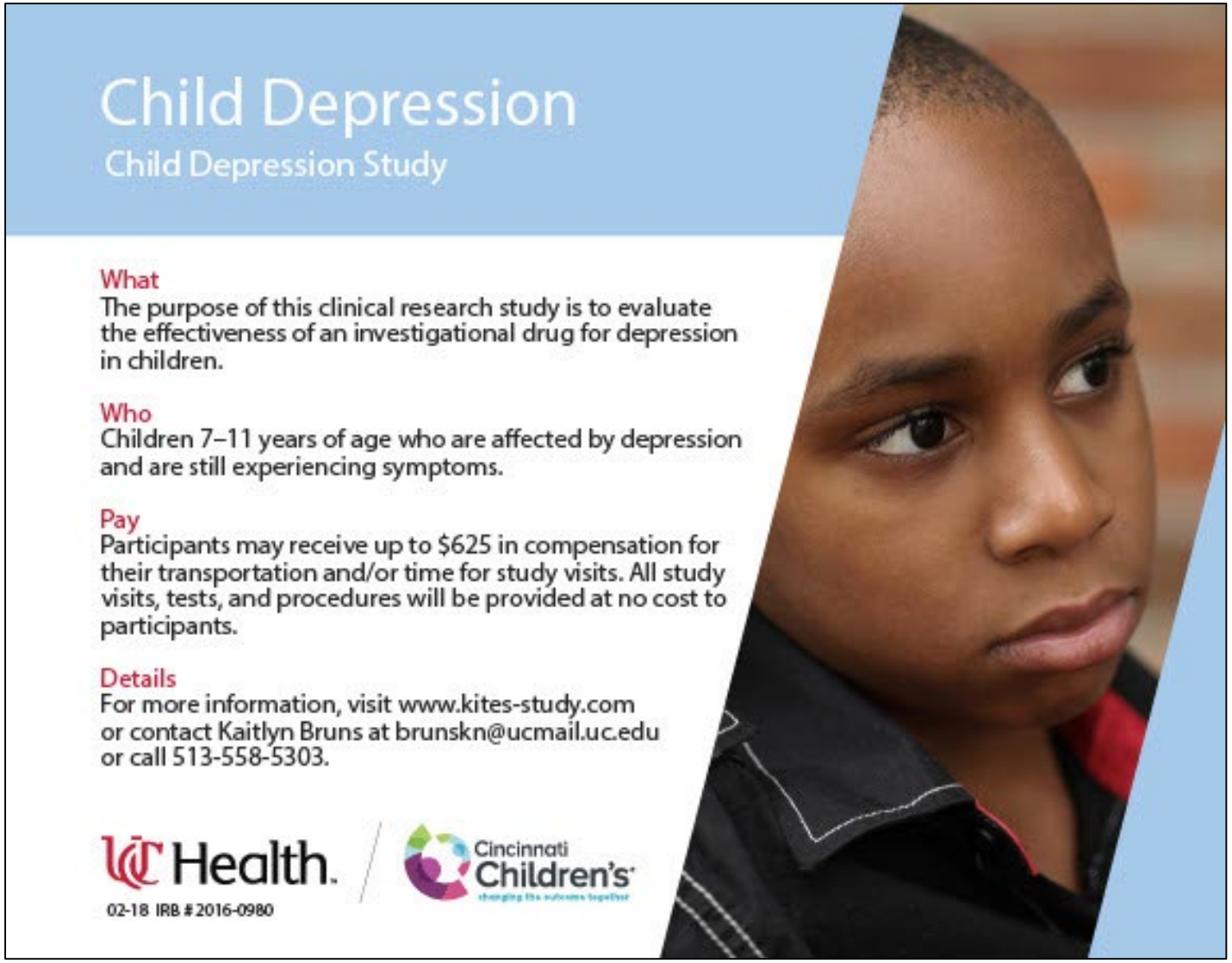
Research Communication with Clinical Care Teams: Best Practices

Thursday, March 18th, 2021

UC Health

March 2021 Study of the Month



Friday, April 2nd, 2021

Budgeting for Federally Funded Research

Kelly Niederhausen

Lisa Schira

Patrick Clark

UC Health

Today's Presentation:

Research Communication with Clinical Care Teams: Best Practices

a discussion of best practices and proven methods of research study team communication and collaboration with clinical care teams and departments for the successful execution of research studies, visits, and procedures, and increased research study awareness among clinical staff.

Autumn Cresie
University of Cincinnati
Heart, Lung and Vascular Institute (HLVI)
Department of Internal Medicine
Studeran@ucmail.uc.edu

UC Health

RESEARCH COMMUNICATION WITH CLINICAL CARE TEAMS

Tips and Ideas for research teams

GENERAL OVERVIEW

- Epic documentation
- Research Key Tips and Ideas
- Clinical Staff Thoughts and Resources

EPIC DOCUMENTATION

Previously:

- Research flag in pt. banner
- Able to plug in direct contact information

Current:

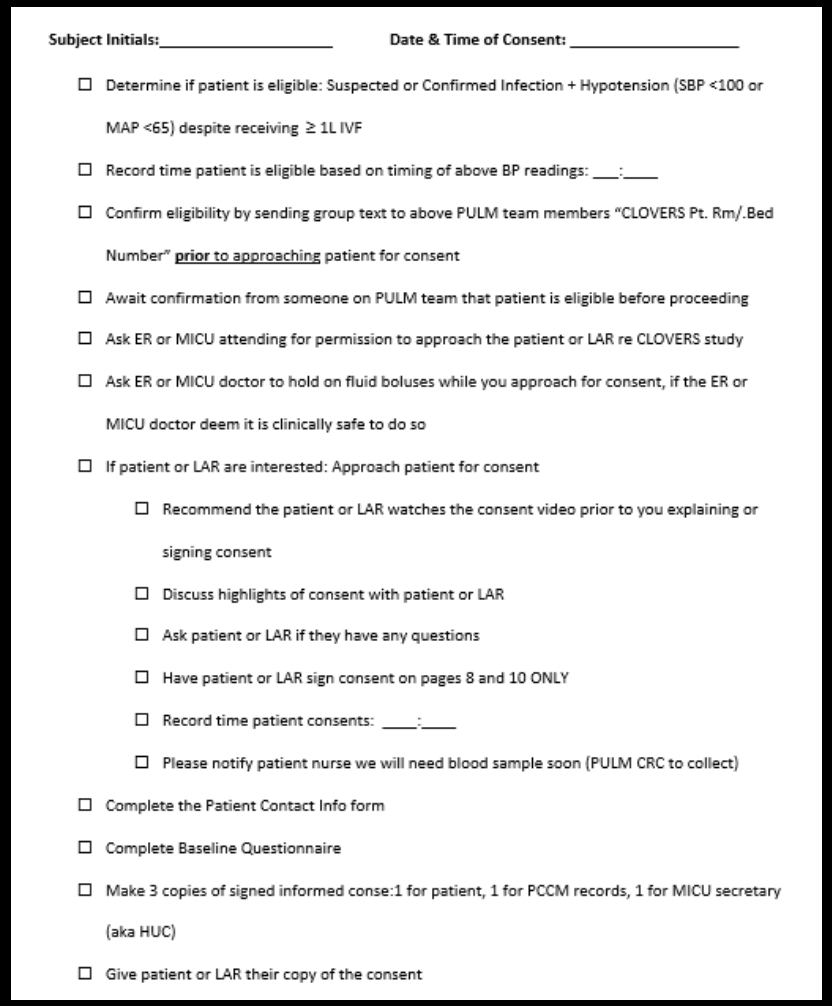
- Now a separate tab. Not easily found
- Create ‘research chart note’ with study info and brief snippet of study.
- Appears to clinical staff as ‘beaker’

EPIC DOCUMENTATION

High Risk Period Alert in EPIC

High Risk Period definition: A period of time when clinical care, patient safety, or research integrity is at high risk of failure if a clinical care team is not notified or is unaware the patient is an active research subject in a clinical trial

- Create a check list for enrollment



Subject Initials:_____ **Date & Time of Consent:** _____

- ☐ Determine if patient is eligible: Suspected or Confirmed Infection + Hypotension (SBP <100 or MAP <65) despite receiving ≥ 1L IVF
- ☐ Record time patient is eligible based on timing of above BP readings: ___:____
- ☐ Confirm eligibility by sending group text to above PULM team members "CLOVERS Pt. Rm/.Bed Number" **prior** to approaching patient for consent
- ☐ Await confirmation from someone on PULM team that patient is eligible before proceeding
- ☐ Ask ER or MICU attending for permission to approach the patient or LAR re CLOVERS study
- ☐ Ask ER or MICU doctor to hold on fluid boluses while you approach for consent, if the ER or MICU doctor deem it is clinically safe to do so
- ☐ If patient or LAR are interested: Approach patient for consent
  - ☐ Recommend the patient or LAR watches the consent video prior to you explaining or signing consent
  - ☐ Discuss highlights of consent with patient or LAR
  - ☐ Ask patient or LAR if they have any questions
  - ☐ Have patient or LAR sign consent on pages 8 and 10 ONLY
  - ☐ Record time patient consents: ____:____
  - ☐ Please notify patient nurse we will need blood sample soon (PULM CRC to collect)
- ☐ Complete the Patient Contact Info form
- ☐ Complete Baseline Questionnaire
- ☐ Make 3 copies of signed informed conse:1 for patient, 1 for PCCM records, 1 for MICU secretary (aka HUC)
- ☐ Give patient or LAR their copy of the consent

RESEARCH TEAMS

- Source documents based on SOC
- Create a bedside checklist
- Speak to staff every location the patient goes (i.e. ED, x-ray, MICU)

RESEARCH TEAMS

- Bright colored clipboards
- Bright colored paper
- Consistent enrollment packet
- ‘One Hit Wonder’ on breakroom bulletin board

University of Cincinnati Clinical Research | UC Health.

Investigational Pharmacy

STUDY FACT SHEET

IDS # 2609-18

[redacted]

TITLE: A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Adaptive Clinical Trial of Vitamin C, Thiamine and Steroids as Combination Therapy in Patients with Sepsis; [redacted]

DESIGN: A multi-center, randomized, placebo-controlled, double-blind, adaptive clinical trial of vitamin C, thiamine and steroids as combination therapy in patients with sepsis.

PHARMACOLOGY: Vitamin C and Hydrocortisone both play important roles in numerous physiologic functions relevant to patients with septic shock including modulation of inflammatory mediators, catecholamine synthesis, endothelial function, and vasopressor sensitivity. Glucocorticoids enhance the transport of Vitamin C into cells, thereby making it available for intracellular use. **Thiamine** deficiency disrupts aerobic metabolism and, if severe enough, can lead to lactic acidosis and death.

DOSAGE AND ADMINISTRATION: Eligible, consented patients will be randomized to one of the following treatment groups (in a 1:1 ratio):

- **Vitamin C** 1.5 grams (IV), **Thiamine** 100 mg (IVP), and **Hydrocortisone** 50 mg (IVP) every 6 hours for 4 days or until ICU discharge.
- **Matching Placebos** (IV) every 6 hours for 4 days or until ICU discharge.

ADMINISTRATION GUIDELINES:

- Randomized patients should receive their first dose of study medication as soon as possible, but no longer than 4 hours from randomization. All subsequent doses should default to the facility's every 6 hour dosing schedule.
- Study medications should be administered through a dedicated IV line.
- **Thiamine / Matching Placebo** is administered (first) by slow IV push over 2 to 3 minutes, followed by **Hydrocortisone / Matching Placebo** administered by slow IV push over 2 to 3 minutes (see instructions below for patient's receiving open-label steroids), then **Vitamin C / Matching Placebo** infusion infused over 30 minutes.
- If the treating MD believes there is an indication for steroids, the study coordinator will work with the MD and the protocol section 8.3 to assure proper patient/protocol treatment. If the prescribed steroids are discontinued before the end of treatment, the study personnel will reorder the steroid portion of the study as randomized.
- Patients will receive study infusions while admitted to the ICU or in the ED while awaiting transfer to the ICU. If a patient's level of care changes prior to the final dose of study intervention will be discontinued upon physical transfer from the ICU to another level of care.
- Patients receiving Vitamin C may have falsely elevated glucose levels when measured using point of care glucometers. For this reason, only study approved glucometers may be used for point of care tests.
- Missed doses are ok to be administered up to 3 hours after scheduled administration time.

UN-BLINDING: In the case of a significant safety concern related to any of the three drugs administered as part of the VICTAS Study, the local PI should evaluate the situation to determine if discontinuing the study intervention is warranted. **The study medication blind shall not be broken**, as breaking the blind will not provide increased safety.

ADVERSE EFFECTS: Vitamin C: lethargy, fatigue, irritation at injection site, nephrolithiasis, hyperglycemia, nausea.

IDS STUDY FACTS SHEET

ADVERSE EFFECTS: Vitamin C: lethargy, fatigue, irritation at injection site, nephrolithiasis, hyperglycemia, nausea. **Thiamine:** injection site reactions and hypersensitivity reactions. **Hydrocortisone:** hyperglycemia, hypernatremia, impaired wound healing, fluid retention, thinning of the skin, muscle weakness, acute mental status changes.

AUTHORIZED PRESCRIBER: Kristin Hudock, MD.

CONTACT PERSONNEL: Autumn Creasie: Phone: 558-0337

RESEARCH TEAMS

- Identify department educator
- Department Huddles
- Lunch and Learns
- Study ‘kick off’ meeting

- Create a Research spot on handoff forms
- Research updates at shift huddles
- ID a research patient in epic
- Understand Research Needs

CLINICAL STAFF

- Check the break room for updates

- Checklist
- Non SOC ‘flags’
- Research time outs
  (before procedures, daily huddles, handoff, etc.)
- Educator Resources
- Relationship outside of research

RECAP

- You can <u>never</u> over communicate