HOBIT

HYPERBARIC OXYGEN BRAIN INJURY TREATMENT TRIAL: A MULTICENTER PHASE II ADAPTIVE CLINICAL TRIAL

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Site Readiness

-Paperwork
-Coordinator Coverage
-Key Collaborators

Subject Recruitment

-Recruiting the Clinical Partner

The Informed Consent Process

-Getting Ready
-Interpreter services
-Know your study, know your consent, know your audience

Site Readiness: The Paperwork

- Master Trial Agreement (MTA)
- cIRB Reliance Agreement- between ADVARRA and your IRB
- HOBIT Readiness Checklist (under construction)
- **1572, FWA & CLIA**
- Site-specific Coordinator Checklist

Site Readiness: The Paperwork

- Master Trial Agreement (MTA) between the CCC University of Michigan and your HUB
- Protocol Trial Agreement: between your site and your SIREN HUB for HOBIT
  - Terms and conditions for HOBIT financial contract

Site Readiness: The Paperwork

- cIRB Reliance Agreement- between ADVARRA and your IRB
  - RA will apply to all SIREN studies – not just HOBIT
  - If your IRB had an agreement with Chesapeake IRB or Schulman IRB, you may already have an agreement with ADVARRA
  - cIRB call to local IRB (IRB to IRB directly-still in process)

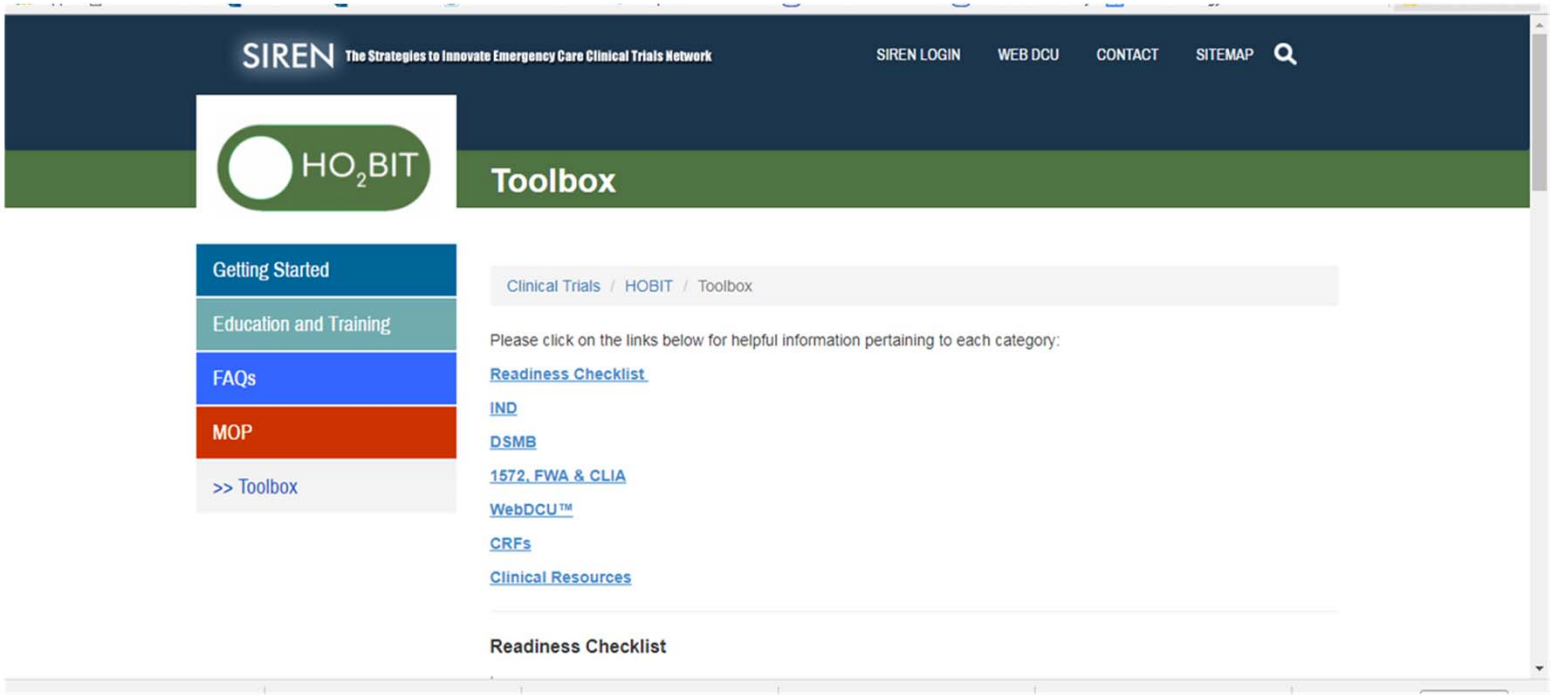
Site Readiness: The Paperwork

- cIRB Submission Components to Consider
  - Local IRB will sign off on the local context form provided by cIRB
    - Local conflict of interest policy. What is the financial threshold?
    - Does it allow the HIPAA to be melded into main study consent or does it need to be a separate HIPAA?
    - What is your patient population: need for translated consents?
    - Consent policies for limited capacity to consent/LAR consents.
  - Local IRB may have other required information or reviews
    - List of study personnel: PI, Sub investigators, coordinators
    - All study personnel must be GCP compliant
    - Ancillary reviews: pharmacy, lab, radiation safety, research charges for SOC v research

Site Readiness: The Paperwork

- HOBIT Readiness Checklist (coming soon!)
  - This checklist will serve as an agenda for the readiness call.
  - It will list all the regulatory documents, for all the people and the spoke that will need to be uploaded into WebDCU PRIOR to the call.
  - The checklist serves as a great guide for spokes to prepare for the study. Often it includes “essay questions”.
  - This time the checklist will include the SIM component.

hobittrial.org



Site Readiness: The Paperwork

- Coordinator checklist
  - A key element will be a process for identifying implantable devices *SEE MOP
  - Establish a list of common device makers in you area
    - For example: We have “the “big fiver” that we see in the Midwest (due to # of devices sold/market share): Medtronic, Boston Scientific, Abbot (formerly St. Judes), Biotronic, Sorin/ELA (German company)
- FDA information line for implantable devices: 1-800-638-2041

Site Readiness: Coordinator Coverage

- Establish a plan for coordinator coverage and coordinator activation
  - Pager
  - Dispatcher
  - Google phone
- At the U of MN we use a “pool” system; we have a pool of coordinators who cover a pool of acute care/ED studies.
  - Coordinators are cross-trained to successfully randomize in any of the pool of studies.
  - Coordinators take a 12 hour shift (7a-7p, 7p-7a).

Site Readiness: Establish Key Collaborators

Examples:

- HBO team (physicians, nurses, techs)
- ED Team (physicians, nurses, scribes/research associates)
- ICU team (physicians & nurses)
- EMS
- Interpreter Services
- Unit Nurse Educators
- SIM team

Start Early. Get AS MUCH FACE TIME AS POSSIBLE

Site Readiness: Questions for the Clinical Team Leadership

After a discussion of what the protocol will entail (relevant to their clinical area)

Ask:

- How do they foresee this study impacting the normal workflow for this type of patient?
- What do they think they'll need to help the protocol run smoothly in their unit?
- Is there a staff member that might like to be a "study champion"?

Site Readiness- Tips

- Tailor the slide/poster to each clinical team: EMS needs different information than the ICU team will need
- Upfront, establish ways to keep the study “on the radar” especially with EMS and in the ED
  - Newsletters? Email Updates? Study progress flyers?
- Do a walk-through of the spaces you’ll be in during the study, take notes
- SIM set-up
  - Setting up a SIM takes time and buy-in, BUT, there is immense value not only in actually running it but in planning it. At lot of “what ifs” can be ironed out in planning and de-briefing the SIM

Subject Recruitment: Recruiting the Clinician Partner

EMS- early identification of possible subjects in the field, early coordinator alerts

- Set up an alert in EPIC (if possible) OR
- Set up a paging system
- Give them a brief “ask”: “Blunt trauma patients 16-65 with a Glasgow Coma Scale (GCS) of 8 or less. Please alert the ED team that this is a possible HOBIT patient”.
- present at a staff meeting/round-up, if possible. Bring reminder cards and donuts.

Subject Recruitment: Recruiting the Clinician Partner

Scribe/Research Associate

- Second set of eyes in the ED, not charged directly with patient care
- Can remind clinical team of study AND active coordinator
- Present the study at a meeting or "huddle" –chocolate!!
- Give them a small, laminated card with an "ask": "blunt trauma patients 16-65 with a Glasgow Coma Scale (GCS) of 8 or less. EXCLUDE: injury older than 24 hours, Penetrating head injury (known) Pregnant, (Known)Prisoner. Call/page coordinator at XXX-XXXX".

Subject Recruitment:
Recruiting the Clinician Partner

ED Physicians and Nurses

- Establish a site champion (CO-I or charge nurse)
- Work with the nurse educator
- Try to do in-person discussions, get on staff meeting agendas and/or staff huddles-CHOCOLATE !!
- Post study flyers with brief inclusion/exclusion and coordinator contact information in break rooms and STAB/Trauma Rooms
- Identifying implantable devices is a key element, ED can help with that.
- **SIM**

Subject Recruitment: Recruiting the Clinician Partner

ICU Physicians and Nurses

- Establish a site champion (CO-I or charge nurse)
- Work with the nurse educator
- Try to do in-person discussions, get on staff meeting agendas and/or staff huddles
- Post study flyers with brief study description and coordinator contact information in break rooms or by the charge desk
- Emphasize how the coordinator will HELP with protocol adherence
- Discuss lines of communication and resources for the clinicians (hotline numbers, coordinator numbers, ect.)
- **SIM**

Subject Recruitment:
Recruiting the Clinician Partner

HBO Physicians, Nurses and Techs

- Try to do in-person discussions, get on staff meeting agendas and/or staff huddles. You guessed it, more chocolate.
- Post study flyers with study information relevant to their involvement in break rooms or by a central desk
- They will be the best information for implantable devices or other HBO safety issues that may impact inclusion/exclusion
- Establish the off-hours activation process ahead of time
- **SIM**

Informed Consent Process: Prior to Approval

- Establish who usually helps find an LAR in a trauma situation at your institution
  - Chaplain, Charge Nurse, Social worker, HUC?
- Walk through the order of LAR/Family Contact
  - For our institution, the coordinator will approach the LAR for consent AFTER the clinical team has made first contact.
- Know your Institution's Language Policy and Capacity Policy
  - Short forms, witnesses, ect.

Informed Consent Process: Prior to Approval

- Learn the LAR hierarchy for your state

  For example in MN it is:

  - ❖Healthcare agent previously appointed by the individual through a health care power of attorney;
  - ❖Spouse;
  - ❖Parents;
  - ❖Adult children;
  - ❖Adult siblings.

Informed Consent Process: Interpreter Services

- As part of you site-readiness, TALK TO YOUR INTERPRETERS
  - Present the study to the Interpreters PRIOR to paging them in the middle of the night.
  - Feedback we've gotten suggests that HOW a study is interpreted makes a difference.
  - Interpreters can be a key player in your acute consent process

Informed Consent Process: Know Your Study, Know Your Consent, Know Your Audience

- Be able to give a bit of context to the LAR about WHY we are doing this study
- Develop an “elevator speech” about the study, practice giving it to people NOT in the medical field to see how quickly you can get them to understand what you’d be asking them
- After reading through the consent, think about what questions someone might have and how you’d answer them
- Read through the FAQ section-the CCC does a GREAT job with this

Informed Consent Process: Know Your Study, Know Your Consent, Know Your Audience

- Understand that we are asking people to make a research decision in (possibly) the worst point in their life
- Be patient, calm, and willing to "go with the flow" of patient care
  - you may need to return multiple times and go over things more than once
- Understand that although you may be giving them a written consent, they are looking to you for the information they need to make a decision
- Verbally cover the required elements of informed consent

Informed Consent Process: After Randomization

- These consent situations are often chaotic, your consent note will tell the story of how consent was obtained. Jot down quick notes about the situation during (discreetly!) or right after the conversation
  - Who was present
  - How much time they had to consider
  - Any other “issues” that came up and how they were addressed
  - Interpreter or witness name, title if applicable

Informed Consent Process: After Randomization

- After randomization, circle back and check in with the family to see if they have additional questions/concerns
- Keep the LAR/family updated on where their loved one is in the protocol and what steps will be next-this is part of the consent PROCESS and a key element to maintaining a good relationship for the study follow-up
- Should the subject regains capacity to consent, they should be given the opportunity to consent to continue to participate or withdraw

THANK YOU!

- Questions?
- Additions?