UW Health Compliance Committee

January 19, 2023, 5:00 - 6:30 PM

Via WebEx: https://uwhealth.webex.com/uwhealth/j.php?
MTID=m665a52122a1743c23cfafce1cf931811

Meeting Number: 2620 507 0994 // Password: 011923
Telephone: +1-415-655-0003 US TOLL // 2620 507 0994

**ADVANCE MEETING MATERIALS ARE POSTED FOR REFERENCE. OCCASIONALLY, THE
POSTED MATERIALS DO NOT REFLECT CHANGES MADE SHORTLY BEFORE OR DURING
COMMITTEE MEETINGS. THE FULL COMMITTEE MINUTES ARE THE OFFICIAL RECORD OF
FINAL COMMITTEE ACTION**
## UW Health Compliance Committee - January 19, 2023 - Public Meeting Notice

### Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter(s)</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>5:00 PM</td>
<td>I. Call to Order and Chair Announcements</td>
<td>Regent Mike Jones</td>
<td>Approval</td>
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<tr>
<td>5:01 PM</td>
<td>II. Meeting Minutes - Open Session</td>
<td>Regent Mike Jones</td>
<td>Informational</td>
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<tr>
<td>5:02 PM</td>
<td>III. UW Health Corporate Compliance</td>
<td>Mr. Troy Lepien</td>
<td>Informational</td>
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<tr>
<td></td>
<td>Presentation - UW Health Corporate Compliance</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>5:07 PM</td>
<td>IV. Research and Clinical Trials at UW Health</td>
<td>Ms. Betsy Nugent, Ms. Nancy Lutz</td>
<td>Informational/Discussion</td>
</tr>
<tr>
<td></td>
<td>Presentation - Research and Clinical Trials at UW Health</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>5:22 PM</td>
<td>V. Closed Session</td>
<td></td>
<td>(Materials Available To Members Only)</td>
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<tr>
<td></td>
<td>Motion to enter into closed session pursuant to Wisconsin Statutes section 19.85(1)(e), for the discussion of confidential strategic matters that for competitive reasons require a closed session, and Wisconsin Statutes section 146.38, for the review and evaluation of health care services, including but not limited to discussion of compliance matters including corporate, reimbursement, pharmacy, and privacy; and pursuant to Wisconsin Statutes section 19.85(1)(g) to confer with legal counsel regarding these and other matters.</td>
<td></td>
<td>6:30 PM</td>
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6:30 PM  VI. Adjourn
Article of Interest

Clinical Trials at UW

Betsy Nugent, MSPH, CCRP
Chief Clinical Research Officer

Clinical Research Office
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH

UWHealth
Defining UW Clinical Trials

Departmental research professionals, CRO Research staff

IRB, OVCRCGE, Contracting, Legal

Systems, Providers, Patients

UW Health

SMPH

UW Clinical Trials Enterprise

UW-Madison
Collaborative Decision-Making

Clinical Trials Leadership Team

Direct reports to CCRO and Key Infrastructure leaders from Departments/CRO/ICTR/UW Health/Compliance/Quality/Strategy

Clinical Trials Advisory Board

Clinical Research Chiefs, VCRGE and key stakeholders

Clinical Trials Tactical Workgroups

Departmental research leaders; Research process owners; Operational staff; Members of the Clinical Trials Leadership Team
Clinical Trials at UW

UW conducts all types of clinical trials

• Therapeutic and exploratory
• All phases (1-4)
• FDA regulated-Investigational New Drugs (INDs) and Investigational Device (IDE)
• Single patient use/Emergency Use/Expanded Access (patient treatment)
• Comparative Effectiveness
• Pragmatic Clinical Trials
Clinical Trial Phases

**Laboratory or “Bench Research”**
- May use animal models to understand what may happen in humans

**Phase 1**
- Small study in humans
- Safety and dosing
- Several months

**Phase 2**
- Larger study
- Safety and dosing and early effectiveness
- Months to years

**Phase 3**
- Largest studies
- Study effectiveness and side effects
- Several thousand

**Phase 4**
- Surveillance
- Longer term data on effectiveness and side effects

8-15 years
Study Conduct

• Studies are mainly conducted within UW Health or the Clinical Research Unit (also within University Hospital)
• They may be conducted within clinical spaces or in research only space depending on clinical trial
• Specialized research personnel to ensure compliance with both study protocol and regulations
  • Certified Clinical Research Coordinators
  • Clinical Research Coordinators
  • Clinical Nurse Specialists
  • Research Nurses
• Human Research Protection Program (HRPP)-oversees ethical conduct of research on human subjects
Compliance

• All clinical trials, including Investigator Initiated, are subject to federal regulations related to the conduct, patient safety and documentation.

• Additionally, Center for Medicare Services (CMS) has research billing compliance rules for clinical trials.

• Clinical trials must follow Good Clinical Practices (GCP).

• Institution needs policies and procedures to ensure compliance with regulations.

• FDA, OHRP and OIG may audit clinical trials and may leverage fines/pursue legal actions.
### Clinical Trial Revenue
(Total Revenue from Deposits, Number of Deposits)

<table>
<thead>
<tr>
<th>Year</th>
<th>Clin Trial Amount</th>
<th>Clin Trial Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2018</td>
<td>1,651</td>
<td>2,000</td>
</tr>
<tr>
<td>FY 2019</td>
<td>1,786</td>
<td>1,500</td>
</tr>
<tr>
<td>FY 2020</td>
<td>1,957</td>
<td>1,000</td>
</tr>
<tr>
<td>FY 2021</td>
<td>1,931</td>
<td>500</td>
</tr>
<tr>
<td>FY 2022</td>
<td>2,227</td>
<td>0</td>
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</table>

### Clinical Trial Dollars

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<tr>
<th></th>
<th>FY 2018</th>
<th>FY 2019</th>
<th>FY 2020</th>
<th>FY 2021</th>
<th>FY 2022</th>
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<tbody>
<tr>
<td>Federal</td>
<td>$14,528,360</td>
<td>$14,547,545</td>
<td>$18,363,725</td>
<td>$17,397,688</td>
<td>$24,132,890</td>
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<tr>
<td>Industry</td>
<td>$1,554,132</td>
<td>$1,270,428</td>
<td>$1,538,336</td>
<td>$1,684,343</td>
<td>$1,771,679</td>
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<tr>
<td>Total</td>
<td>$16,082,492</td>
<td>$15,817,974</td>
<td>$19,902,061</td>
<td>$19,082,031</td>
<td>$25,904,569</td>
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*Data Analysis provided by Bridget Montour*
Questions?

Betsy Nugent enugent2@wisc.edu