the ability to find, understand and use research information and services (studies) to inform decisions, social interactions and research participation?
- To what degree do organizations equitably enable individuals to find, understand, and use research information and services (studies) to inform decisions, social interactions and research participation?

# Relationship Centered Communication

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The relationship centered communication model focuses on developing shared meaning between people within a network of strong relationships toward effective interactions/actions.

- Foster relationships – get to know the community; broader than patients who come into the office or individuals facing condition you are studying (they may not know they are facing these challenges yet, but can know research)
- Positive regard – be genuine and engage yourself in self reflection and self awareness
- Show interest and ask questions – seek information from participants and other in the community
- Active listening – pay attention to what people are saying; don't interrupt; ask follow up questions to improve understanding
- Empathy – you don't have to agree; this is about understanding the feelings and perspective of others

# Moving Through the Process

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Where are the opportunities for having relationship centered communications? Think through this from the participant perspective. When and where do people encounter information about research? It isn't always on a tear off pad or clinician's office. Social spheres include school, work, family, religious life, media and other sources. Think about where your team is in those spaces and work your way outward using mapping with your team or direct feedback from research participants. What does each step look, feel and sound like for potential and enrolled participants in the following areas:

Identifying studies that matter to the individual

Being approached about research

Going through the informed consent process

Undertaking study procedures

Ending participation

Circling Back

# Take Aways

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- Don't underestimate the value of effective communication in all social spheres and across a broad range of audiences.
- Acknowledge communication barriers as well as the perspectives and concerns of others
- Provide information that enables all individuals to make decisions for themselves with regard to research broadly. This includes providing research that people want to see that addresses specific issues they are facing in their lives.
- Collaborate with the community in research communications. Greet interactions with respect and the value being added from research to the community.

YOU CAN START NOW