Update on the Health Science Center IRB-01

R. Peter Iafrate, Pharm.D.

Chair, IRB-01

UF Institutional Review Boards

- IRB-01 Health Science Center (Biomedical)
- IRB-02 UF Campus (Behavioral Science)
- IRB-03 Shands Jacksonville (Biomedical)
- IRB-04 Western Institutional Review Board (WIRB) - (Biomedical)

Health Center IRB-01 Structure

- Vice President for Research, UF (David Norton, Ph.D.)
- Chairman, IRB-01
  - Peter Iafrate, Pharm.D.
- Vice Chairman, IRB-01
  - Keith Peters, M.D. (Radiology)
  - Juan Aranda, M.D. (Cardiology)
  - Ray Moseley, Ph.D. (Ethics)
  - Charles Riggs, M.D. (Adult Oncology)
  - Matt Morrow, Pharm.D. (VA Pharmacy)
  - Sue McGorray, Ph.D. (Biostatistics)
  - Dianne Farb, J.D.
- Legal Counsel
  - David Lewis, J.D.

What I will cover

- IRB Changes over the past few years
- PI and Study Staff Training
- Common Rule Saga
- NIH and single IRBs
- AAHRPP Accreditation
- Faculty Survey
- IRB Metrics
- Coming Attractions

IRB Changes
(last 3 years)

- All minor revisions reviewed within 1 working day
- All “Exempt” and “Non-human” reviews completed within 24 hrs
- “Transfer” studies for new faculty to facilitate moving their research from their old institution.
- Consent forms tailored to study type
- Discretionary policy (6/2015) for Non-Federally Funded Studies
  - 885 studies approved for 3 years instead of 1 year.
- Policy written to clarify students role in research
- Task force resulted in hiring a full time vice chair in Sept 2016
- State reciprocity agreement to allow research between the 12 state Universities.

IRB Changes
(last 3 years)

- OneFlorida IRB that covers the 12 partners within OneFlorida
- Moved all protocol submissions to myIRB
- Initiate committee on recruitment via Social Media
- Investigator Guidelines to provide instuctions to study staff and to provide more consistent answers http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html.
- Reliance team within the IRB to facilitate ceded reviews and single IRBs
- Decreased time to assign protocols to Full Board
- Staff\Board Member approving retrospective data review studies within 2-3 days
- Revised IRB training from 60 minutes to 15 minutes

Common Rule Changes Update

- Federal Human Research Regs (45 CRF 46) 1981
- Delayed at least 6 months, occurred the day before the implementation date (1/18/18).
- Now taking any additional comments
- Don’t hold your breath
- But, we may make changes anyway:
  - Revise Informed Consent Form
  - May apply all or some of the changes for non-Federally funded studies
  - Stay tuned!

NIH & Single IRBs (sIRB)

- For any NIH funded multicenter study
  - "For applications with due dates on or after January 25, 2018.."
  - There are exceptions, we'll see
  - Can you charge NIH for this function?
- When someone is asking you to "cede" to another IRB, or you want to initiate UF being the "Single IRB"
- How to apply within the UF system?
  - IRB-01 has established a "Reliance Team"
  - myIRB software built to allow these submissions
  - Email or call Renee Collins or Ivana Simic in the IRB office 273-9600

sIRB - Impact

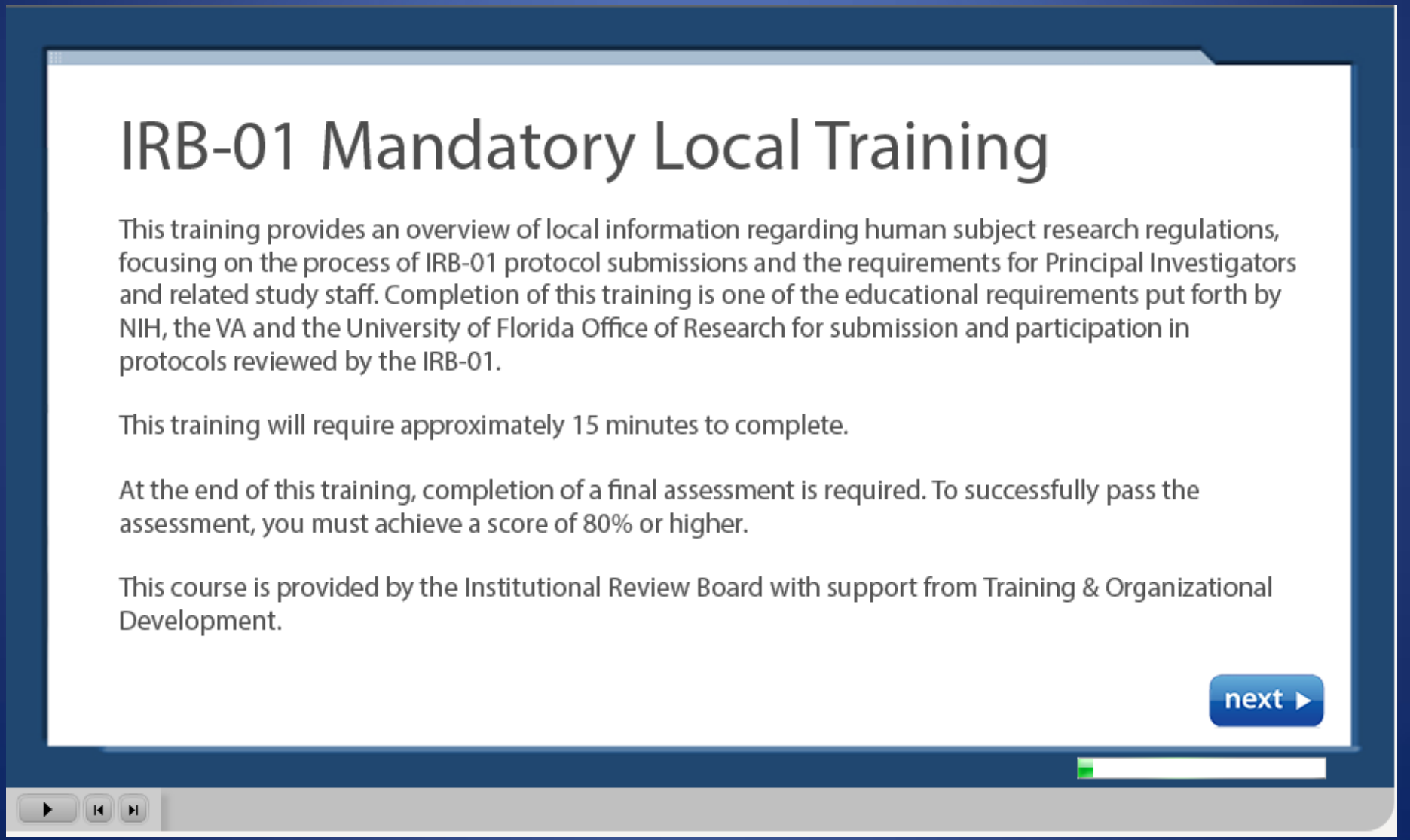
- NIH Definition: "The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites."
- Software and IRB Process changes made (both IRB and Investigator\Staff)

Function	IRB-01	Cede Review
Contracts, OCR, HURRC, COI, SRMC	Local Review	Local Review
Reliance agreement – separate institutional agreements (each one is different)	N\A	IRB Administration & General Counsel's Office
Protocol Submission	Via myIRB	Via myIRB (light)
Protocol & Consent Review	By Full Board or via Exec Review	Exec Review
Privacy Board	IRB-01	IRB-01 or Reviewing IRB
State and UF Policies Enforced	Always	Always

IRB Training

- Will be the same now for IRB-01, 02, & 03
- Includes:
  - NIH (every 30 years)
    - CITI is an option, not recommended
  - HIPAA for Researchers (yearly per Privacy Office)
  - IRB Local Training
    - IRB800 - Initial Training (once)
    - IRB802 – Refresher (every 3 years – you will get pinged)
- No more Iafrate video!!!!
- VA – additional training, contact research office (JB Jennings)

IRB Training



IRB Training

Students as Researchers

If your study involves students, make sure you understand the tasks that a student is permitted to perform. For example, undergraduate students cannot consent patients for greater than minimal risk studies. All student researchers must have a mentor and that must be designated in the protocol. Refer to the table below for more information.

	Minimal Risk				Greater Than Minimal Risk			
Student Type	**PI**	**SS**	**PHI**	**Consent**	**PI**	**SS**	**PHI**	**Consent**
Volunteer								
Undergrad								
Graduate								
Doctoral or Resident								
Post-Doc Fellow								

Color Key	
	Not allowed
	Decided on a case-by-case basis
	Allowed

◄ back next ►

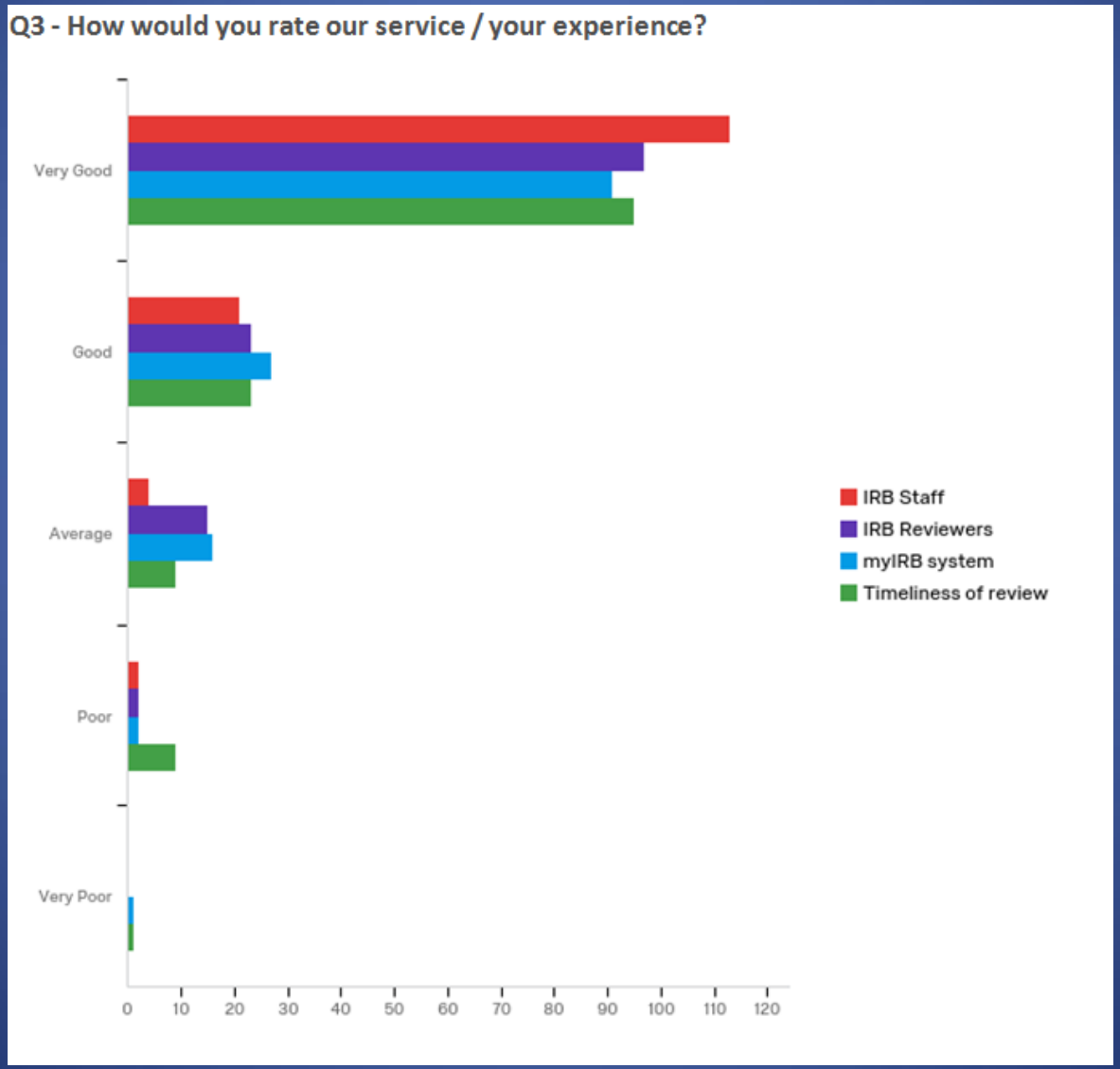
AAHRPP

(Association for the Accreditation of Human Research Protection Programs)

- The “institution” is seeking accreditation.
- State cancer grant was the impetus
- Updated all policies and procedures
- On site inspection was January 10-12th
  - A few issues were identified that I will describe today
  - We must respond by February 20th.

Satisfaction with IRB Survey

Calendar 2017



IRB-01 Metrics

Active Studies as of 2/9/18

Review Type	IRB-01	IRB-02	IRB-03
Full Board	464	3	41 27 legacy
Expedited	1669	613 83 legacy	255 37 legacy
Exempt\Non-Human	402\610	1361\65	26\4
Total =	3145	2125	390

WIRB Studies = 330 (Gnv), 107 (Jax)

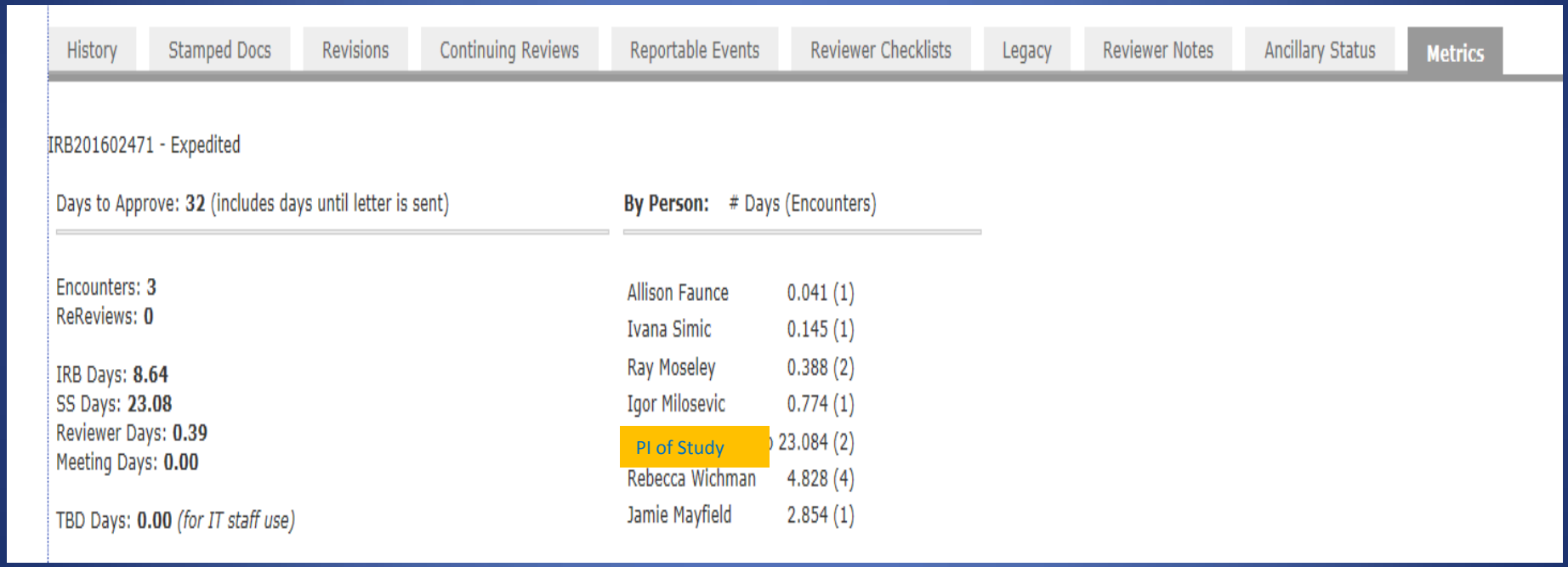
Ceded Studies ~ 60

Full Board New Protocols

Median Data

Calendar Year	Days to Approval	No. of Full Board Mtgs	Days with the IRB	Days with the Study Staff	Days with the Reviewer	Days waiting for the IRB Meeting
2016	63.0	1.0	10.5	14.1	10.0	22.1
	(188)	Avg. % of days to approval	15%	34%	17%	32%
2017	64.0	1.0	8.0	18.5	10.0	18.3
	(162)	Avg. % of days to approval	11%	47%	14%	26%
January 2018	59.5	1.5	2.0	25.2	10.1	16.7
	(8) 2 tabled twice	Avg. % of days to approval	8%	41%	15%	33%

Metrics on All Approved Studies

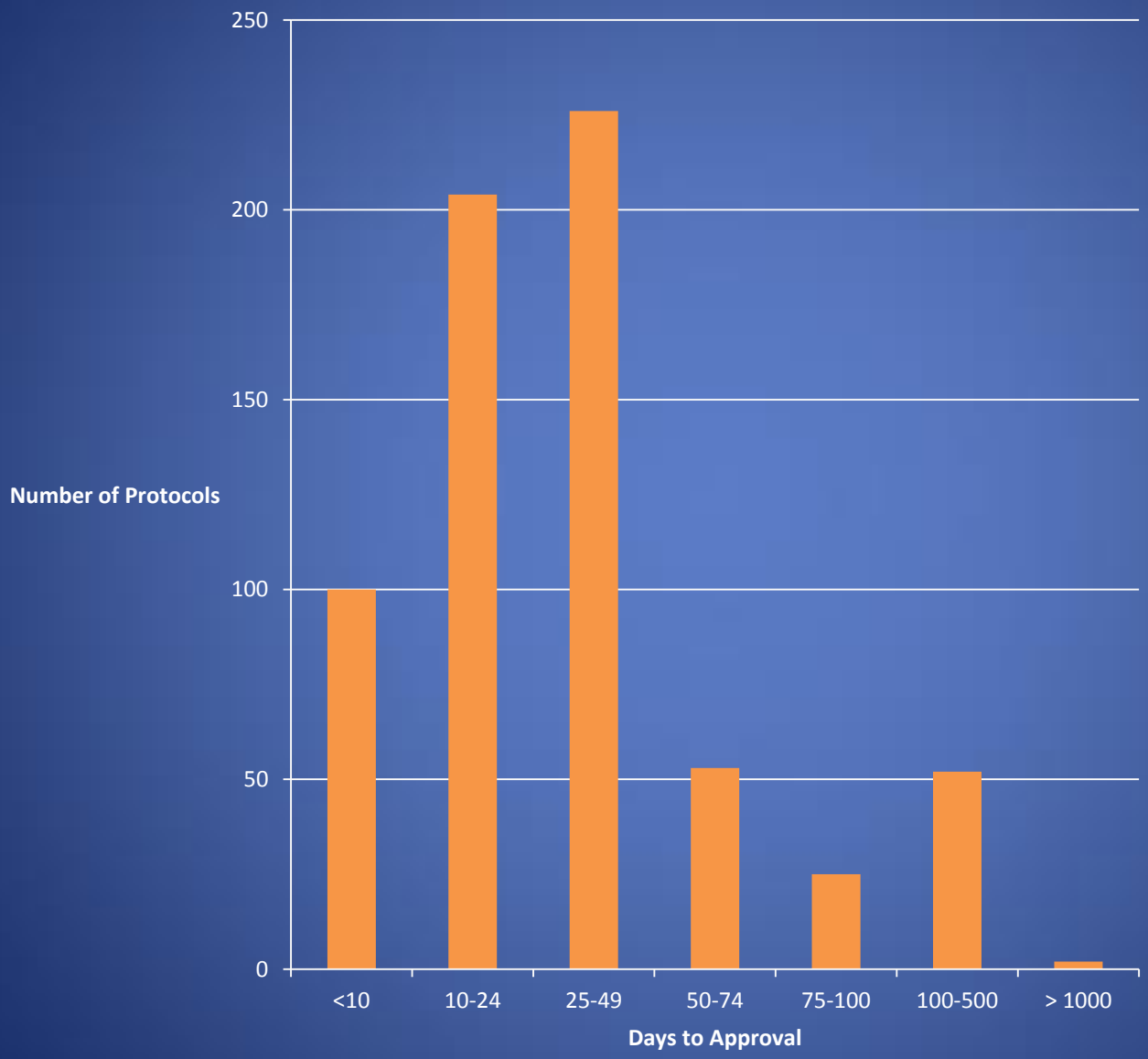


Expedited New Protocols

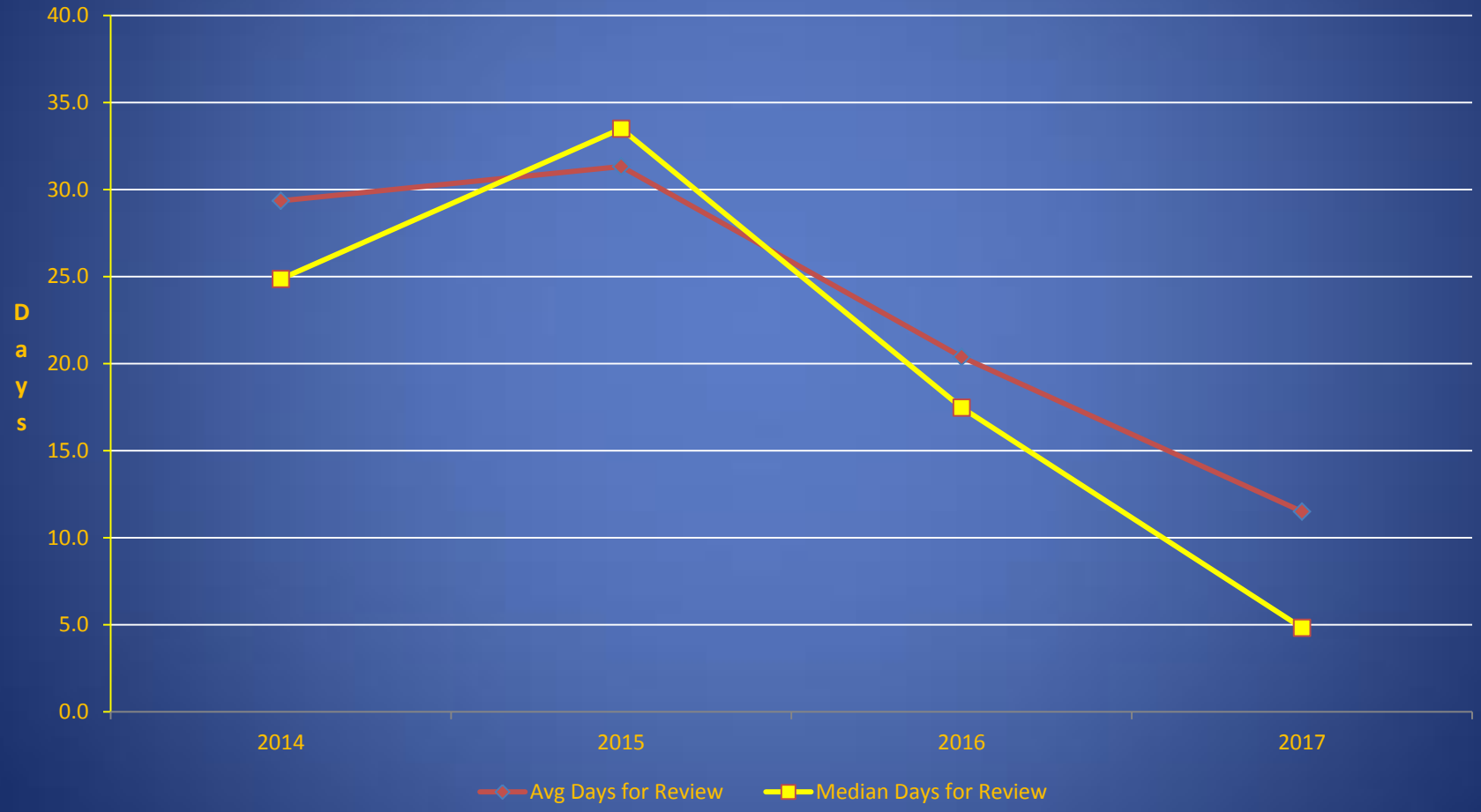
Median Data

Calendar Year	Days to Approval	No. of Full Board Mtgs	Days with the IRB	Days with the Study Staff	Days with the Reviewer	Days waiting for the IRB Meeting
2016	37.5	NA	5.6	10.8	14.3	NA
	(574)	Avg. % of days to approval	13%	44%	41%	NA
2017	28.0	NA	4.5	8.2	7.2	NA
	(696)	Avg. % of days to approval	12%	58%	27%	NA
January 2018	22.0	NA	0.8	5.0	0.1	NA
		Avg. % of days to approval	6%	66%	21%	NA

Expedited New Protocols 2017

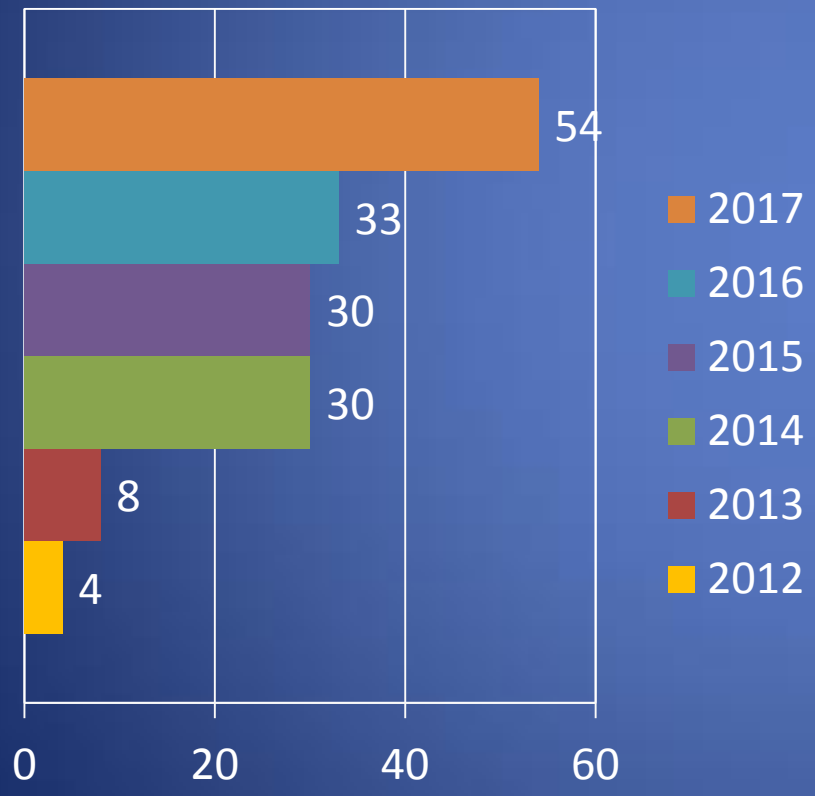


IRB-01 Executive Reviewer Turn-Around-Time



Delinquent PI Responses: IRB-01

New Protocols Currently Delinquent for >60 days (162)



All items Currently Delinquent for > 60 days

- New = 162
- Continuing Reviews = 22
- Revisions = 38
- Adverse Events = 9

Delinquent Reminder

- Sent at 30 and 60 days:

Date: 11/26/2017

Study: IRB201701327 - Global Metabolomics and Psychoneurologic Symptoms of Chronic Graft-versus-Host Disease after Allogeneic Hematopoietic Cell Transplantation

On 9/27/2017 1:39 PM the IRB returned your new study IRB201701327 to you for additional information.

This is a courtesy reminder to reply to the IRB's issues. This protocol will remain **unapproved** until you reply to the IRB's issues.

NOTE: the IRB Chair has been copied on this message and will be contacting you to discuss if the study should be withdrawn from the system.

Selected Audit Results Within the last year

1. Consenting Issues:
   a) Can't locate all consent forms
   b) Patients screened for disease to determine eligibility without consent
   c) For in 18-45 y.o. women
      - 60% did not meet eligibility; (males, children, elderly)
   d) Wrong consent forms used for wrong studies
   e) Consent forms not back translated

Selected Audit Results
Within the last year

2. Compliance with approved protocol
   a) Blood collected from patients without targeted disease
   b) Numerous subjects receiving study interventions not approved by the IRB
   c) Pregnancy tests not completed as required per protocol
   d) Consent indicated multiple lab tests to be done, none done, not approved by IRB
   e) Many subjects did not have inclusion/exclusion criteria verified

Potential Upcoming Changes

- Weekly meetings?
- CLICK Smart Form changes d/t common rule
- More routine audits?
- Involve IRB reviewers up-stream to avoid tabling at Full Board Meetings
- Continued Enhancements based on Metrics and feedback

Take Home Messages?

1. Consent subjects correctly
2. Mentor your students
3. Follow Your Protocol !
4. Ask before you act


Questions??