A Few Housekeeping Notes

• Q&A time will follow presentation

• During the presentation, use the chat box in WebEx to ask questions

• Please remain muted unless you need to speak. This minimizes background noise.

• When you speak, please identify yourself by name and work area to help others recognize you.

• This WebEx is being recorded and will be posted on the CTSI website
Welcome to Duke CTSI Grand Rounds

May 16, 2019
Moderated by L. Ebony Boulware, MPH, MD
Director, Duke CTSI

Please note that you have been muted upon entry to this WebEx.
Click the microphone by your name in the participant list to unmute as needed.

This presentation is being recorded.
Duke Early Phase Clinical Research conducts high quality and innovative early phase research to accelerate the availability of therapies, diagnostics, and medical devices to improve the health of every human being.
Duke Early Phase Clinical Research (DEPRU): Structure and Definitions

- DEPRU is a SOM Clinical Research Unit
- Duke clinical research institute
  - Unit
  - Supporting services (data management, stats, clinical study report, monitoring)
- CTSA
  - Participant and Clinical Interaction (PCI) core
- Early phase trials
  - First in human
  - Proof of concept
  - Phase 2/3 with intense procedures/confinement
  - Studies requiring rapid recruitment of large cohorts
  - Device/new technology studies
Duke Early Phase Clinical Research (DEPRU): What is our differentiator?

- One of the largest early phase clinical research units in the US
- Generate regulatory-grade data for submission to FDA
- Infrastructure to evaluate new molecules, devices, tech for first time in humans
- Systems and safety checks in place for high intensity/risk research
Early Phase Unit:
Standard and specialized studies

Standard
- Phase 1
- First-in-human
- Escalating dose
- Bioavailability/bioequivalence
- Drug-drug interaction
- Food effect

Specialized
- Phase 0
- Proof-of-concept
- Patient/hybrid studies
- Invasive procedures/monitoring
- Innovative PD endpoints (EEG, biomarkers)
- Device/app validation
- Imaging Studies (CT, echo, MRI)
- Endotoxin
- Pediatrics/geriatrics
- Sleep
Early Phase Unit: Leadership

**Faculty Director**
Michael (Micky) Cohen-Wolkowiez, MD, PhD
Early phase, ID, clinical pharmacology, pediatrics

**Associate Faculty Director**
Jeff Guptill, MD, MA, MHS
Early phase, neurology, neuromuscular disease

**Director of Operations**
Donna Hamel, RCP, FAARC, FCCM
Early phase, pulmonary, pediatrics
Early Phase Unit:
Operational groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Name</th>
<th>FTEs</th>
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<tbody>
<tr>
<td>Research Coordinators</td>
<td>Meg Stewart</td>
<td>8</td>
</tr>
<tr>
<td>Recruitment</td>
<td>Nick Eberlein</td>
<td>4</td>
</tr>
<tr>
<td>Laboratory/Project Management</td>
<td>Lynn Jordan</td>
<td>6</td>
</tr>
<tr>
<td>Nursing</td>
<td>Debra Freeman</td>
<td>10</td>
</tr>
<tr>
<td>Nutrition</td>
<td>Aramark</td>
<td>2</td>
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</tbody>
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Early phase research unit supported by 42+ highly-skilled operational professionals
Early Phase Unit: State-of-the-art space (industry standard and SOPs)

- High intensity and procedure heavy
- Confinement (34 beds) and cohorts
- 24/7 emergency medical personnel
- Wireless ECG telemetry
- Investigational pharmacy on site
- Laboratory collection, processing, analysis
- Metabolic kitchen
- Pulmonology function laboratory: ALA certified Respiratory Therapists
- Human Physiology Lab
  - On-site anesthesiologist
  - Invasive and non-invasive hemodynamic monitoring
Early Phase Unit Experience:
By the numbers (average per year)

- 70 active studies
- 3,000 outpatient visits
- 300 confinement visits
- 18,200 lab samples processed
- 1,500 meals served
- ~5 audits
  - ~50 since inception
Early Phase Unit Experience: Adult Trials by Health Status (2012 – 2018)
Early Phase Unit Experience: Adult Trials by Funding Source (2012 – 2017)
Early Phase Unit Experience:
Adults Trials by Study Phase (2012 – 2017)
Early Phase Unit: How do we support research teams?

- **DEPRU leads**
  - Study is run through our CRU (financial and regulatory oversight)
  - DEPRU staff executes in partnership with investigator (PI can be investigator)
  - Best fit
    - Phase 1 cohort studies
    - Heavy confinement/procedures
    - If more than 2 DEPRU services

- **DEPRU supports**
  - Study is run by PI’s CRU
  - Outside CRU staff executes in partnership with DEPRU (PI is investigator)
    - DEPRU provides ‘a la carte’ services
  - Best fit
    - Occasional confinement, small patient studies
Early Phase Unit: How do we support research teams?

- Investigator Advocate
  - Single point of contact
  - Partners with study teams to assure optimal support

- ‘a la carte’ services based on specific needs
  - Laboratory services with newly operational safety lab analysis capabilities
  - Recruitment / advertising
  - Nursing services
  - Confinement
  - Pulmonary function laboratory
Early Phase Unit: How do we support research teams?

- Broad support of Duke Investigators
  - ~40% of DEPRU visits support Duke PI studies
  - 18 CRUs utilized our unit since inception

- Early studies of Duke IP/contracts (examples)
  - Drug for traumatic brain injury (Cerenova, Danny Laskowitz)
  - Duke Vaccine Treatment Unit (NIH DVTU, Chip Walter / Geeta Swamy)
  - Antibiotic Resistance Leadership Group (NIH ARLG, Vance Fowler)
  - Neuro Phase 1 CTU (NIH NINDS, Jeffrey Guptill)
  - Anti-infectives Phase 1 CTU (NIH NIAID, Michael Cohen-Wolkowiez)
  - Baseline Study (Verily Lifesciences, Svati Shah)
  - Non-pharmacological interventions for pain (Steve George)
Early Phase Unit: How do we support research teams?

- Early phase clinical research training program
  - Track A: 6 months to 2 years
    - Target: MDs (fellows), PharmDs (fellows)
    - Training completed: 4 MDs
  - Track B: 4 weeks
    - Target: Students in PA, RN, MD, PharmD (Campbell), NCCU schools
    - Training completed: 3 PAs, 2 RNs (hired as CRC after training)
    - Anticipated FY19: 4 PharmD (05/19), 2 PA (Q4/19)
Early Phase Unit: We want to work with you!

- Product development
  - Science, regulatory pathway
- Clinical study design and feasibility
  - Safety, early efficacy, clinical pharmacology, bioanalysis
- Clinical study execution
  - DEPRU leads or supports, project management, core laboratory
- Contact me or Donna directly!
Thank you!

Please join us for our next Grand Rounds:

**Pilot Programs**

July 18, 2019 | 12:00 p.m.