

Research Conflicts of Interest at Boston University

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Outline

- BU Policies
- Investigator responsibilities
- Metrics and statistics at BU

BU FCOI Policies – Based on Sponsor

<p>BU General Policy (October 31, 2003)</p>	<p>BU PHS Addendum (August 24, 2012)</p>
<p>Based on 1995 PHS and NSF federal regulations</p> <p>Covering grants at BU proposed for funding by all sponsors not listed in the other column, including unfunded/departmentally funded human subjects research</p>	<p>Based on 2011/2012 PHS federal regulations Covering BU grants sponsored by:</p> <p>Public Health Service (PHS) Agencies OG, OASH, ASPR, AHRQ, ATSDR, CDC, FDA, HRSA, HIS, NIH, SAMHSA</p> <p>Non-PHS Agencies Alliance for Lupus Research (ALR) American Asthma Foundation American Cancer Society (ACS) American Heart Association (AHA) American Lung Association (ALA) Arthritis Foundation (AF) Juvenile Diabetes Research Foundation (JDRF) Lupus Foundation of America (LFA) Susan G. Komen for the Cure CurePSP</p>

Investigator Disclosures Under Each Policy Scheme

	BU General Policy	BU Addendum
Disclosures	Only SFIs that investigator determines could affect research	All SFIs that investigator determines are related to institutional responsibilities
Threshold	Salary, Royalties, Consulting, Patent and Copyright payments: \$10k – look forward 12 months Equity: No thresholds	Salary, Royalties, Consulting, Patent and Copyright payments): \$5k – look back 12 months Equity: \$5k for publicly traded entities – no threshold for privately held entities
Travel	Not explicitly covered	Included over \$5k
Exclusion of income from seminars, lectures, advisory committees, review panels	Excluded if sponsored by any public or non-profit entity	Excluded if sponsored by government, university, or medical center

Additional Policy Differences

	BU General Policy	BU Addendum
Annual Investigator Disclosure?	No	Yes
Investigator Training	Not covered	Every 4 years
Public Accessibility (providing info on request)	Not covered	Website or must provide certain info on FCOIs of senior personnel on request

Investigator Responsibilities

- Financial Interest Disclosure Training (under “BU Addendum” only)
 - On investigator policy responsibilities
 - Once every 4 years while engaged in research
 - Via Blackboard Learn
 - Email is sent from coi@bu.edu if training is needed
- Disclose
 - Financial interests related to your professional responsibilities at BU
 - Prior to grant submission, annually during the award, update within 30 days of newly acquired/discovered interest
 - Online or using “paper” Adobe/Word form (both at bu.edu/orc/)

There are no special responsibilities for BU leadership.

How to Train

- Get a BU username
 - https://www.bu.edu/link/bin/uiscgi_research_compliance.pl
- Get a Blackboard Learn account
 - <https://learn.bu.edu>
- Search for “Financial Interest Disclosure Training”
- Get a score of 80

How to Disclose

- Go to <https://share.bu.edu/sites/fcoi/>
- Grant admins pre-fill form for PIs (optional)
- PIs get email; disclose
- Investigators get email; disclose
 - “investigators” = all those responsible for design, conduct and research of project, including senior/key personnel at minimum

For more info:

Go to <http://www.bu.edu/orc/forms/coi/>

Financial Interest Disclosure Module

Office of Research Compliance > Financial Interest Disclosure Forms



SharePoint Collaboration Services

For All Investigators (including pending forms):

[My Financial Disclosure Forms](#) >

For Principal Investigators only:

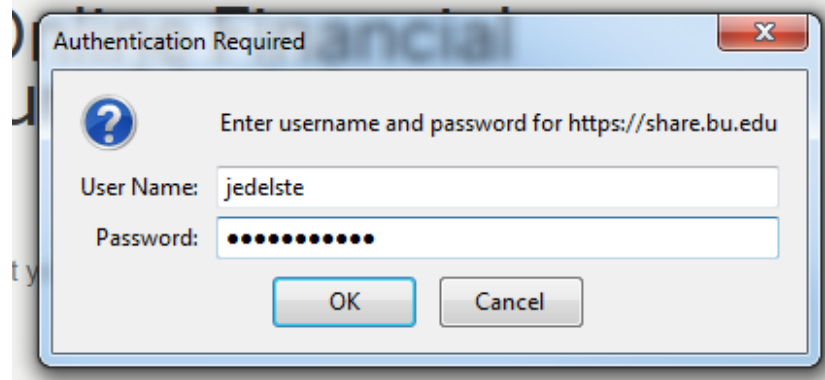
[View Submission Status](#) >

For Grant Administrators only:

[Manage Projects](#) >

Troubleshooting

- coi@bu.edu
- 617-414-4751
- Go to <http://www.bu.edu/orc/forms/coi/>
- When not connected to BU network, your User Name is your BU email address (e.g., jedelste@bu.edu instead of jedelste)



Metrics

Important Dates:

- August 2012** New policy implemented (BU Addendum)
- March 2013** Birth of FIDDLE
(Financial Interest Disclosure Database Limited Ed.)
- November 2013** New online disclosure system was launched

Data Set:

The COI Unit in the Office of Research Compliance handles disclosures for research at BU and BMC. These numbers encompass both.

FIDDLE


RESEARCH PROJECT DETAILS

Project Track: Disclosures Needed Training Needed SFI Discovered Internal Review FCOI Discovered Committee Review Scheduled Management Plan Drafting Management Plan Finalizing ALL CLEAR

Governing Policy: **BU-PHS-FIND1** Project ID: 4109

Principal Investigator

347
Investigator ID:



Cozier, MPH, D.Sc.,
Yvette C.

Career Title:
Assistant Professor

Department:
Epidemiology

Home Institution:
BUSPH - Boston University School of Public Health

Department Administrator:
Nozomi Ito

Project Specific Admin.:

Project Title: Air pollution, psychosocial stress, and sarcoidosis incidence in U.S. black women

OSP/OGA Admin: Goodridge-BU-MED

Funding Stage: Proposal

PHS Sponsor: NIH - ?

Award/Contr. #: Proposal 7/1/2014

NonPHS Spons:

Budget:

Prime Recipient: BUSM - Boston University School of Medicine

Date Awarded:

Sub Recipient:

Human Subjects Yes No

Special Designations

SBIR Phase 1

STTR Phase 1

Pre-Clinical

Clinical Study/Trial

IND or IDE

None of Above

Project Start Date: 7/1/2014

Project End Date: 6/30/2017 **3** Year Study

Last Modified: 3/27/2014 2:10:43 PM

PHS Continuation Date: 6/30/2015

Compliance Status: **All Clear**

Project Personnel

User:

Surname	First Name	Project Role	Train Date	Grade	F1Submit	F2Submit	FormsClear
Berman, MD	Jeffrey S.	Clinician	2/7/2013	80	11/8/2013		11/12/2013
Coogan, MPH, D.Sc.	Patricia F.	Co-Investigator	9/26/2012	90	11/12/2013		11/12/2013
Cozier, MPH, D.Sc.	Yvette C.	Principal Investigator	10/22/2012	80	11/7/2013		11/12/2013
Rosenberg, MS, ScD, M	Lynn A.	Co-Investigator	9/26/2012	80	11/7/2013		11/12/2013
White, PhD	Laura Forsberg	Biostatistician	11/13/2012	100	11/6/2013		11/12/2013
Yu	Jeffrey	Data Analyst	10/5/2012	90	11/7/2013		11/12/2013

Double Click to Edit Disclosure

Project Creator: chapmanr

Project Status Log

StatusDate	Classification	StatusNotes
11/12/2013 2:57:59 PM	All Clear	

Double Click to Edit Status Item

Last Check-In:

Compliance Pass

Management Plan Yes No

Disclosure Module Announcement

Boston University Research Compliance

TO: Research Community
FROM: Kate Mellouk, Associate Vice President, Research Compliance
DATE: January 9, 2015
SUBJECT: New and Improved: Financial Interest Disclosure Module

Dear Colleagues:

We are pleased to announce a new and improved financial interest disclosure module that enhances the online module Boston University and Boston Medical Center have been using for the past year as we transition away from the paper disclosure process in research compliance.

To reduce paperwork burden and save valuable investigator time, this module will:

- Allow grant administrators to pre-fill project information for principal investigators;
- Save and pre-fill prior disclosed financial interests;
- Serve as a holding place for all financial interest disclosures submitted through the module; and
- Allow grant administrators and PIs to track when disclosure forms are completed by the other investigators in the project.

Should you need any assistance, we are here to help.

Call: Andre Chapman (617) 414-4751

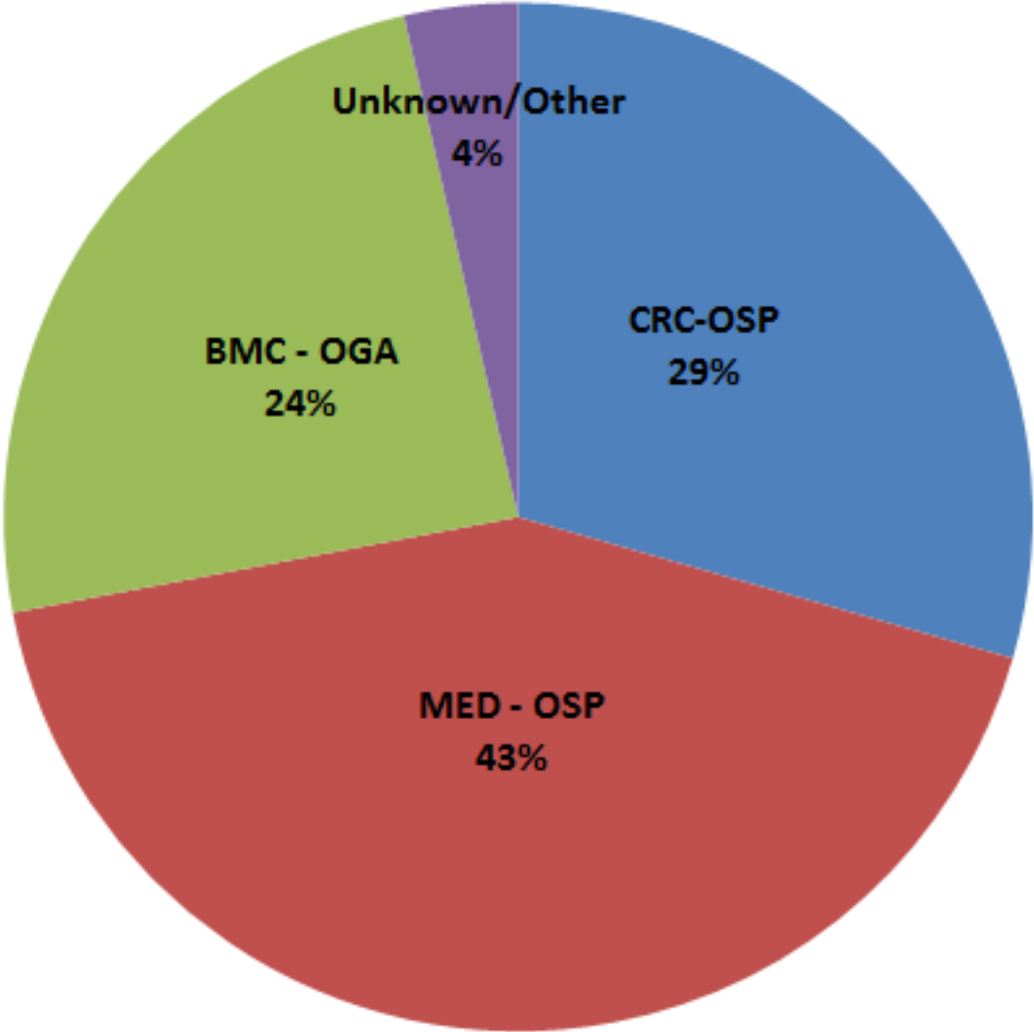
Email: coi@bu.edu

[Quick Tips](#)

Reminder: A BU username is required to disclose. You can electronically request a BU username [here](#).

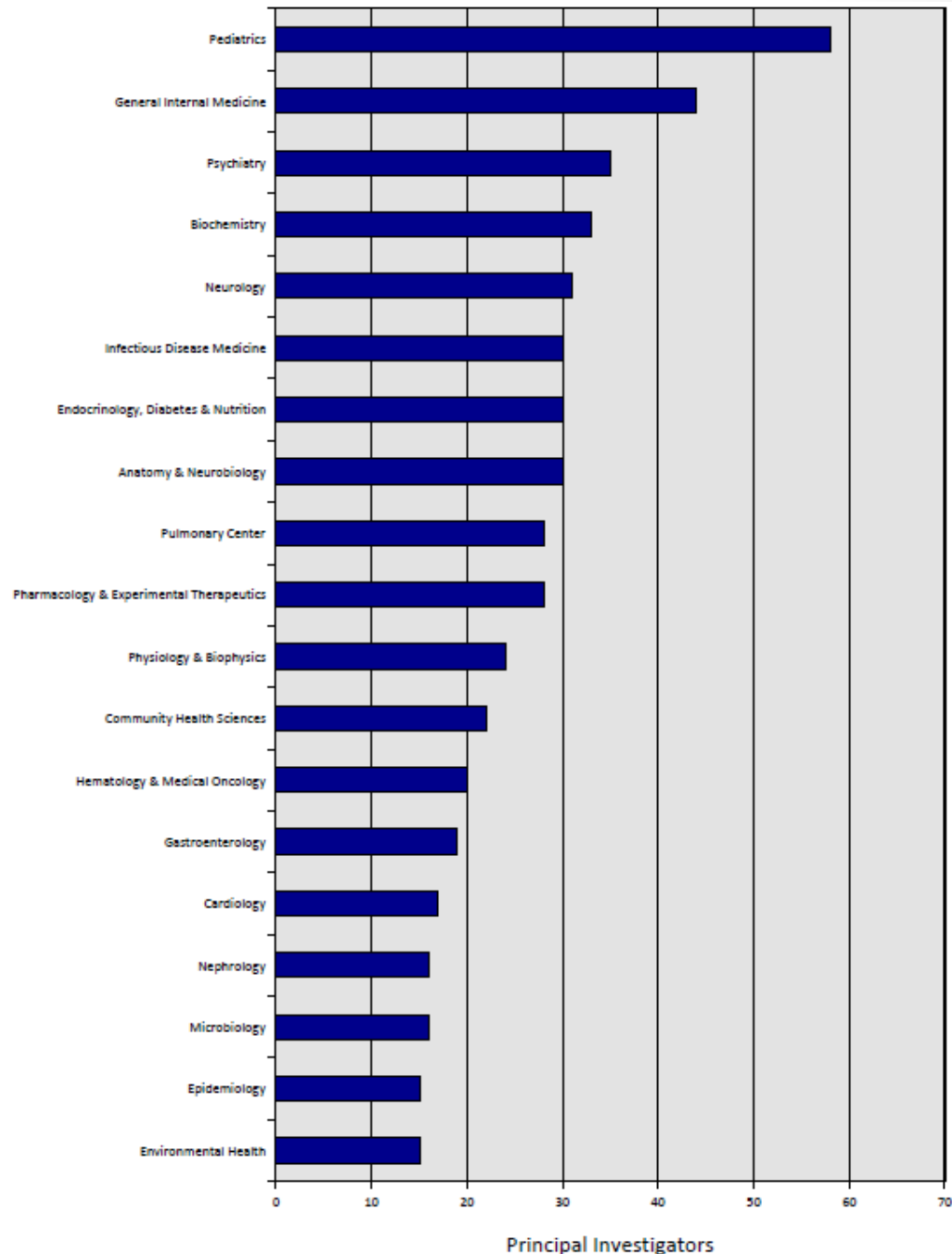
We are working hard to continuously improve and help increase efficiencies within the Research Compliance areas. If you have any additional feedback, please feel free to email coi@bu.edu or email me [directly](#).

Disclosures per Administering Office

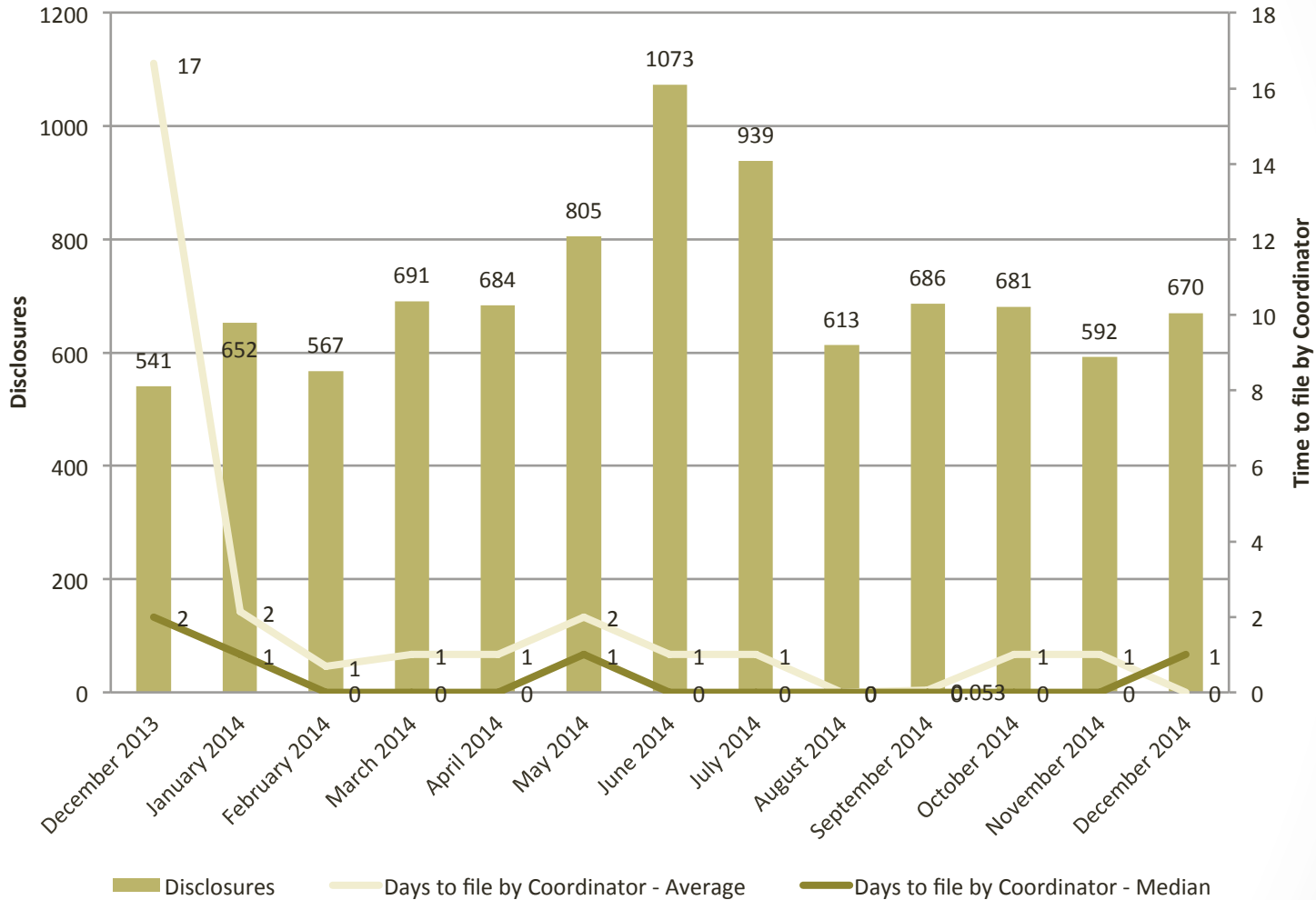


Principal Investigators per Medical Campus Department (1/20/15)

- 1) Pediatrics
- 2) General Internal
Medicine
- 3) Psychiatry
- 4) Biochemistry
- 5) Neurology
- 6) Infectious Disease
Medicine
- 7) Endocrinology,
Diabetes & Nutrition
- 8) Anatomy &
Neurobiology
- 9) Pulmonary Center
- 10) Pharmacology &
Experimental
Therapeutics

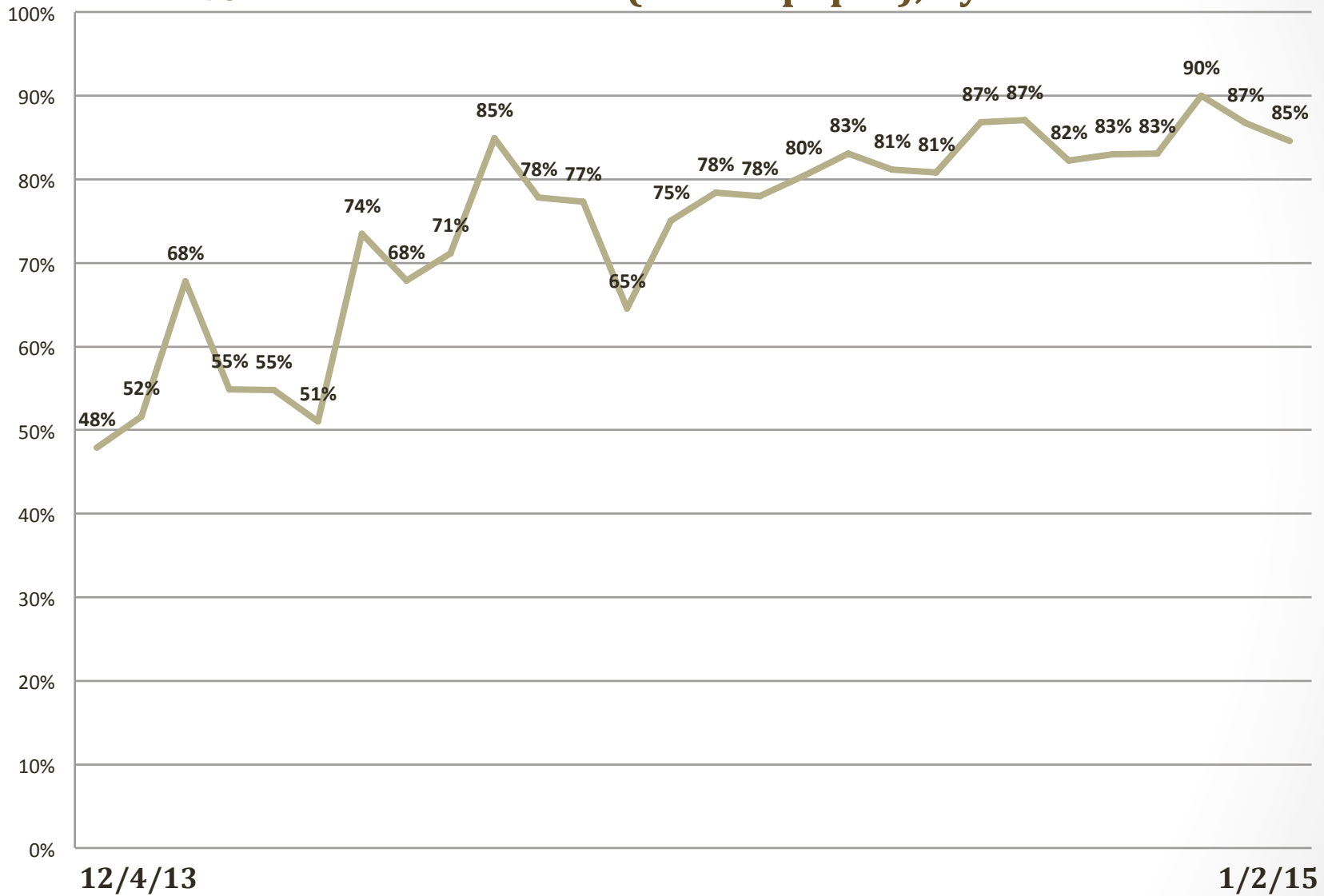


Total # of Disclosures per Month | Time to File by Coordinator

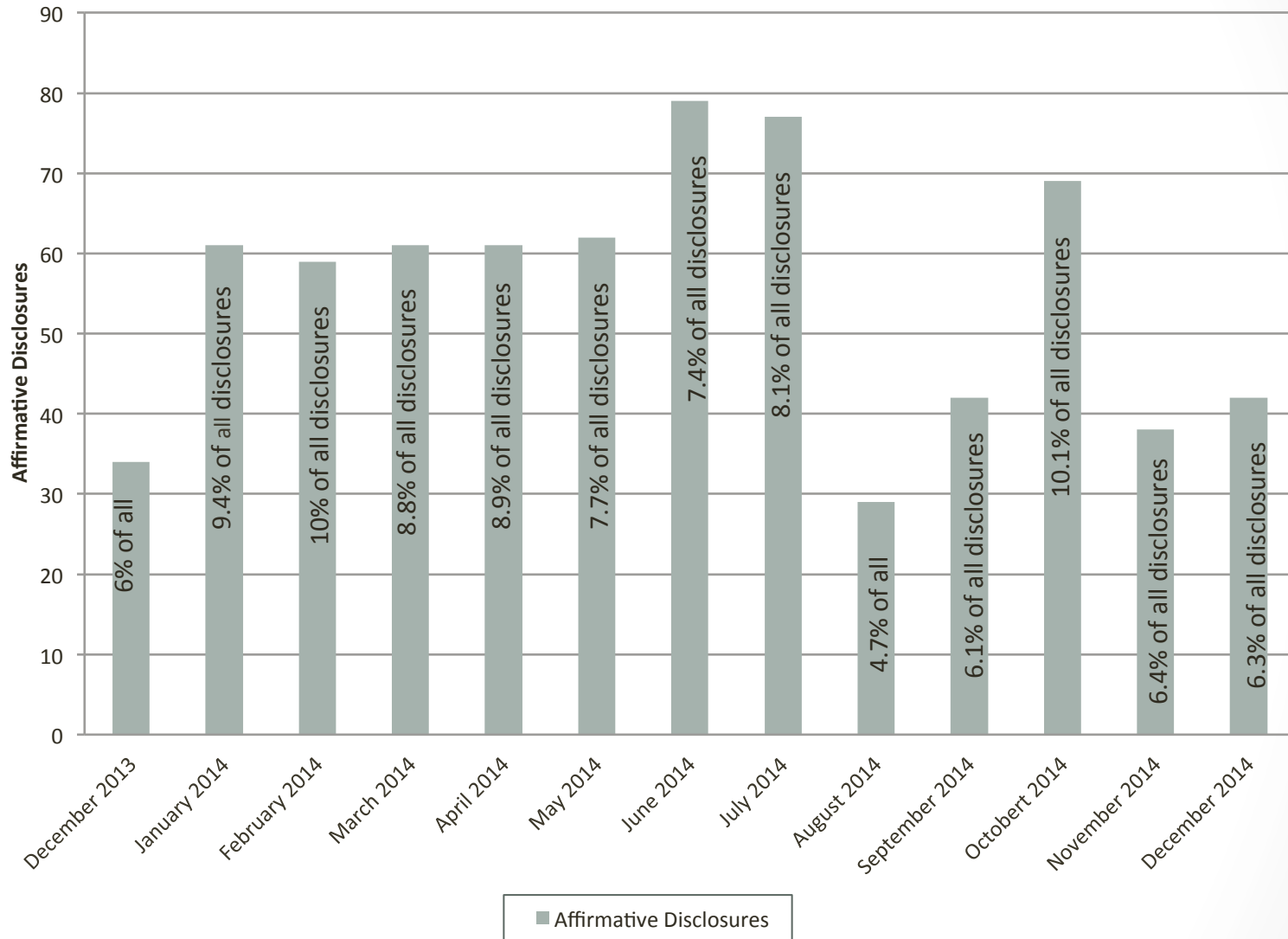


Average = 707

% Online Disclosures (versus paper), by Month

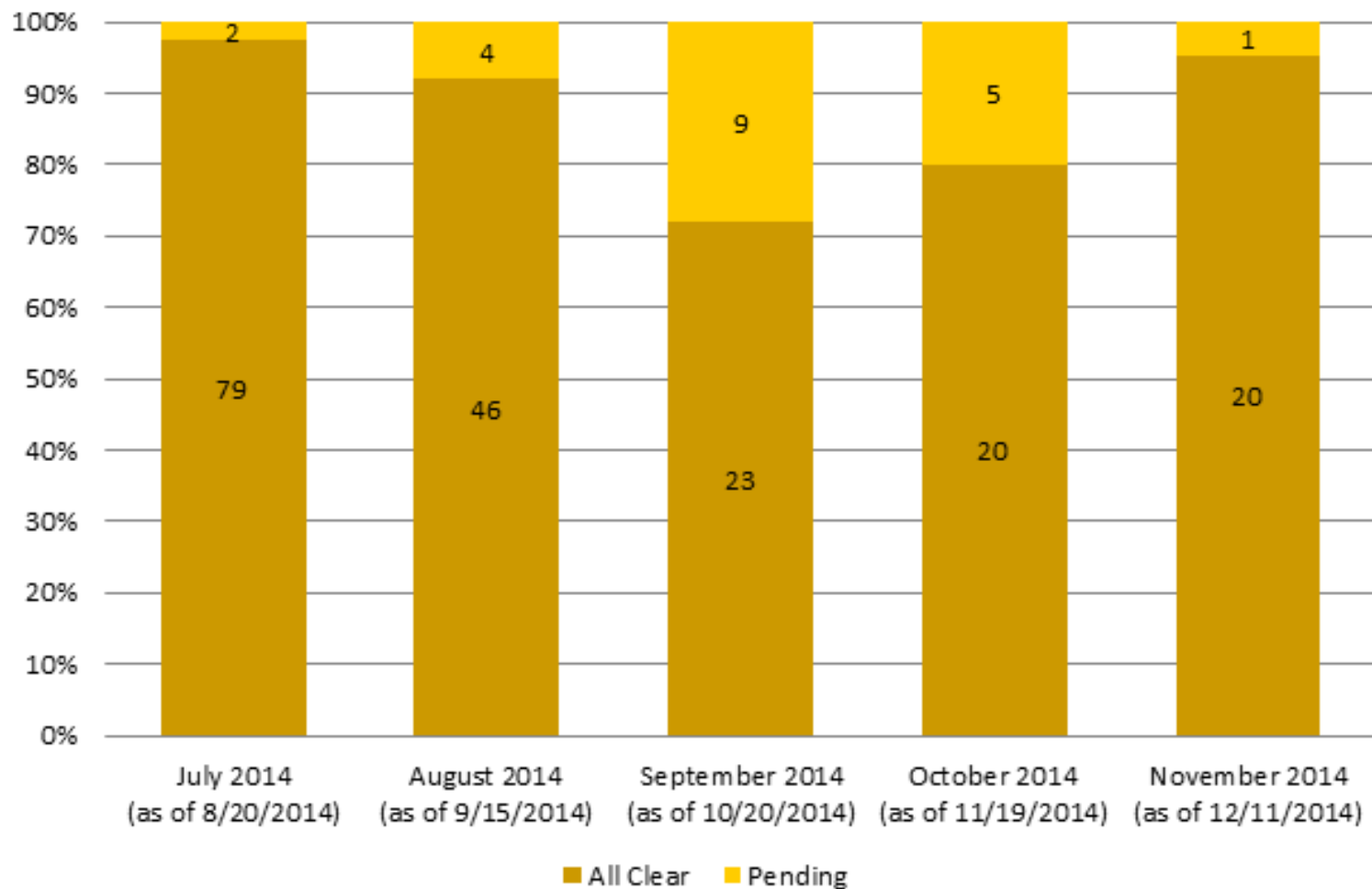


% Affirmative Disclosures per Month



Average = 7.7%

Award Continuations | Clearance Rates



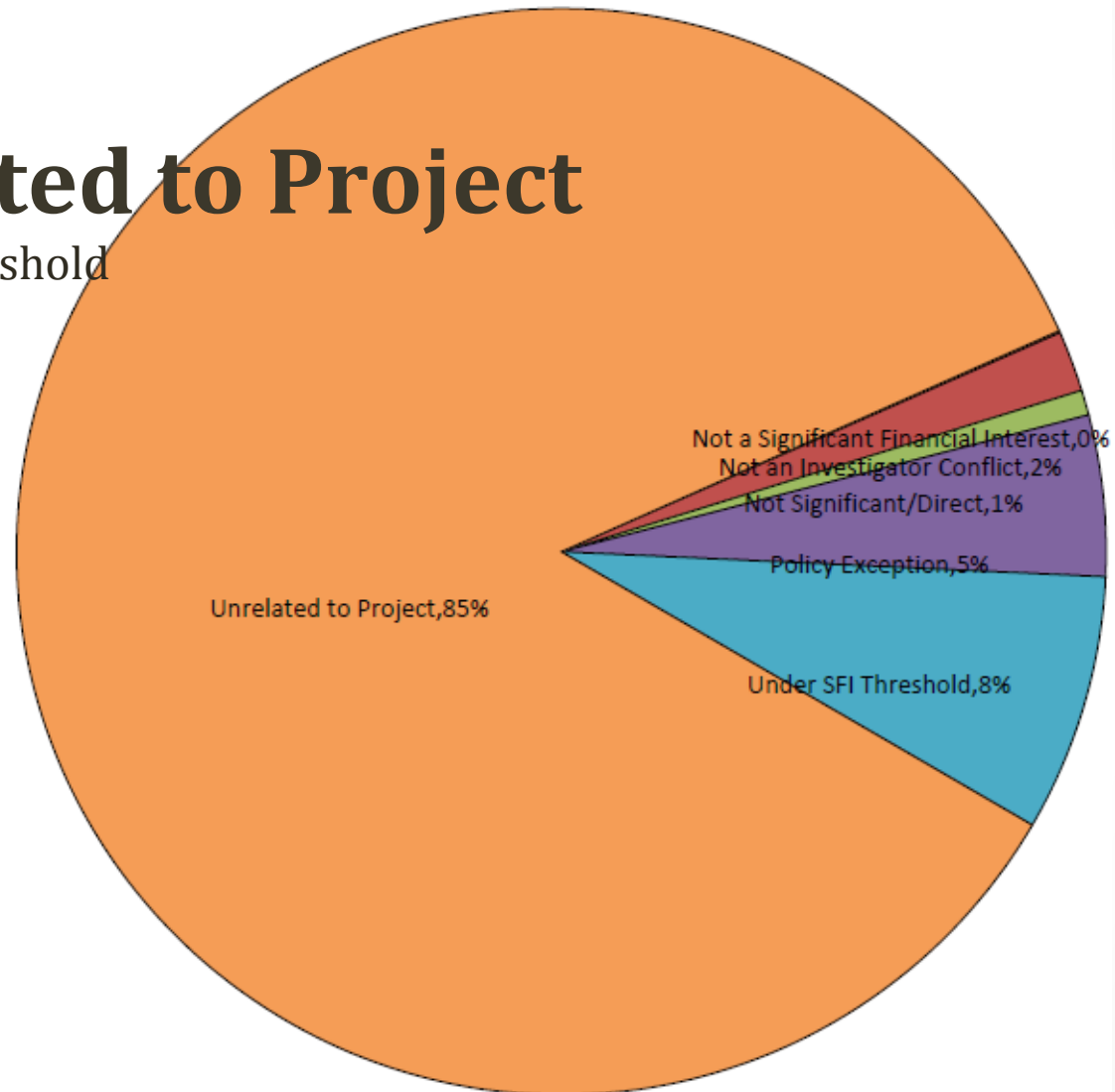
Average = 87.3% all clear at continuation

Also, December 2014: **75%** of New Awards had “All Clear” by Project Start

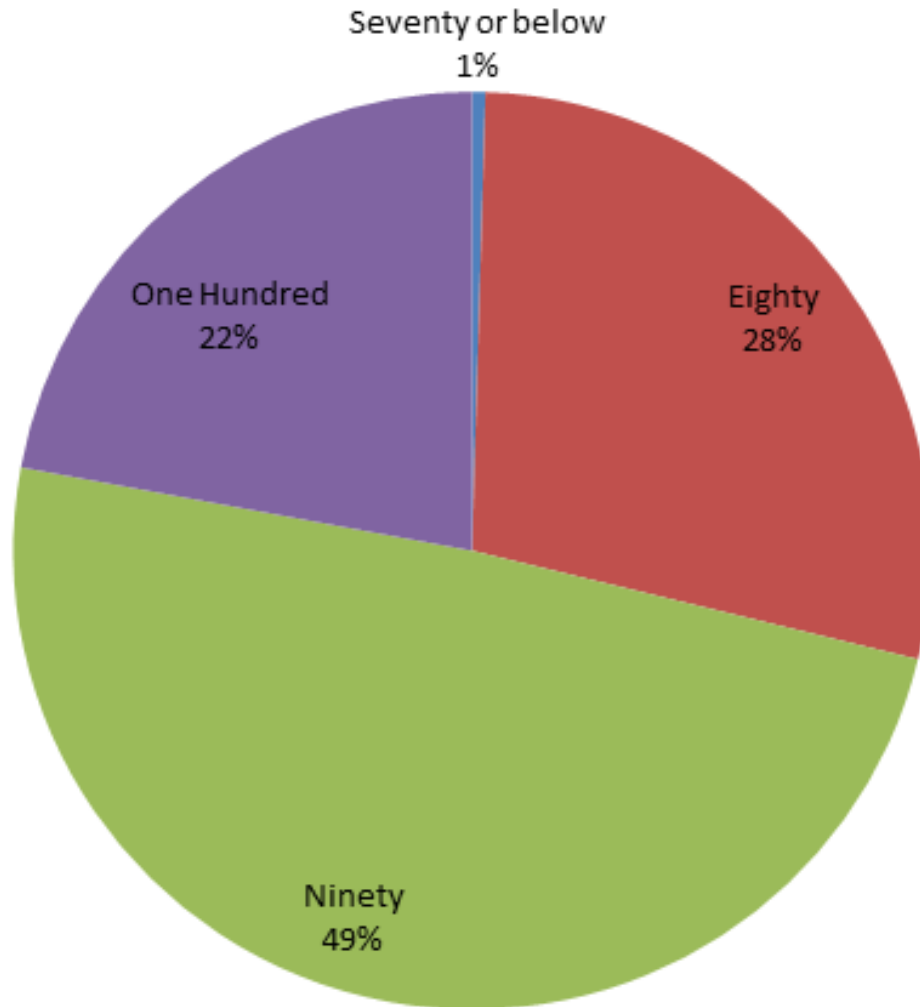
Reasons Affirmative Disclosures Were Not FCOIs

1. Unrelated to Project

2. Under SFI Threshold
3. Policy Exception



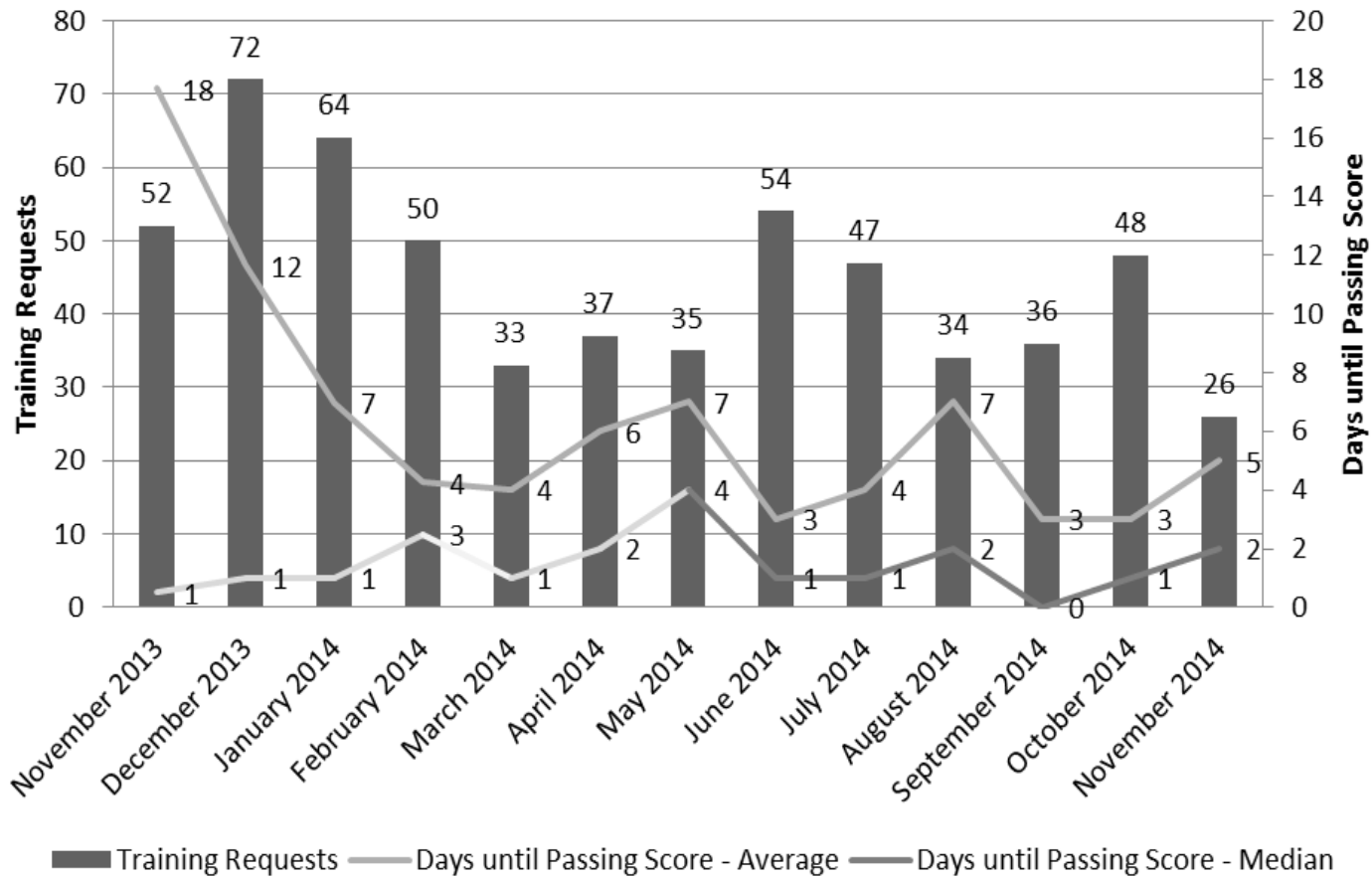
Score Achieved on Investigator's Financial Interest Disclosure Training



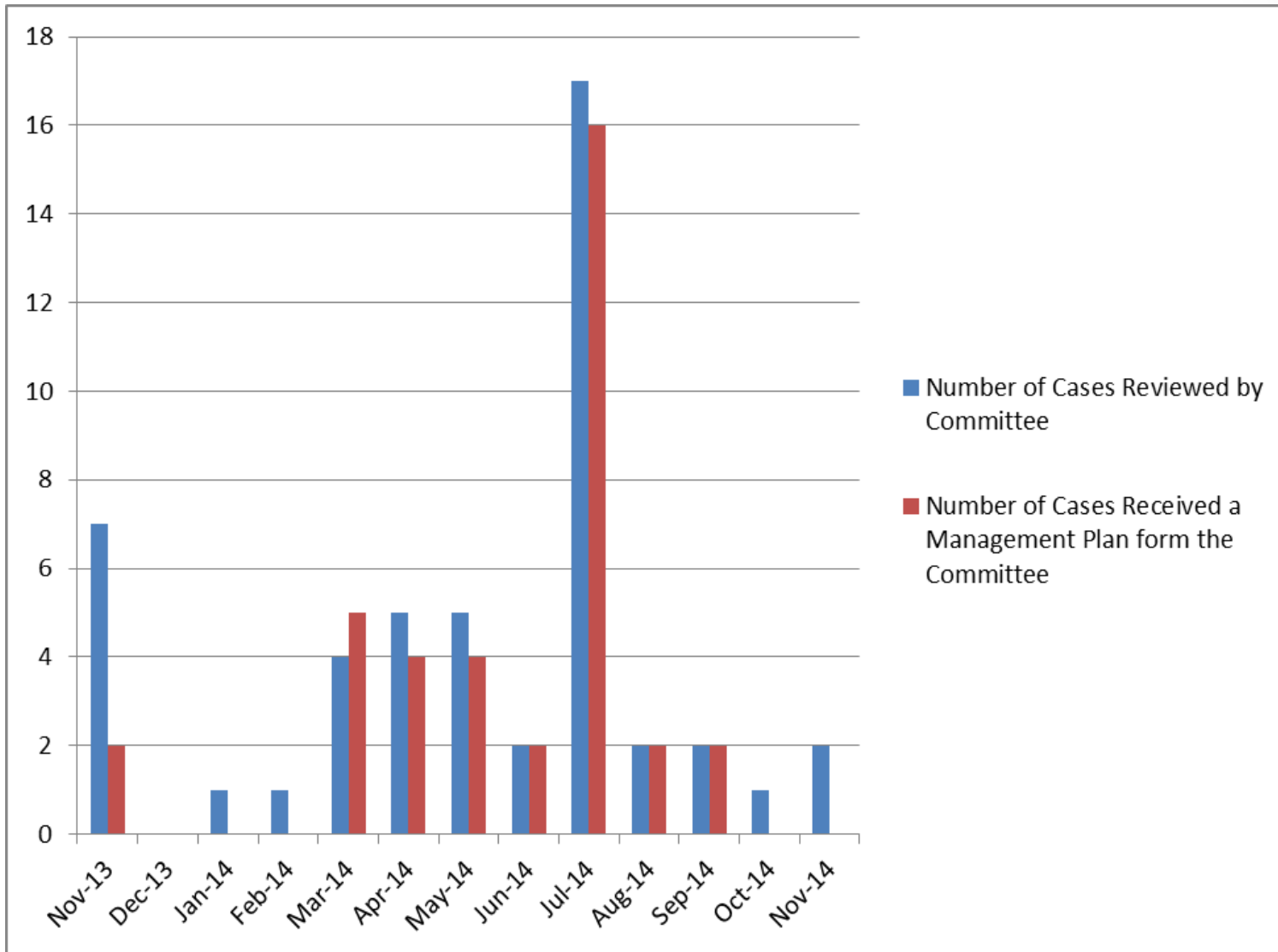
3232 total
recorded
scores
(1/20/15)

80 is a
passing score

Training Requests | Investigator Time to Completion



FCOI Faculty Committee Caseload



Thank you!

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Boston University
and Boston Medical Center
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