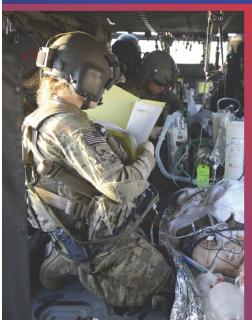
## Innovations in Technologies to Extend the Golden Hour





An interagency workshop to propel innovative solutions for military and civilian trauma and emergency care



March 21 - 22, 2019

**Natcher Conference Center** 

National Institutes of Health Bethesda, MD 20892







# The National Institute of Biomedical Imaging and Bioengineering (NIBIB), the Uniformed Services University of the Health Sciences (USUHS), and the Food and Drug Administration (FDA) welcome you to:

### Innovations in Technologies to Extend the Golden Hour

An interagency workshop to propel innovative solutions for military and civilian trauma and emergency care

The National Institute of Biomedical Imaging and Bioengineering, the Uniformed Services University of the Health Sciences, and the Food and Drug Administration welcome you to the first workshop "Innovations in Technologies to Extend the Golden Hour" to discuss bioengineered solutions for improved diagnostic treatment of acute injuries and shock. The purpose of this meeting is to link nascent bioimaging and bioengineered solutions with the needs of the Departments of Defense and Health and Human Services, while offering an opportunity for subject matter experts to gather and determine the state of the science and regulatory policy in critical care trauma and resuscitation while discussing current and future research efforts that will lead to concrete solutions.

We look forward to your interactive participation throughout these two days. Enjoy the meeting!

COL Todd E. Rasmussen, MD, Uniformed Services University (USU), Walter Reed National Military Medical Center

Šeila Selimović, PhD, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

Heather Agler, PhD, Food and Drug Administration (FDA)

#### With Gratitude to the Members of the Steering Committee:

Neil Aggarwal, PhD, NIH/NHLBI Manfred Boehm, PhD, FDA Khaled Bouri, PhD, FDA Jeremy Brown, MD, NINDS COL Kevin Chung, MD, USUHS COL Michael Davis, MD, CCCRP RADM (ret) Bruce Doll, PhD, USUHS Anthony Garza, PhD, FDA
COL Matthew Hepburn, MD, DARPA
Andrei Kindzelski, MD/PhD, NHLBI
Todd Merchak, NIBIB
Marcello Pilia, PhD, USU/HJF
George Sopko, MD, NHLBI
Justin Yang, MBA, BARDA

#### **And Thanks for Additional Support From:**

Henry M. Jackson Foundation for the Advancement of Military Medicine

















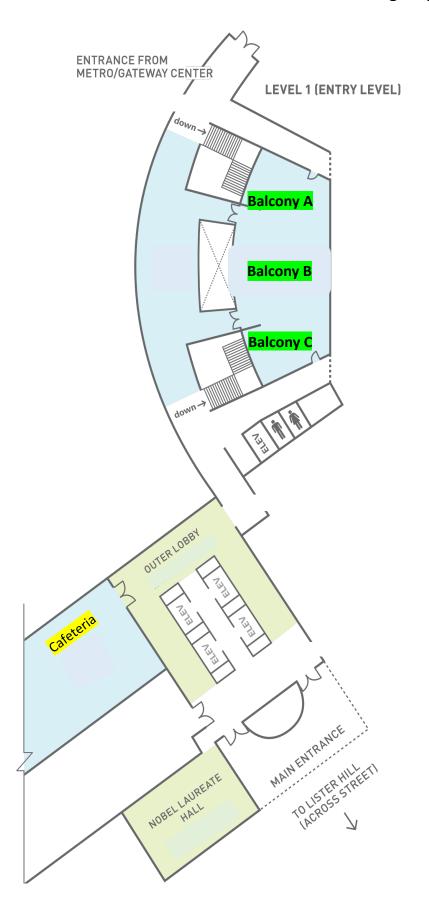


| AGENDA: March 21, 2019 |  |  |  |  |  |  |
|------------------------|--|--|--|--|--|--|
| 0800 – 0830            | Registration   |  |  |  |  |  |
| 0830 – 0900            | Welcoming Remarks and Introductions  |  |  |  |  |  |
| 0830 – 0845            | Bruce Tromberg, PhD – Director, NIBIB  |  |  |  |  |  |
| 0845 – 0900            | Arthur Kellermann, MD, MPH – Dean of the School of Medicine, USUHS   |  |  |  |  |  |
| 0900 – 1200            | SESSION I – Introduction   |  |  |  |  |  |
| 0900 - 0920            | Current status and needs in managing severe injuries and shock – the civilian perspective Thomas Scalea, MD – Physician-in-Chief, Adams Cowley Shock Trauma Center, University of Maryland |  |  |  |  |  |
| 0920 - 0925            | Questions and Answers with Dr. Scalea  |  |  |  |  |  |
| 0925 – 0945            | Current status and needs in managing severe injuries and shock – the military perspective Col Todd Rasmussen, MD – Vice-Dean of Research, School of Medicine, USUHS                        |  |  |  |  |  |
| 0945 - 0950            | Questions and Answers with Dr. Rasmussen   |  |  |  |  |  |
| 0950 – 1010            | Status of related research supported by NIH  Jeremy Brown, MD – Office of Emergency Care Research, NIH   |  |  |  |  |  |
| 1010 – 1015            | Questions and Answers with Dr. Brown   |  |  |  |  |  |
| 1015 – 1100            | Break & Networking   |  |  |  |  |  |
| 1100 – 1130            | Status of related research supported by DOD agencies Col Michael Davis, MD – Director, Combat Casualty Care Research Program   |  |  |  |  |  |
| 1130 – 1200            | FDA Guidance Michael Hoffman, MS – Deputy Director, Neurological and Physical Medicine Devices, FDA  |  |  |  |  |  |
| 1200 – 1300            | Lunch & Networking   |  |  |  |  |  |
| 1300 – 1500            | SESSION II – Up-and-Coming Technologies from Current Research  |  |  |  |  |  |
| 1300 – 1315            | Clinically Informed Wound Repair Biomaterials: Chemistry and Engineering Mark Grinstaff, PhD – Boston University   |  |  |  |  |  |
| 1315 – 1330            | Imaging – Ultrasound for Emergency Medicine Will Mauldin, PhD – Rivanna Medical  |  |  |  |  |  |
| 1330 – 1345            | Organ support, polytrauma, acute respiratory diseases syndrome Andriy Batchinsky, MD – US Army Institute of Surgical Research (USAISR)   |  |  |  |  |  |
| 1345 – 1400            | Radiobiology – Radiation Exposure CAPT John Gilstad, MD – Armed Forces Radiobiology Research Institute (AFRRI)   |  |  |  |  |  |

| 1400 – 1415                | Biosensors<br>Shalini Prasad, PhD – University of Texas, Dallas   |   |   |   |   |  |  |  |
|----------------------------|---|---|---|---|---|--|--|--|
| 1415 – 1430                | Hemostatic Medical Devices John Holcomb, MD – University of Texas, Houston                                    |   |   |   |   |  |  |  |
| 1430 – 1445                | Biosensors<br>Natalie Wisniewski, PhD – Profusa   |   |   |   |   |  |  |  |
| 1445 – 1500                | Laser Optical Diagnostics  Matthew Brenner, MD – University of California, Irvine                             |   |   |   |   |  |  |  |
| 1500 – 1515                | Break & Networking  |   |   |   |   |  |  |  |
| 1515 – 1645                | SESSION III – Working Session I: Breakout Session   |   |   |   |   |  |  |  |
| 1515 – 1645                | Extracorporeal<br>Organ Support<br>Technologies   | Radiation<br>Exposure / Burn<br>and Wound<br>Healing  | Hemostatic<br>Medical<br>Devices  | Portable<br>Imaging<br>Technologies                                       | Wearable<br>biosensors  |  |  |  |
| Discussion lead            | Jennifer Gurney<br>(USAISR)   | Eric Elster<br>(USUHS)  | Craig Goolsby<br>(USUHS)  | Matt Hepburn<br>(DARPA)   | Justin Yang<br>(BARDA)  |  |  |  |
| Discussion<br>participants | Kevin Chung (USUHS)  George Sopko (NHLBI)  Fernando Aguel (FDA)  Nicole Gillete (FDA)  Claire Hambright (FDA) | David Rampulla (NIBIB)  George Zubal (NIBIB)  Narayan Iyer (BARDA)  Lixin Liu (FDA)  Laura Marquart (FDA) | Michael<br>Dubick<br>(USAISR)<br>Traci<br>Mondoro<br>(NHLBI)<br>Kira Moore<br>(FDA) | Andrew Hersh, Vincent Ho (USUHS) Randy King (NIBIB) Jeffrey Ballyns (FDA) | Michael Davis<br>(CCCRP)<br>Christian<br>Hartshorn (NCI)<br>Šeila Selimović<br>(NIBIB)<br>Linda Ricci (FDA) |  |  |  |
| 1645 – 1700                | Summary & Adjournment of Day 1  |   |   |   |   |  |  |  |
| 1800 – 2030                | Conference dinner   |   |   |   |   |  |  |  |

| AGENDA: March 22, 2019     |   |  |  |   |   |  |  |
|----------------------------|---|--|--|---|---|--|--|
| 0800 – 0830                | Registration  |  |  |   |   |  |  |
| 0830 - 0845                | Welcoming Remarks and Outline for the day   |  |  |   |   |  |  |
| 0845 – 1100                | SESSION IV – Working Session II: Conclusion   |  |  |   |   |  |  |
| 0845 – 1015                | Extracorporeal<br>Organ Support<br>Technologies   | Radiation<br>Exposure / Burn<br>and Wound<br>Healing   | Hemostatic<br>Medical<br>Devices                               | Portable<br>Imaging<br>Technologies                                       | Wearable<br>Biosensors  |  |  |
| Discussion lead            | Jennifer Gurney<br>(USAISR)   | Eric Elster<br>(USUHS)   | Craig Goolsby<br>(USUHS)                                       | Matt Hepburn<br>(DARPA)   | Justin Yang<br>(BARDA)  |  |  |
| Discussion<br>participants | Kevin Chung (USUHS)  George Sopko (NHLBI)  Fernando Aguel (FDA)  Nicole Gillete (FDA)  Claire Hambright (FDA)   | David Rampulla<br>(NIBIB)<br>George Zubal<br>(NIBIB)<br>Narayan Iyer<br>(BARDA)<br>Lixin Liu<br>(FDA)<br>Laura Marquart<br>(FDA) | Michael Dubick (USAISR) Traci Mondoro (NHLBI) Kira Moore (FDA) | Andrew Hersh, Vincent Ho (USUHS) Randy King (NIBIB) Jeffrey Ballyns (FDA) | Michael Davis<br>(CCCRP)<br>Christian<br>Hartshorn (NCI)<br>Šeila Selimović<br>(NIBIB)<br>Linda Ricci (FDA) |  |  |
| 1015 – 1030                | Break & Networking  |  |  |   |   |  |  |
| 1030 – 1100                | Readout of the Roundtable Summaries   |  |  |   |   |  |  |
| 1100 – 1215                | SESSION V - Closing Session   |  |  |   |   |  |  |
| 1100 – 1200                | Panel Discussion: Challenges in the Development and Translation of New Technologies   |  |  |   |   |  |  |
| Panel lead                 | Šeila Selimović (NIBIB)   |  |  |   |   |  |  |
| Panelists                  | Bruce Doll (USU), Jeremy Brown (NINDS), Michael Davis (CCCRP), Jacqueline Gertz (FDA),<br>Justin Yang (BARDA), Matt Hepburn (DARPA), Todd Merchak (NIBIB) |  |  |   |   |  |  |
| 1200 – 1215                | Summary & Adjournment of Workshop   |  |  |   |   |  |  |

#### Natcher Conference Building map - Level 1



Sessions III, IV:

Extracorporeal Organ Support Technologies:

Balcony A

Radiation Exposure / Burn and Wound Healing:

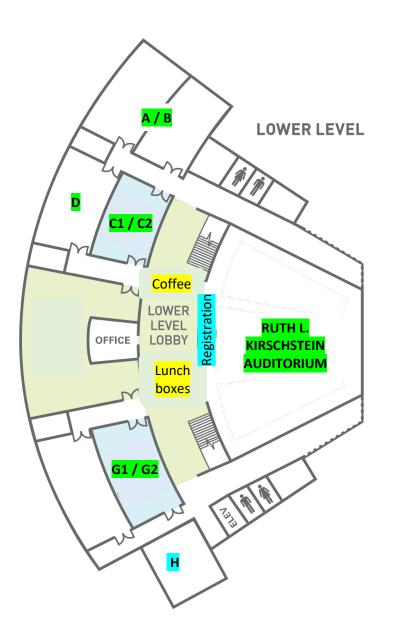
Balcony B

**Hemostatic Medical** 

**Devices**:

Balcony C

#### Natcher Conference Building map – Lower level



Sessions I, II, V, readout of the roundtables:

Ruth L. Kirschstein Auditorium

Sessions III, IV:

Wearable Biosensors: Room A/B

**Portable Imaging Technologies**:
Room D

Lounge / Luggage and Work Space: Room H

#### Logistics

#### Check-in

Check-in will begin at 0800 on both meeting days.

#### Wireless access

Wireless internet is free and can be accessed using the network **NIH-Guest**.

#### Food

Food and drinks cannot be brought into the auditorium. You can purchase snacks or lunch at the Natcher cafeteria, which is open from 0630 to 1430, and the Natcher concession stand, open from 0700 to 1530.

You can also purchase lunch ahead of time here:

https://eurestconferencecatering.catertrax.com/

Pre-ordered lunch boxes will be ready for pick-up outside the Natcher Auditorium. Coffee and snacks during the breaks will be available in front of Balconies A and C.

#### **Conference dinner**

Shangri-La Nepalese and Indian Cuisine 7345-A Wisconsin Ave, Bethesda, MD 20814 March 21, 2019: 1800 – 2030

Those who signed up for the dinner should plan to arrive at the restaurant in downtown Bethesda the evening of Day 1, March 21, 2019 by 1830. If you are waitlisted, please check additional availability at the registration desk.

The restaurant is a short walk away from the Bethesda Metro Station (about 25-minute walk from the NIH campus). Parking is available in public garages nearby. The buffet price is \$30 and includes one meal per person with a glass of wine or beer (and tax and tip). Please bring cash, if possible.

#### **Transportation**

Please allow adequate time to get to the NIH main campus and to get through security at the NIH Gateway Center Entrance. You will need to state the purpose of the visit and obtain a visitor's badge, so please bring a government-issued photo ID (driver's license, passport, green card, etc.). Please allow 20-30 minutes for taxis, Uber or Lyft to arrive and ask to be picked up at the MEDICAL CENTER METRO STATION.

#### Lounge

Room H in the basement of Natcher Conference Center is available for work, phone calls, and to store your luggage.