SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-04S2.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

January 2022: **A Conversation with NIH and OHRP about Single IRB**

February 8 & 10, 2022: ***Single IRB Boot Camp: A How-To-Guide with SMART IRB***

FYIs

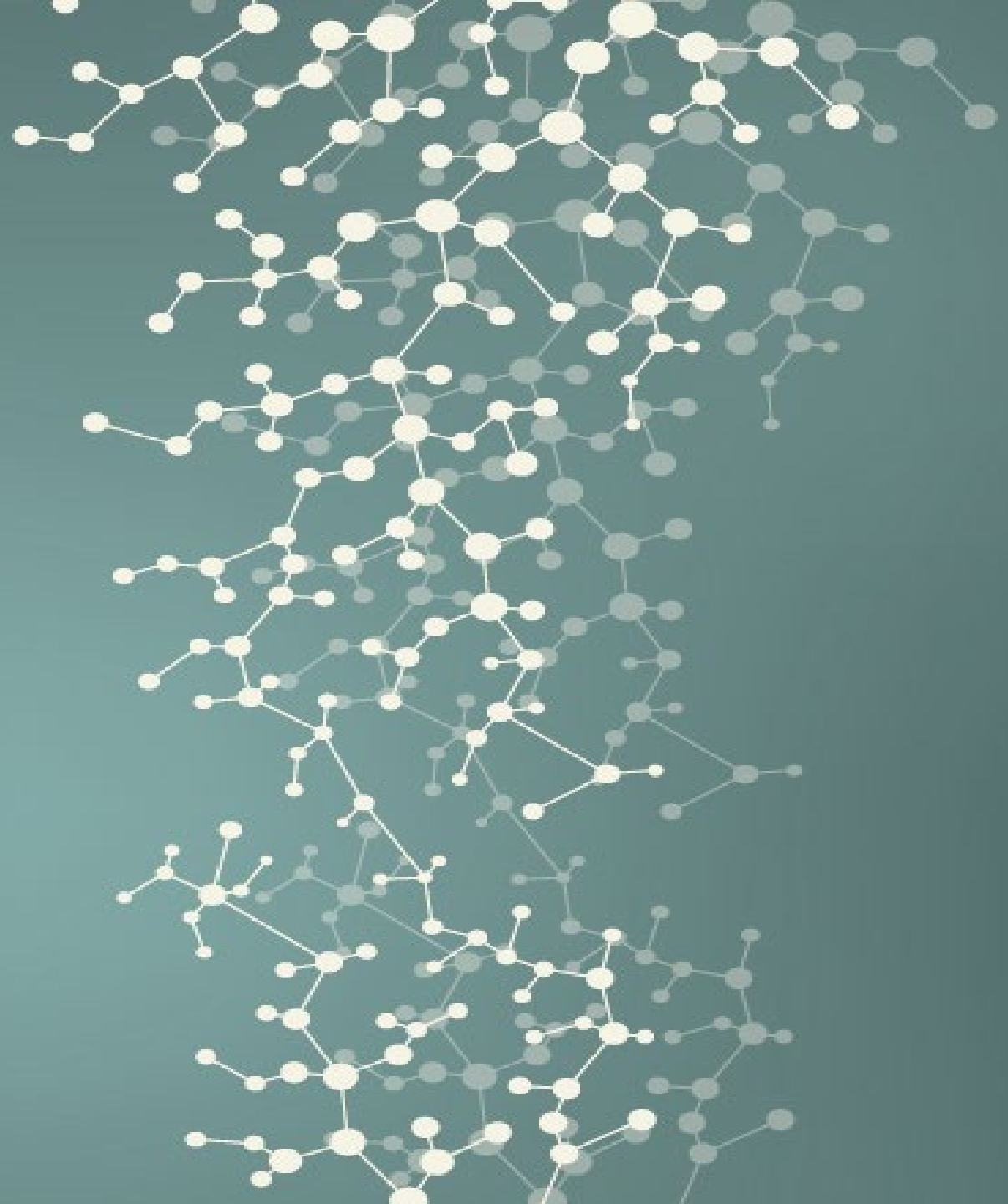
Please provide feedback by completing the survey – a link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

SMART IRB Updates



Harmonization Steering Committee Recommendations

- Ancillary Review NEW!
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance

When You're Not the Reviewing IRB - Impact of Using External IRBs on Organizations

- **Elizabeth Buchanan**, Director, Research Services, Research Scientist and Coordinator of Medical Ethics, Marshfield Clinic Health System
- **Geo Estronza**, Manager, Regulatory Affairs, Moffitt Cancer Center
- **Scott Lipkin**, Vice President for Research, Baptist Health South Florida; Chief Research Officer, Miami Cancer Institute

Moderator: Nichelle Cobb

SMARTIRB.org

SMART Talk
When you're not the reviewing IRB – The impact of Using External IRBs

Moffitt Cancer Center

Geo Estronza, MS, CIP

Manager, Regulatory Affairs

MOFFITT CANCER CENTER

Moffitt Cancer Center (1 of 4)

- **NCI Designated Cancer Center**
  - First Stage Review – each disease group will review and document approval into our CTMS
  - Feasibility Committee – to evaluate the viability of the studies
  - SRC Committee – 6 committees (3 medical, 1 behavioral/ 1 basic sciences/ 1 Multicenter ORIEN) reviews all New Studies and Protocol Amendments

- **Regulatory Affairs Department composition:**
  - Regulatory Manager and Supervisor – Training, QA and HR tasks
  - 3 Startup Regulatory Coordinators – to process new study IRB/SRC/IBC submissions (2 open positions)
  - 14 Regulatory Specialists (I, II, Sr. Levels) – to process maintenance IRB/SRC/IBC submissions (CR, Amendments, Modifications and reportable events, etc.) (2 open positions)

- **Moffitt's Regulatory Affairs Department covers all Human Research Protection issues/questions:**
  - NHSR Determinations are processed internally
  - Still IRB Exempt Determinations are processed internally
  - HSR Regulations/Guidance/Education
  - IRB Reliance Agreements

No Internal IRB or IBC, every study is reviewed by external IRBs/IBCs

Moffitt Cancer Center (2 of 4)

- **Volume of Studies at Moffitt as of 11/2021:**
  - Open to Accrual Studies (all) = 1, 381
  - Open to Accrual Tx Interventional Studies = 295
  - Closed to Accrual Studies (all) = 819
  - Closed to Accrual Tx Interventional Studies = 356

- **Volume of Moffitt's IRB Authorization Agreements as of 11/2021: 33**

Moffitt Cancer Center (3 of 4)

- **IRB Services used by Moffitt Cancer Center**
  - Commercial/Independent IRBs (We have Master Agreements with Western and Advarra)
  - Academic IRB – USF IRB
  - NCI IRB – only for NCI funded trials
  - Other Institutional IRBs as per single IRB requirements

- **Moffitt IRB Reliance Internal Process including SMART IRB:**
  - Single IRB Regulatory Staff Training – Single IRB Guidance (work in progress)
  - Centralized process: Regulatory Affairs Manager process and tracks all IRB Reliance Agreements, inside an outside of SMART IRB
  - When using SMART IRB – Online Reliance System is used but we also keep track of studies internally
  - SCR approval needs to be received in order to move forward
  - If the reviewing IRB is not AAHRPP accredited, additional justification needs to be provided
  - VP of Research approval/sign off is required for all IRB Reliance Agreements

Moffitt Cancer Center (4 of 4)

- **Moffitt's Challenges with our reliance process implementation:**
  - Our Regulatory Specialists act as the contact staff for IRB questions, so training is fundamental
  - Multiple platforms/policies/handbooks to follow, also different forms to complete depending on the IRB reviewing the study
  - Education and Training for new research staff and continuing education when there are new regulations or changes to current ones
  - Having multiple ICF templates and keeping track of changes
  - Workload coverage during staff turnover and communicating staff changes to all applicable IRBs
  - No Internal IRB staff to help with Institution's ICF templates, HIPAA and Injury Institutional Language, we need to go to our Legal, Privacy and COI contacts for guidance

Miami Cancer Institute
BAPTIST HEALTH SOUTH FLORIDA

SMART IRB | SMART Talk

December 15, 2021

Scott J Lipkin, DPM, CIP
Corporate Vice President of Research | Baptist Health South Florida
Chief Research Officer | Miami Cancer Institute
Scottli@baptisthealth.net

Baptist Health South Florida | Miami Cancer Institute

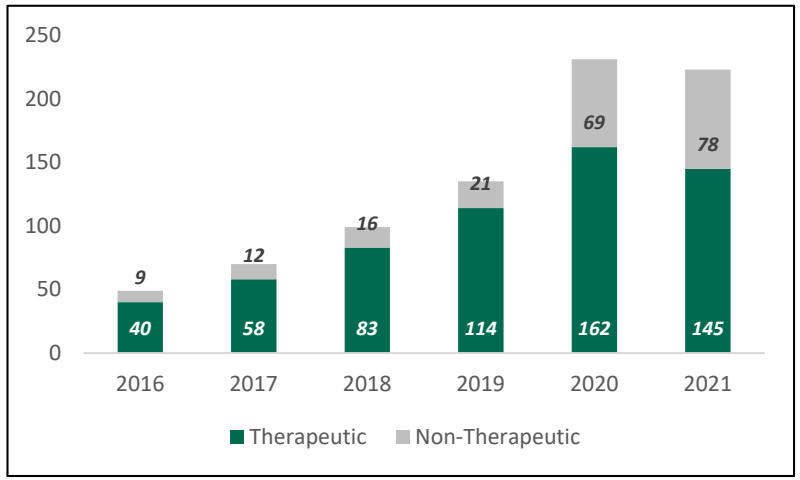
Baptist Health South Florida is the largest healthcare organization in South Florida with 12 hospitals, more than 24,000 employees, 4,000 physicians and 100 outpatient centers, urgent care facilities and physician practices spanning across Miami-Dade, Monroe, Broward and Palm Beach counties. Baptist Health has internationally renowned centers of excellence in cancer, cardiovascular care, orthopedics and sports medicine, and neurosciences.

MCI Snapshot of Human Research Activity (10.31.2021)

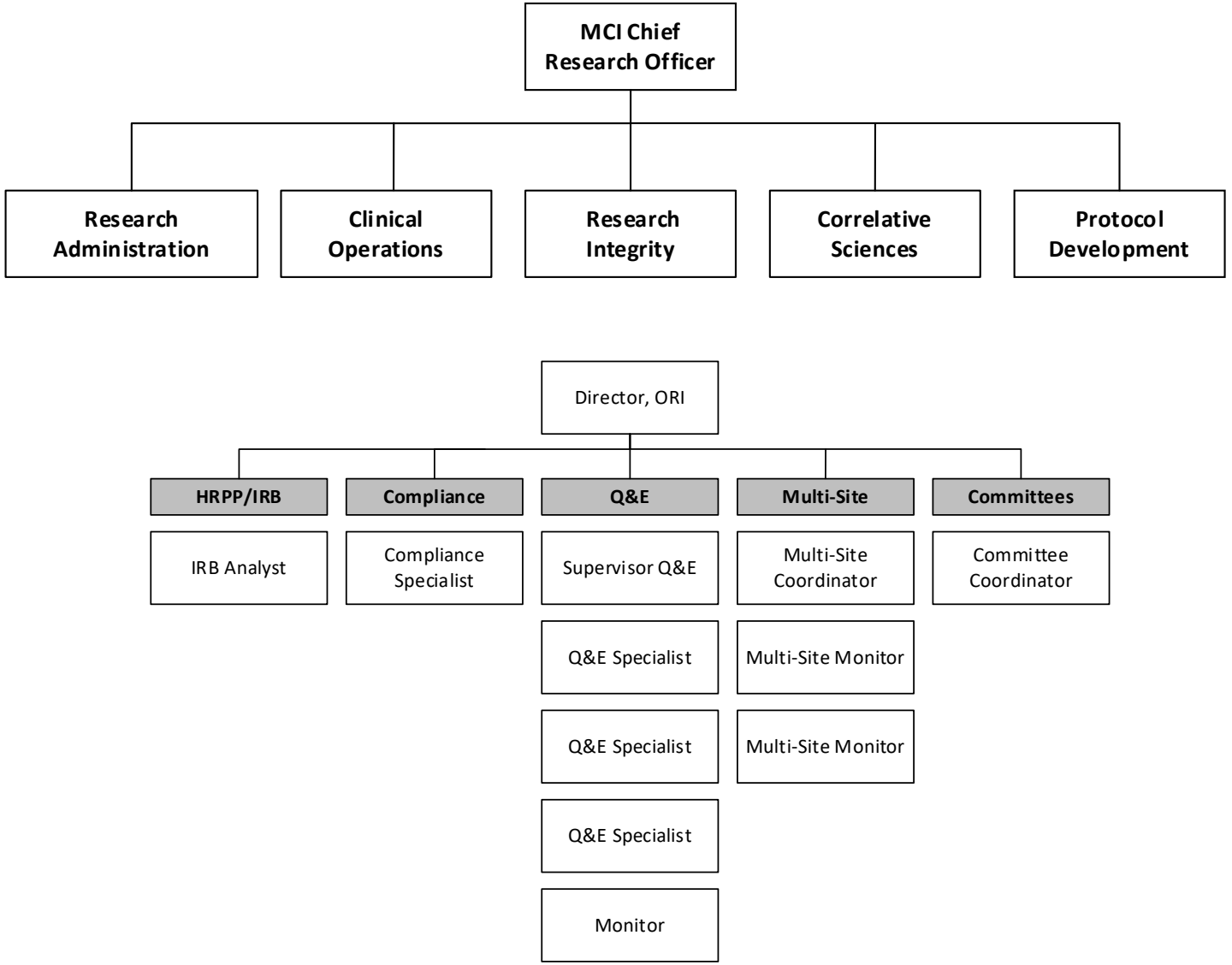
223 Active Human Research Studies

- 145 Therapeutic Studies
- 41 Non-Therapeutic Studies
- 37 Retrospective Studies

of Active Human Research Studies



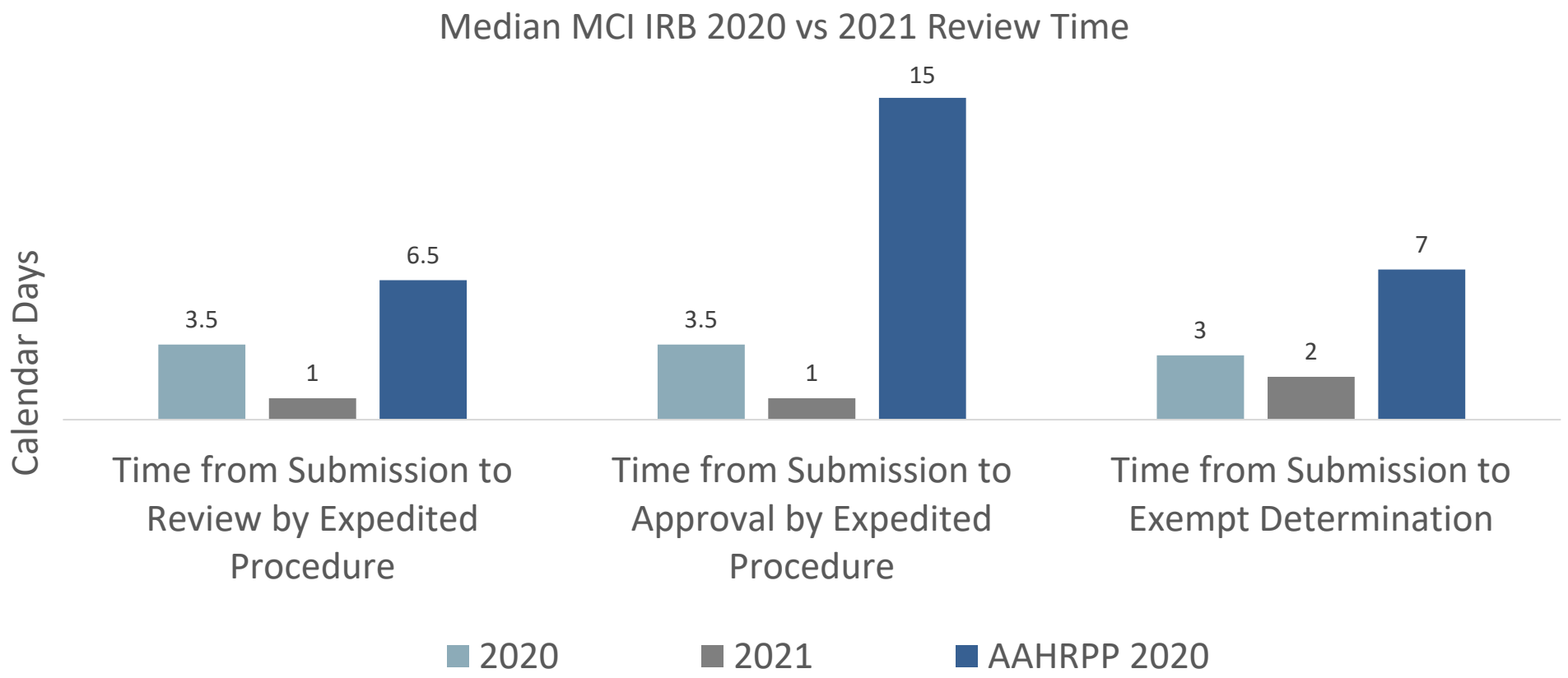
** As of 10.31.2021*



MCI IRB | Volumes & Operational Metrics

2021 *(January – September)*

Review Type	Exempt	Expedited	Full Board	Admin	Ceded	Total
Number of Reviews	22	50	13	104	13	202



Discussion & questions

Save the date for the next
SMART Talk
January 19, 2022
2:00-3:30 pm ET

A Conversation with NIH and OHRP about Single IRB

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

Sign up for our mailing list to be notified of future offerings