# TAP Leadership - Johns Hopkins University

## ICTR
- **Daniel E. Ford, MD, MPH**
  - Director, Johns Hopkins Institute for Clinical and Translational Research (ICTR)
  - David M Levine Professor of Medicine

- **Charles Flexner, MD**
  - Chief Scientific Officer for Strategy and Integration

- **Craig Hendrix, MD**
  - Deputy Director, Translational Sciences Core

- **Liz Martinez, RN, BSN, CCRC**
  - Advocate Senior Clinical/Research Liaison

## BIOS
- **Daniel F. Hanley, MD**
  - Director, BIOS Clinical Trials Coordinating Center
  - ICTR Deputy Director for Support & Innovation in Multi Center Trials, Principal Investigator

- **Karen Lane**
  - Deputy Director, BIOS Clinical Trials Coordinating Center
  - Trial Coordination

- **Nichol McBee**
  - Executive Director, BIOS Clinical Trials Coordinating Center
  - Data Coordination and Quality

- **Angeline Nanni & Jessica Baird**
  - Consult Navigators

## CCTES
- **Douglas Jabs, MD, MBA**
  - Director, Center for Clinical Trials and Evidence Synthesis

- **Amy Zemanick**
  - Research Program Manager
Overview of the ICTR Trial Advisor Program (TAP)

Composed of 3 key organizational partners
ICTR, BIOS, a JHU-based academic research organization, and
Center for Clinical Trials and Evidence Synthesis (CCTES)

- The TAP is committed to facilitating the development of investigative expertise and invite all investigators, including K-grant, T-grant, and other early career investigators, to participate.
- The TAP works with trials funded by the NIH, commercial sponsors, foundations, and other.
Purpose of the TAP

To support and advise all JHMI Principal Investigators in all departments, in all disease areas in their clinical trial pursuits
The TAP provides expert consultative support to investigators with small, local multi-center translational studies needing to:

1. **Improve** research study design, trial operations, and analysis plans

2. **Explore** opportunities for single and multi-center trial innovation

3. **Commit** to diversity and community engagement in clinical trials

4. **Assess** translational pathway and readiness for multi-center trials

5. **Provide** strategic assistance with grant applications

6. **Develop** and improve the overall stewardship, efficiency, accountability, and transparency of clinical trials.
TAP Strategies

- Develop a portal for local investigative teams to access trial development resources available within the CTSA
- Formalize the strategic organization of trial planning by integrating team’s study development with the appropriate CTSA cores and CRUs
- Provide learning and mentoring opportunities for young investigators (K and T awardees)
- Develop relationships with University of Maryland, Kaiser Permanente, and Morgan State University to expand research opportunities
- Collect TAP metrics to gauge program success
Requests/Resources

Requests
- Study Design
- Study Budget
- Projected Timelines
- Recruitment Feasibility Assessment
- Study Feasibility
- Comparative Effectiveness

Resources
- Single IRB
- Standard Agreements
- Recruitment and Retention Plan
- Community Engagement Studio
- EHR-Based Cohort Assessment
  — PCORNet, TriNetX
Addressing Barriers to Clinical Research within the Trial Advisor Program

**BARRIERS**

- Flawed design
- Inefficient conduct
- Lack of stakeholder engagement
  - Eligibility criteria too burdensome
- Start-up delays, e.g. IRB review, contract execution
- Fragmented operating models
  - Infrastructure rebuilt
- Recruitment challenges
  - Long timelines, altered study designs
- High costs of data collection & management
  - Inadequate data collection & management

**TAP OPPORTUNITIES**

- Consultations with local clinical trial, disease, statistical, and recruitment experts
- Specialized support from the Recruitment Innovation Unit
- JHM Single IRB coordination, Standard Agreement toolkits
- Referral to ICTR resources/cores for Clinical Coordinating Center, Data Coordinating Center, and Recruitment/Retention Planning depending on investigator needs (see ICTR website)
Johns Hopkins/Maryland ICTR TAP Consultations

114 Consultations Requested of the TAP from 2018 to 2023

Trial Advisor Program Consults by Year 2018-2023

- 2018: 8
- 2019: 14
- 2020: 24
- 2021: 29
- 2022: 15
- 2023: 24

Data downloaded on 3/17/2024
TAP Proposals by Therapeutic Areas

- Anesthesiology
- Cardiology
- Emergency Medicine
- Gynecology and Obstetrics
- Gastroenterology
- Infectious Disease
- Orthopedic
- Pediatric
- Biomedical engineering
- Psychiatry and Behavior Sciences
- Epidemiology
- International Health
- Neurology
- Otolaryngology
- Oncology
- Plastic and Reconstructive surgery
- Radiology
- Urology
- Rheumatology
- Internal medicine
- Other

TAP largest # of consults
1. Neurology
2. Psychiatry and Behavior Sciences
3. Gastroenterology
TAP initial consultation satisfaction surveys began May 2021.

Average Likert score of returned surveys: 9.48
TAP Triage for JHU Investigators

Request a TAP consult via the ICTR website

5 business days to schedule an initial consult

Initial consult is a 1 to 2-hour meeting with content appropriate experts
Follow-up meetings may occur; consultation will be completed within 30-60 days

TAP results could include

- TAP Comprehensive Consultation
  - Referred to utilize BIOS infrastructure will evaluate potential collaboration and a shared funding application

- Referral to ICTR Studio
  - A master class to help investigators improve the quality and impact of their research

- Referral to specific ICTR cores
  - Referral to locally support specific proposal needs (fee and non-fee based support)

- Referral to TIN for consultation
  - Referral to nationally support specific proposal needs

- No further support
  - Initial Consultation satisfies all needs; no further support is requested/needed
In conclusion... Contact us: TAPTeam@jhu.edu

• It Takes a Village!
  — Services are at ‘no cost’ to Hopkins Investigators
  — Consider applying or referring investigators to request a TAP consult

• Team approach to success!
  — TAP (and ICTR) Goal:
    “Clinical trials are tough and we want to support investigators to ensure successful trials.”
How to Apply to the TAP

The Trial Advisor Program (TAP), formerly known as the Trial Innovation Unit (TIU), is a service powered by the ICTR, the BIOS CTCC and the CCTES.

Attend the next Third Thursdays with the ICTR March 21 at 2:00 pm to learn more about TAP! Register.
Please use the QR Code to Complete the survey