

# Strategic Improvement in Human Subject and Animal Research Regulatory Processes

An aerial photograph of a university campus at dusk. The sky is a clear, light blue. In the foreground, there are dense green trees. In the middle ground, a tall, brick clock tower stands prominently. To its right, there are several Gothic-style buildings with red roofs and white window frames. The overall scene is well-lit, suggesting the 'golden hour' of late afternoon or early evening.

**David Norton, PhD**  
Vice President for Research

Michael Mahoney  
Director of Research Operations and Services

# **Strategic Improvements in IRB and IACUC - Working Groups**

**In 2022, UF Research launched a holistic review of processes used in satisfying the regulatory requirements for human subject (IRB) and animal (IACUC) research, focusing on process efficiency and stakeholder experience.**

**Two separate working groups were formed to identify areas for improvement and propose executable solutions.**

**These working groups consisted of stakeholders that included researchers, regulatory staff, and administrators who bear responsibilities within associated processes.**

**The Faculty Senate Research and Scholarship Council was provided with periodic updates on progress.**

**The efforts summarized here are part of a continuous improvement process for supporting human subject and animal research at UF**

# Animal Research Working Group

# Working Groups

## Animal Research Working Group

**Dr. Jennifer Bizon**, Professor and Chair, Department of Neuroscience, Committee Chair

**Dr. Dan Brown**, Associate Professor, Department of Infectious Diseases & Immunology, IACUC Chair

**Dr. Nancy Denslow**, Professor and Chair, Physiological Sciences

**Dr. Laura Eurell**, Attending Veterinarian and Associate Director, Animal Care Services

**Erica Gonzaga**, Associate Director of Research Services, Environmental Health and Safety

**Dr. Eric Krause**, Associate Professor, Department of Pharmacodynamics

**Michael Mahoney**, Director of Research Operations and Services, Office of Research

**Dr. Cherie Stabler**, Professor, Department of Biomedical Engineering

**Dr. Dan Wesson**, Associate Professor, Department of Pharmacology

# IACUC PROCESS IMPROVEMENT WORKING GROUP

- IACUC Process Improvement Working Group formed by Vice President for Research in February 2022
- Working Group Charge:
  - Identify concerns among investigators and staff regarding efficiency and burden of IACUC process for regulatory compliance involving animal research at the University of Florida.
  - Determine needs and provide actionable items for improving processes related to animal research.
- The committee met weekly from February-July, conducted approximately 25 focus groups inclusive of more than 100 investigators from across the University, Animal Care Services veterinarians and technicians, members of the IACUC staff and committee, and individuals from multiple divisions of Environmental Health & Safety.

# Areas Identified for Improvements

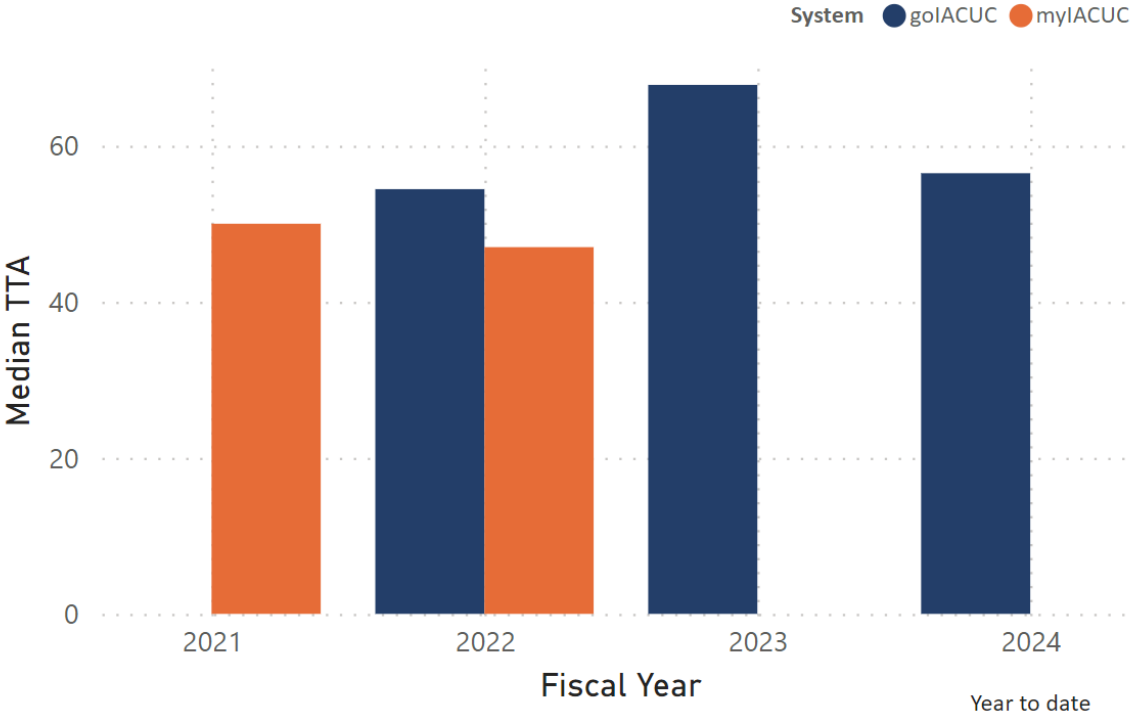
- **IACUC Committee Member Expertise and Expectations:** Investigators expressed a desire for the IACUC committee to incorporate a greater breadth of scientific expertise, and for more transparency and investigator input with respect to member selection and accountability.
- **Onboarding:** Specific concerns were raised by “new-to-UF” investigators regarding lack of direction for efficient onboarding.
- **GoIACUC Transition:** Investigators and IACUC staff raised concerns regarding inadequate support for making the GoIACUC transition as seamless as possible.
- **Process:** Investigator concerns regarding process included 1) a continual escalation in the administrative burden resultant from maintaining protocols and laboratory compliance; 2) consistency of protocol review between reviewers and from one submission to the next; and 3) expediency of protocol review.
- **Staffing:** Investigators, ACS veterinarians and staff all expressed concern regarding ACS understaffing.
- **Communication and Culture:** Feedback across focus groups indicated need for improved communication and trust between the IACUC, ACS and the researchers.

# IACUC Committee Changes

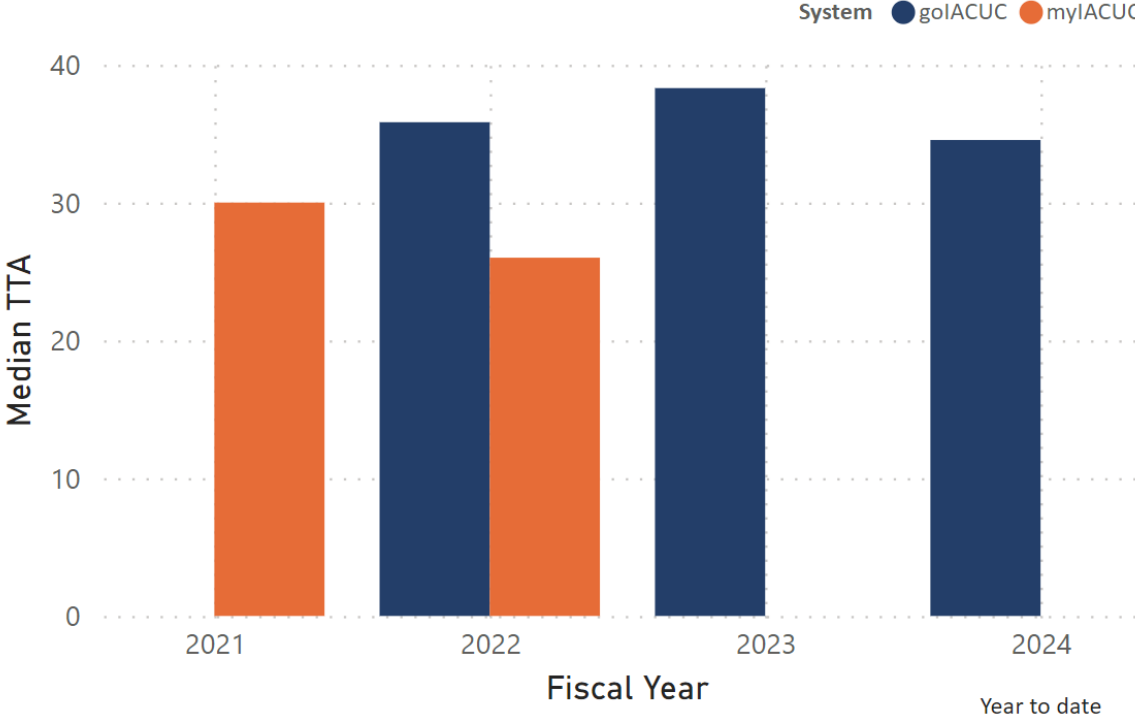
- Changes made in IACUC leadership and committee membership
- Defined expectations for Chair, Vice Chairs, and members, including the creation of a formal Mission Statement and Code of Conduct
- Implemented robust training after every IACUC meeting to increase knowledge and enhance consistency
- Provided additional support (personnel and materials) to support the GoIACUC transition and in onboarding researchers new to the UF IACUC processes
- Improved communication and relationship building through luncheons with researchers and IACUC staff, networking events, regular meetings with ADRs
- Ongoing feedback solicitation after every study approval, on demand from website, and periodically from luncheon attendees and other stakeholders
- Working within GoIACUC to make tracking of individual protocols easy
- Retained external consultant to be engaged later in 2024 for additional review
- Collecting detailed metrics on protocol timelines with plans to make these metrics available to all stakeholders

# IACUC METRICS

myIACUC vs goIACUC Median Time To Approval (TTA)  
for New Studies approved via **Full Committee** FY21-FY24



myIACUC vs goIACUC Median Time To Approval (TTA)  
for New Studies approved via **Designated Review** FY21-FY24





# Human Research Working Group

# Working Groups

## Human Research Working Group

**Dr. Lyle Moldawer**, Professor, Department of Surgery, Committee Chair

**Dr. Azra Bihorac**, Professor, Medicine, Surgery and Anesthesiology

**Dr. Rhonda M Cooper-DeHoff**, Assoc. Professor of Pharmacology & Translational Research

**Dr. Roger B. Fillingim**, Professor, Department of Community Dentistry and Behavioral Science

**Dr. Jennifer Fishe**, Associate Professor, Pediatric Emergency Medicine

**Dr. Thomas J. George**, Professor, Department of Medicine

**Dr. R. Peter Iafrate**, Office of Research, IRB Chair

**Dr. Duane Mitchell**, Professor, Department of Neurosurgery

**Dr. Adam J. Woods**, Professor, Department of Clinical and Health Psychology

**Michael Mahoney**, Director of Research Operations and Services, Office of Research

# HUMAN SUBJECTS RESEARCH IMPROVEMENT WORKING GROUP

- Human Subjects Research Improvement Working Group formed by Vice President for Research in March 2022
- Working Group Charge:
  - Identify opportunities for improvement in the UF human subjects research approval and activation process.
- Commissioned survey sent to current users (faculty and staff) of the human subjects research enterprise.
- Multiple focus group meetings held with faculty and clinical research staff to discuss the findings of the survey in greater detail.
- Held town halls with staff and board members of the Institutional Review Board and the Office of Clinical Research (OCR)

# Main Areas Identified for Improvements

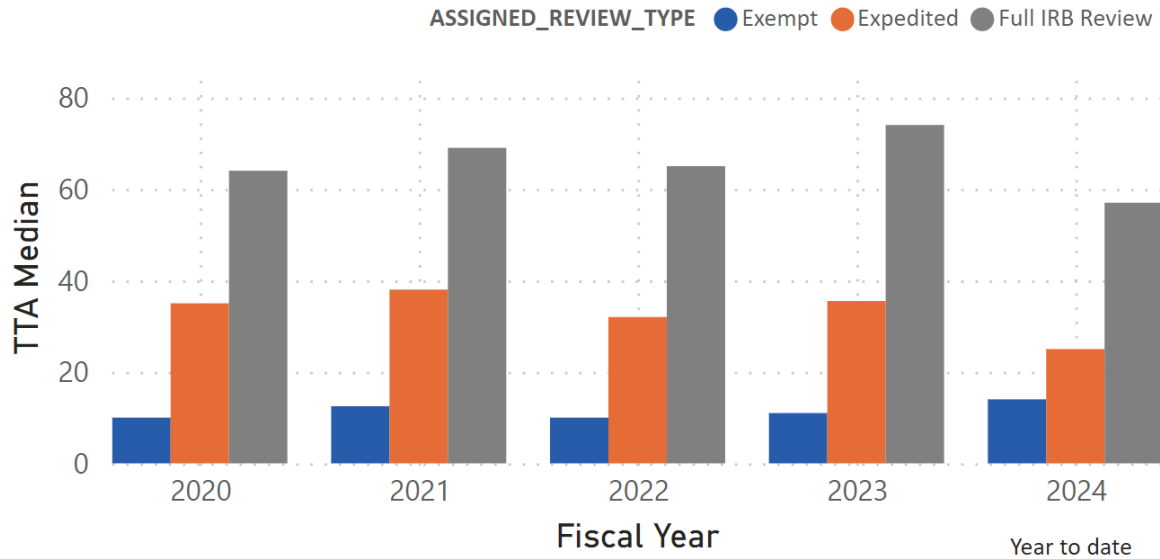
- **Exempt Study Determination:** IRB review of studies later determined to be exempt is inefficient.
- **Coordination of Multiple Entity Review/Approval for Activation of Study :** Human subject research approval and activation process requires review and approval of various units (IRB, college, clinical unit) that is often difficult to navigate.
- **Clinical Study Approval Tracking:** There is no real-time software platform that indicates where a clinical study request is within the review process.
- **Process:** Overall IRB review and study activation timelines. Funded and unfunded protocols not differentiated.
- **Education and Training:** Improvements needed to assist faculty and staff in understanding and navigating the human subjects research approval and activation process.
- **UF Health Integrated Data Repository:** Access to Integrated Data Repository needs to be improved.

# Human Subject Research Improvements

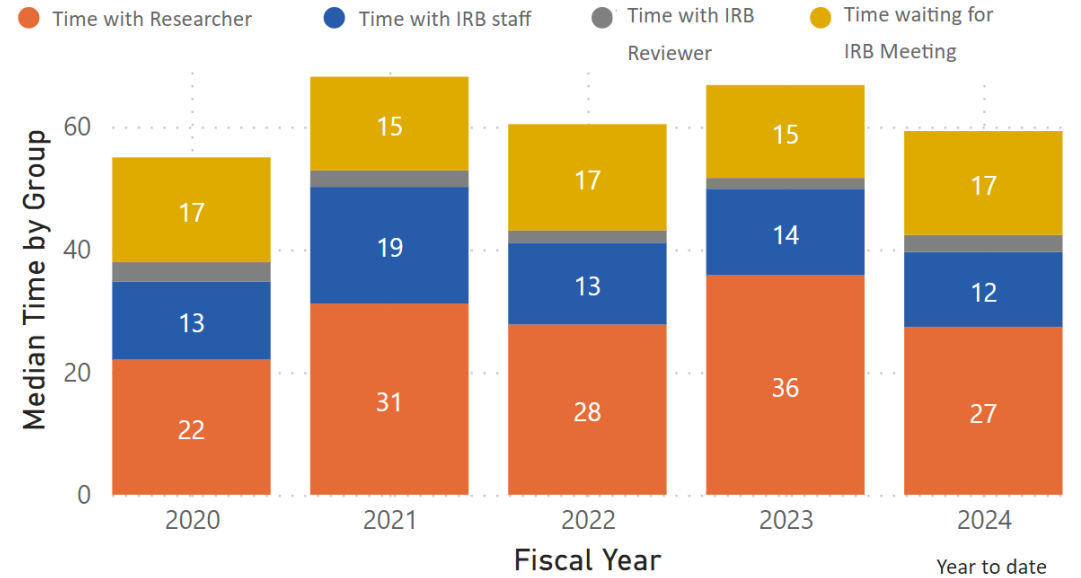
- Developed Auto Determination Tool for Exempt, Nonhuman, and Nonmedical QI projects
  - Innovative: few institutions using something similar, none to the extent now being used at UF
  - Feedback being incorporated into further enhancements
- Reduced requirements for international research
- Reduced number of ancillary approvals needed for IRB approval
- Standardizing injury / cost language in informed consent forms
- Improving communications
  - Attending department faculty meetings; “Chat” feature on website; Ongoing feedback solicitation after every study approval
- Based on feedback, built reports/dashboard to help researchers and units who support researchers:
  - training lookup, COM protocol lookup, CTSI queries and IND drug lookup, Jax reports, VA reports, Identity Management report, etc.
- Making protocol review metrics available

# IRB-01 METRICS

IRB01 Median Time To Approval (TTA)  
for new studies past 5 fiscal years



IRB01 Median Time To Approval (TTA) **Breakdown**  
for New **Full Board** Studies for the past 5 Fiscal Years.



# Additional Changes Under Consideration

- External Consultant
- Working Groups
  - Mentoring / education
  - Data use/access (IDR, OMOP, etc) + needs/prioritization of resources
  - Establish goals for protocol activation and prioritization of research
- Committee changes
  - Increase full Committee meetings from twice monthly to weekly
  - Implement review/nomination process for new members
  - Committee size/structure
  - Utilize more scientific consultation
  - Member training
  - Succession planning
- Obtain metrics from other human research related units

**Thank you!**