

# Rethinking Approaches to Research Integration at NYU Langone Medical Center

July 31, 2014

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# Presenters



**Gregg Fromell**

M.D., Vice President of Science Operations and Transformation,  
NYU Langone Medical Center



**Nick Stier**

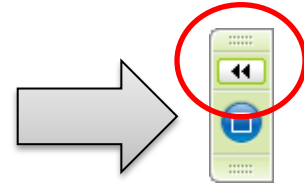
Managing Director, Huron Education

# Goals

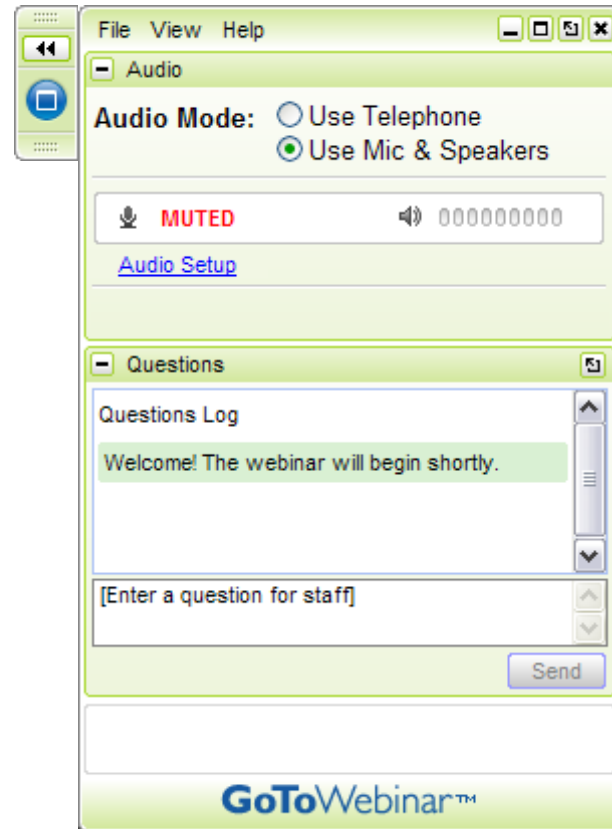
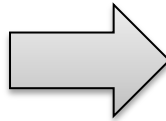
- Emphasize the importance of an enterprise strategy/vision
- Discuss value of incorporating the study team perspective
- Evaluating readiness for implementing the enterprise vision
- Provide a high-level view of an approach to integration strategy
- Review human research as an example of operationalizing the strategy

# GoToWebinar Toolbar

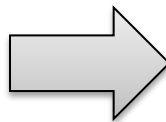
GoToWebinar Menu should appear in the upper-right corner of your screen.



Click the Expand icon to reveal your webinar tools



Enter a Question in this dialog area at any time.



# Approaches to Integrating Research Administration:

- *Developing an enterprise strategy*
- *Maintaining a research team focus*

*Gregg Fromell, MD  
VP, Science Operations  
NYU Langone Medical Center*

# NYU Langone Medical Center

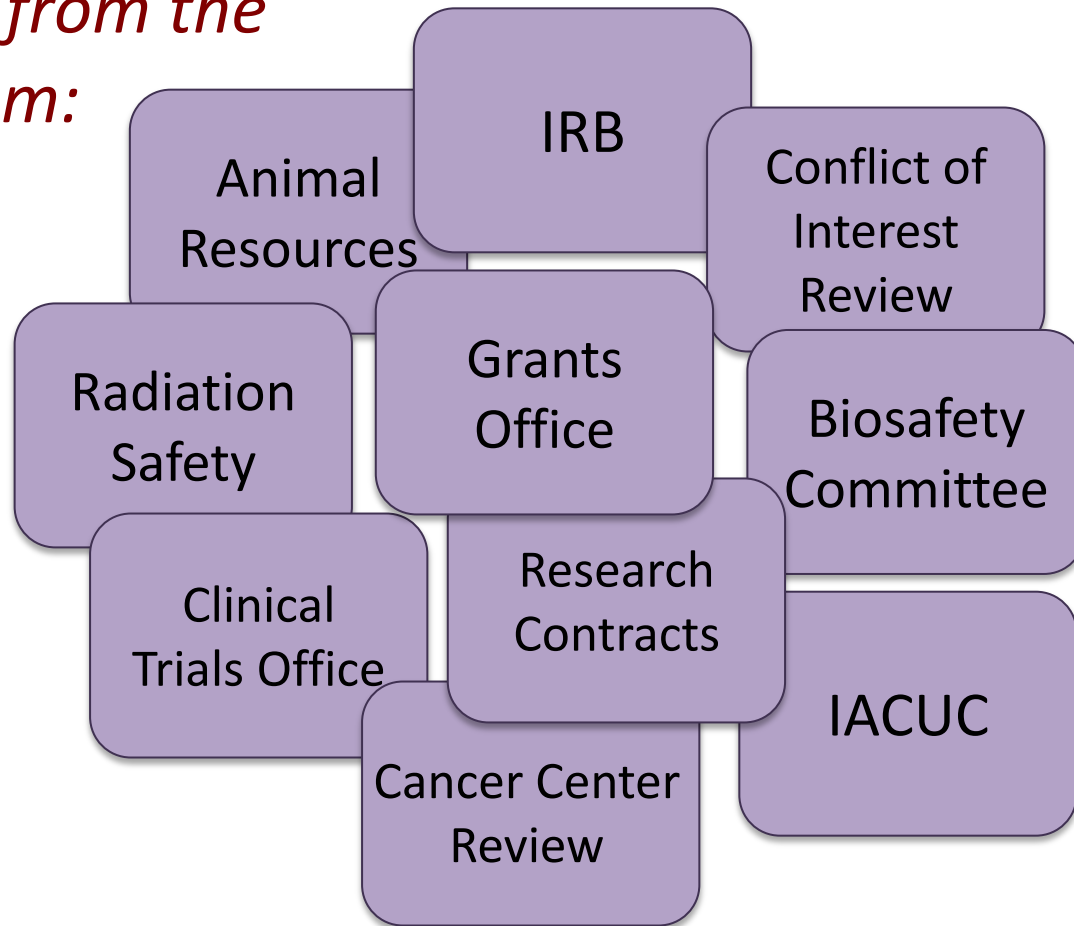
<b>Total Grant Funding</b>	<b>\$265M</b>
<b>Active Human Research Studies</b>	<b>2,100</b>
<i>Active Clinical Research</i>	<i>700</i>

# Enterprise vision/strategy

- Why do we need one?

# Research Administration

*The view from the study team:*



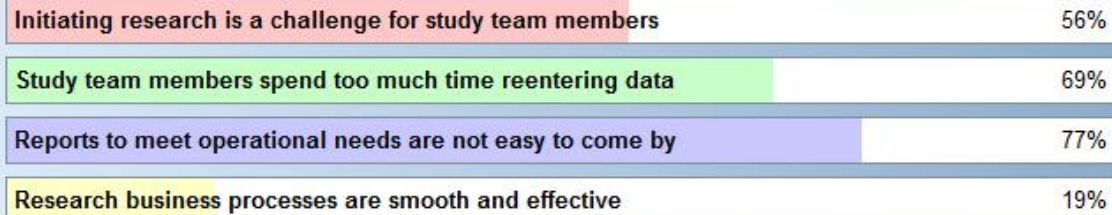


# Results of Poll #1

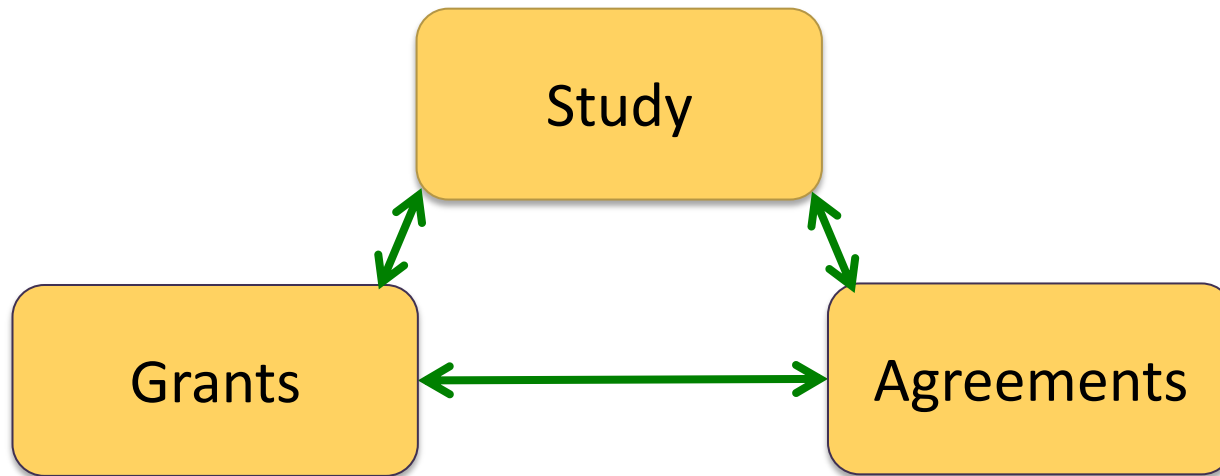
## QUICKPOLL

### Select the statements that you agree with:

Poll Results (multiple answers allowed):

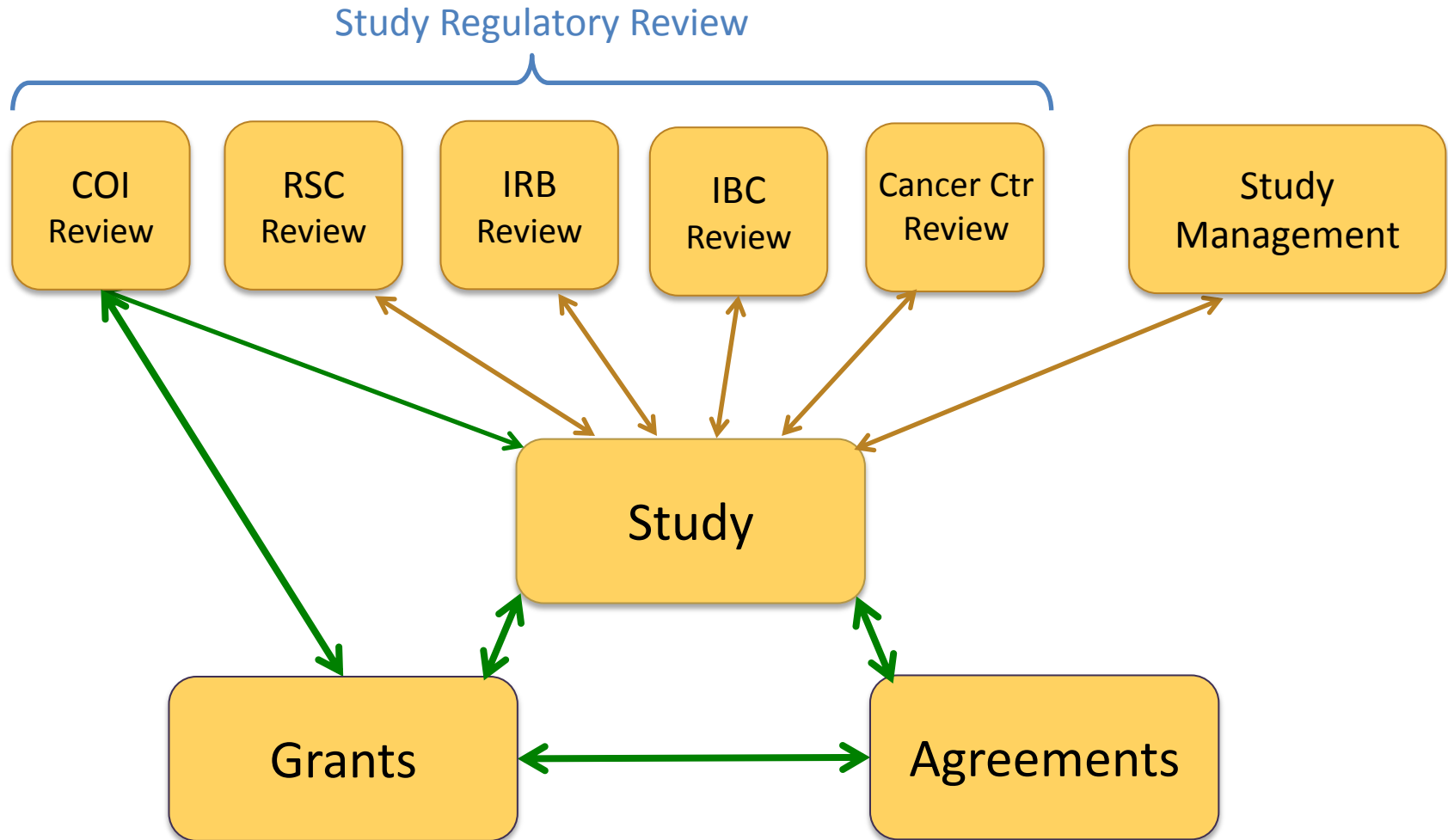


# Rethinking the approach: *Clinical Research Example*



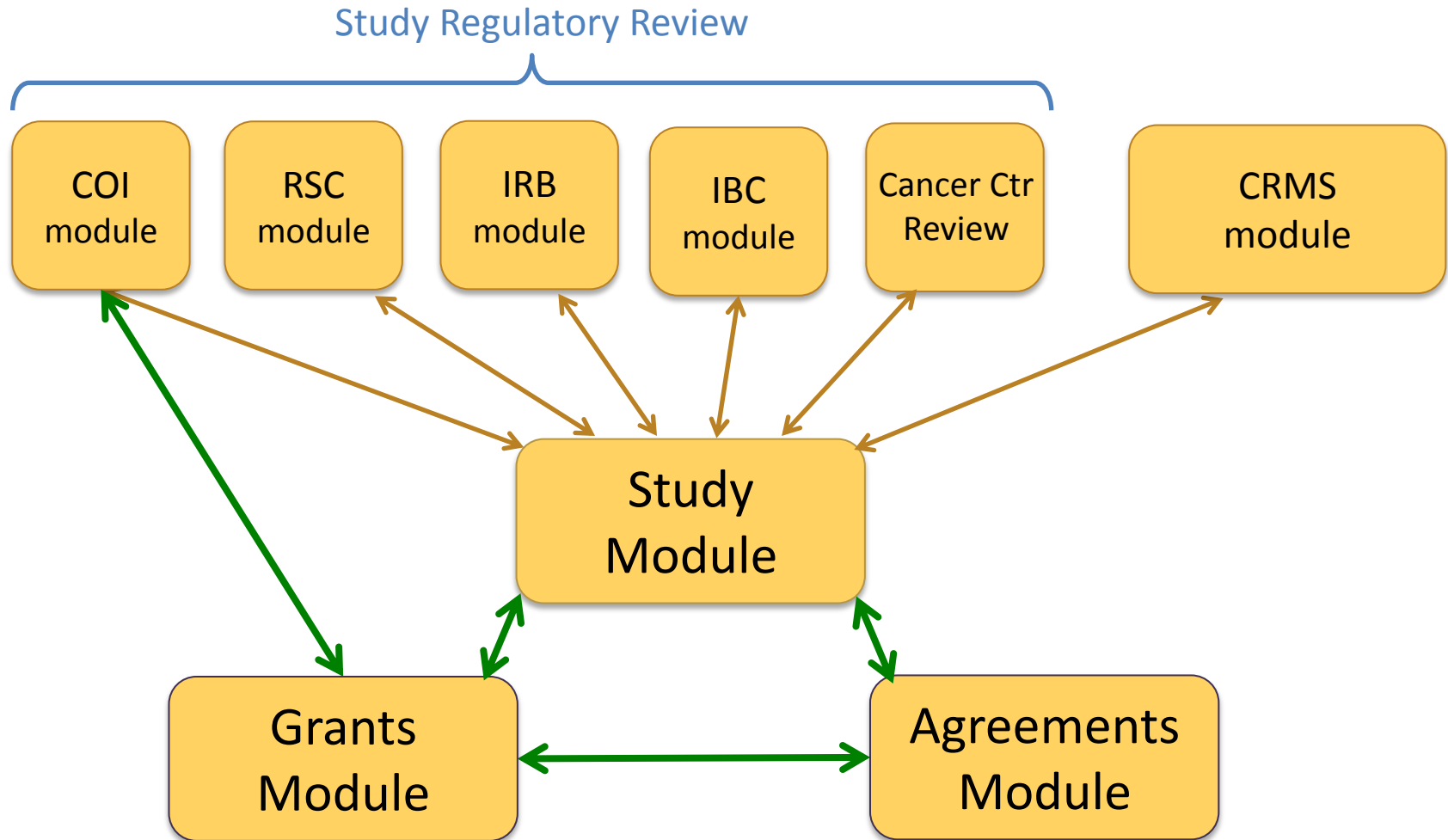
COI: Conflict of Interest  
IBC: Institutional Biosafety Committee  
IRB: Institutional Review Board  
RSC: Radiation Safety

# Rethinking the approach: *Clinical Research Example*



COI: Conflict of Interest  
IBC: Institutional Biosafety Committee  
IRB: Institutional Review Board  
RSC: Radiation Safety

# Rethinking the approach: *Clinical Research Example*



COI: Conflict of Interest

IBC: Institutional Biosafety Committee

IRB: Institutional Review Board

PRMC: Protocol Review & Monitoring Committee

CRMS: Clinical Research Management System

# Readiness for integration strategy

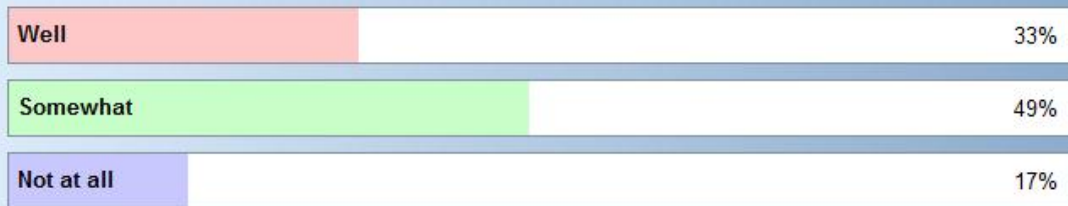
- True partnership between research administration and IT department
- “Integration” – making sure we’re all speaking the same language
- Leadership & collaboration
  - Communication between/among research administrative offices
- Common data elements
- Incorporating the study team perspective
- Project team logistics

# Results of Poll #2

## QUICKPOLL

### Our institution's IT organization understands our research administration operations:

Poll Results (single answer required):



# “Integration”

- **IT vs Operational definition**
  - *Copying data from one module into other(s)*
  - *Publishing data from one module to other(s)*
  - *Viewing data from one module in a different module*
  - *Linking data between modules*

# Leadership & collaboration

- **Identifying project owner**
  - *Responsible for eliciting cross-dept vision*
  - *Responsible for implementing the vision*
- **Defining common needs**
  - *Understanding each other's business processes enough to "row together"*
- **Structuring project teams**
  - *Module specific teams*
  - *Inter-module working groups*



# Common Data Elements

- **Common data dictionaries;** e.g. gold standard source of common information:
  - Persons
  - Organizations
  - Study interventions (drugs, devices, etc.)

# Results of Poll #3

## QUICKPOLL

**To what degree has your institution established the use of common data elements across administrative departments?**

Poll Results (single answer required):

No 2 departments are using common data elements	20%
2 or more departments are using common data elements	49%
We have a global initiative to standardize data elements	31%

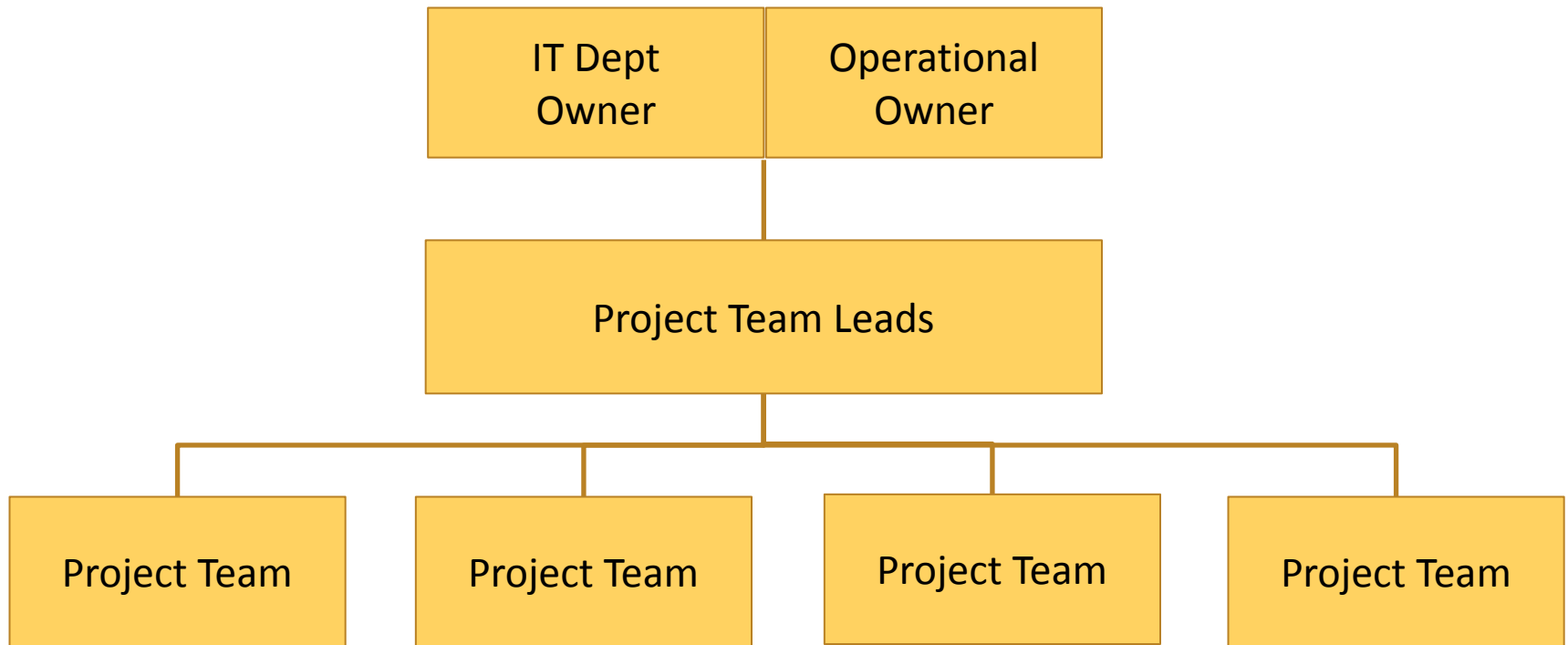
# The study team perspective

- **Direct:**
  - *Focus groups*
  - *Feedback groups*
  - *Involvement in system testing*
- **Indirect:**
  - *Members of central administrative team with research experience*

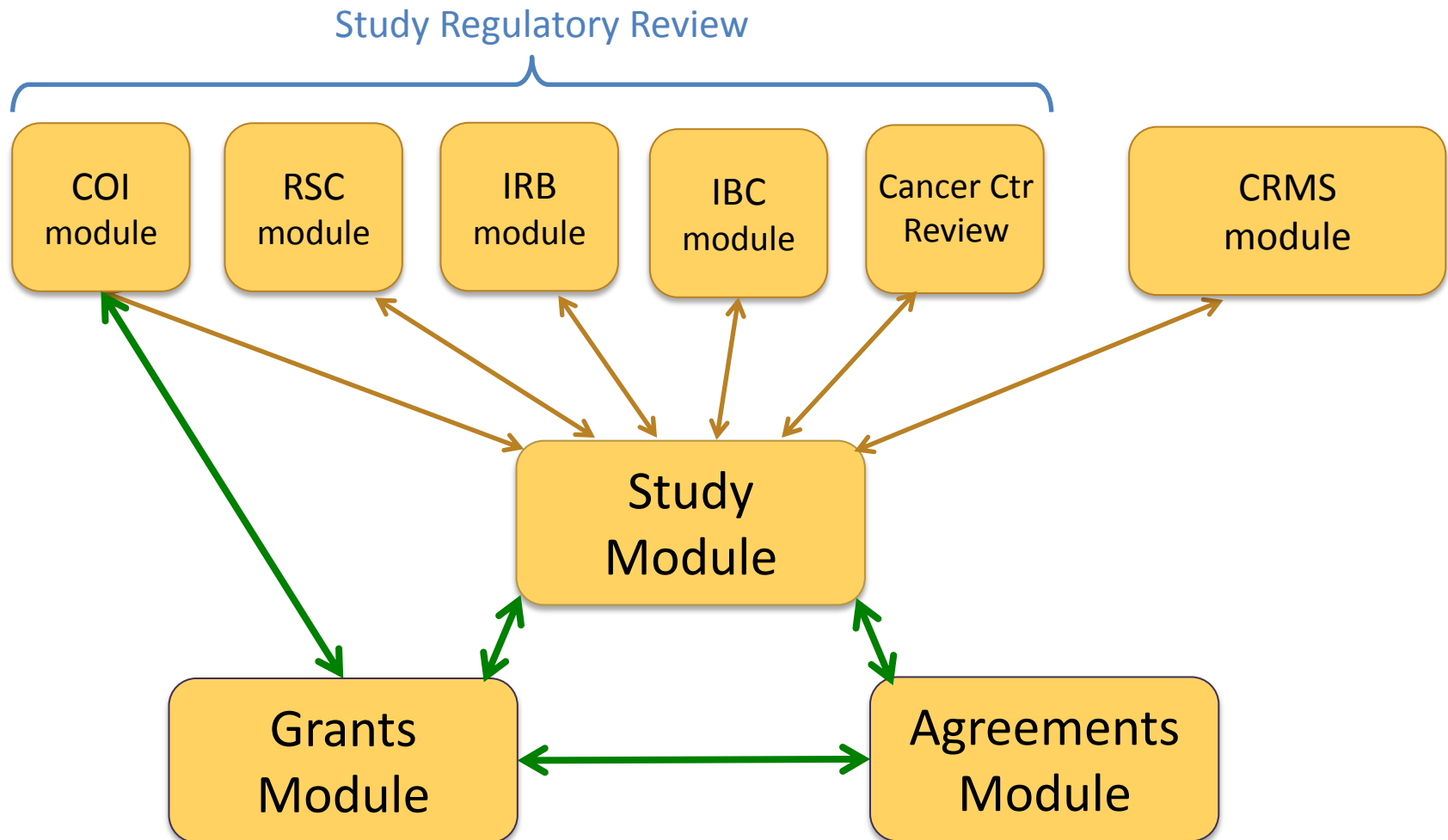
# Project teams

- Many different approaches
- Important to design an approach that fits with your organizational structure/culture

# Project Management



# Rethinking the approach: *Clinical Research Example*



COI: Conflict of Interest

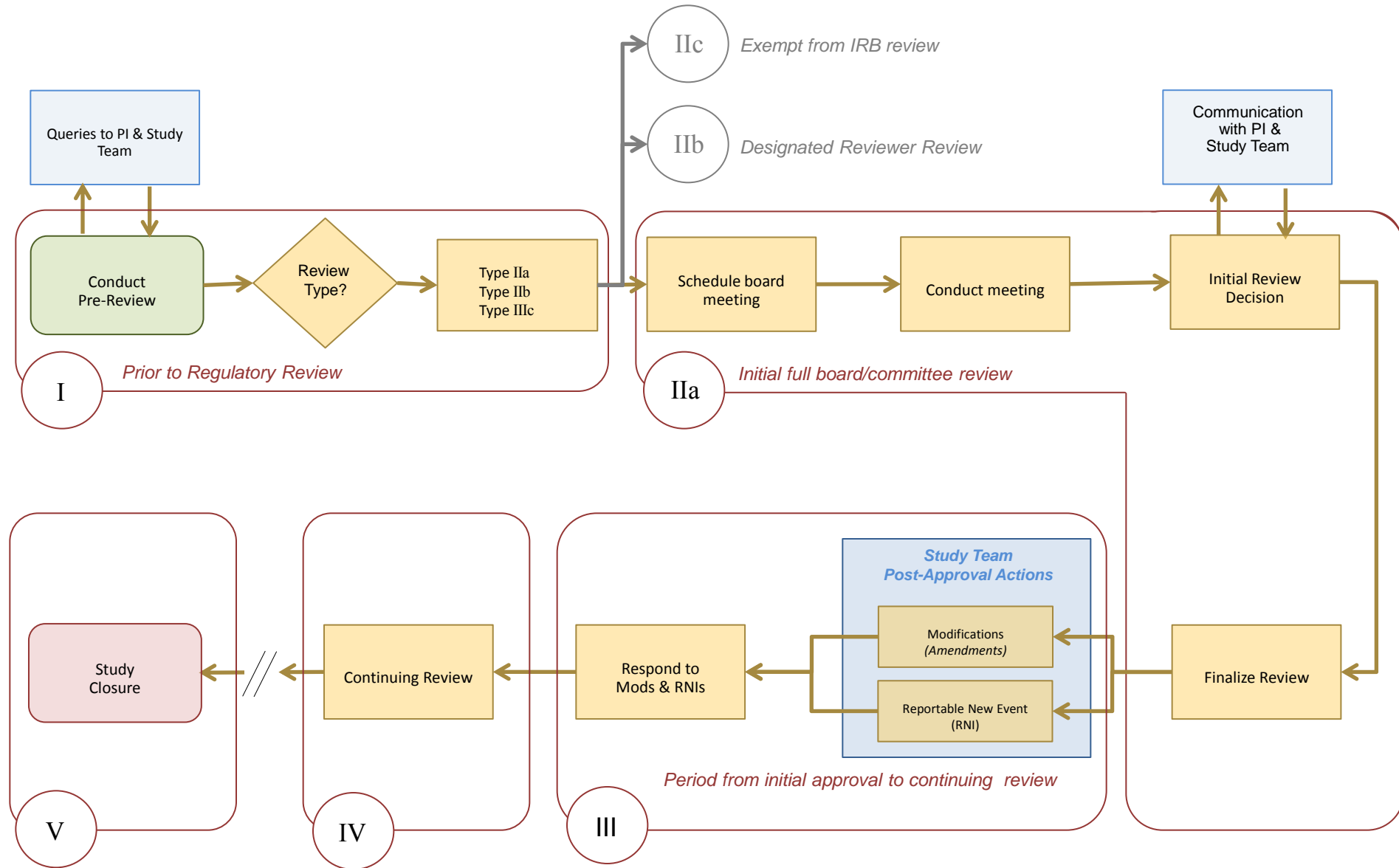
IBC: Institutional Biosafety Committee

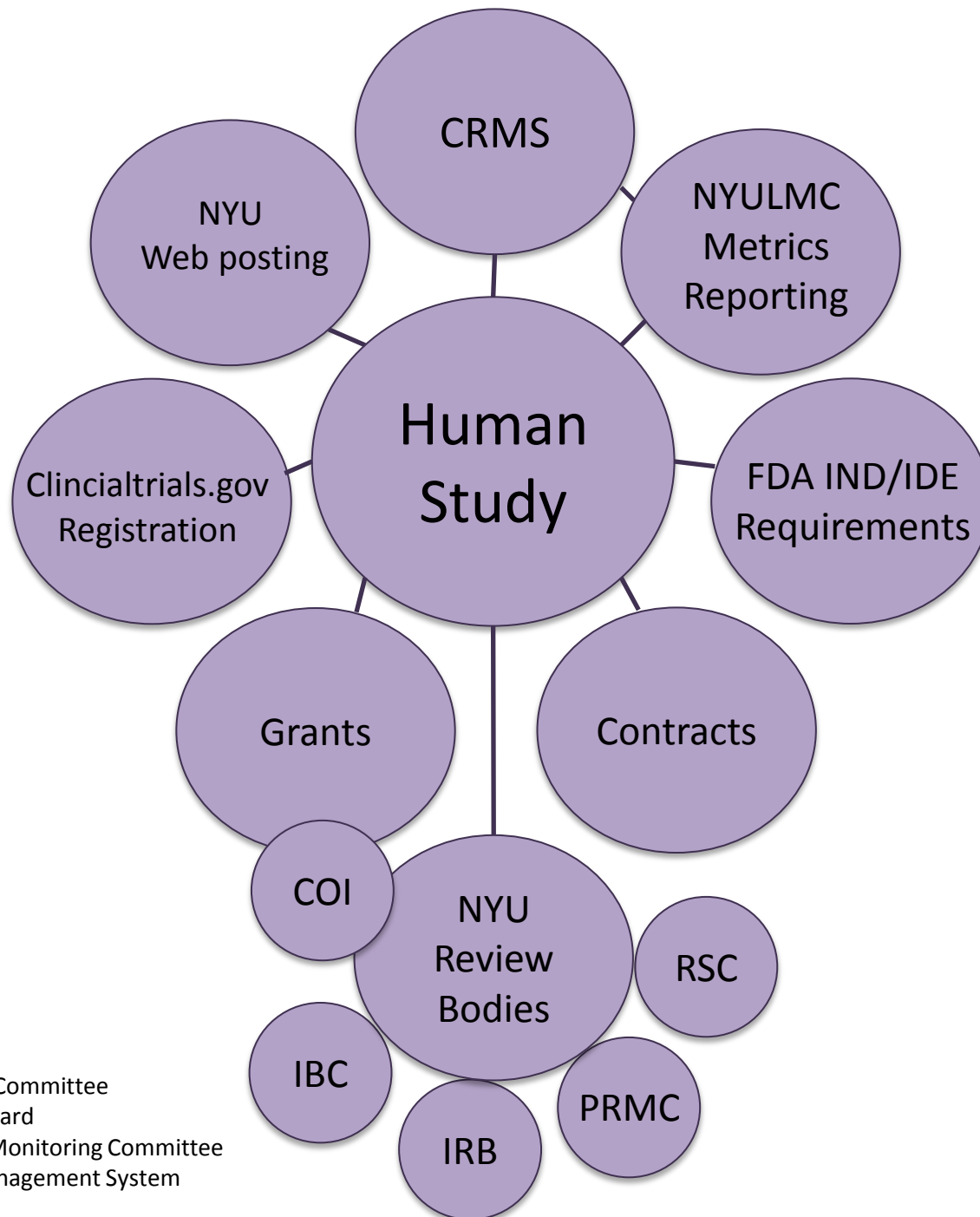
IRB: Institutional Review Board

PRMC: Protocol Review & Monitoring Committee

CRMS: Clinical Research Management System

# The Regulatory Review Process





COI: Conflict of Interest

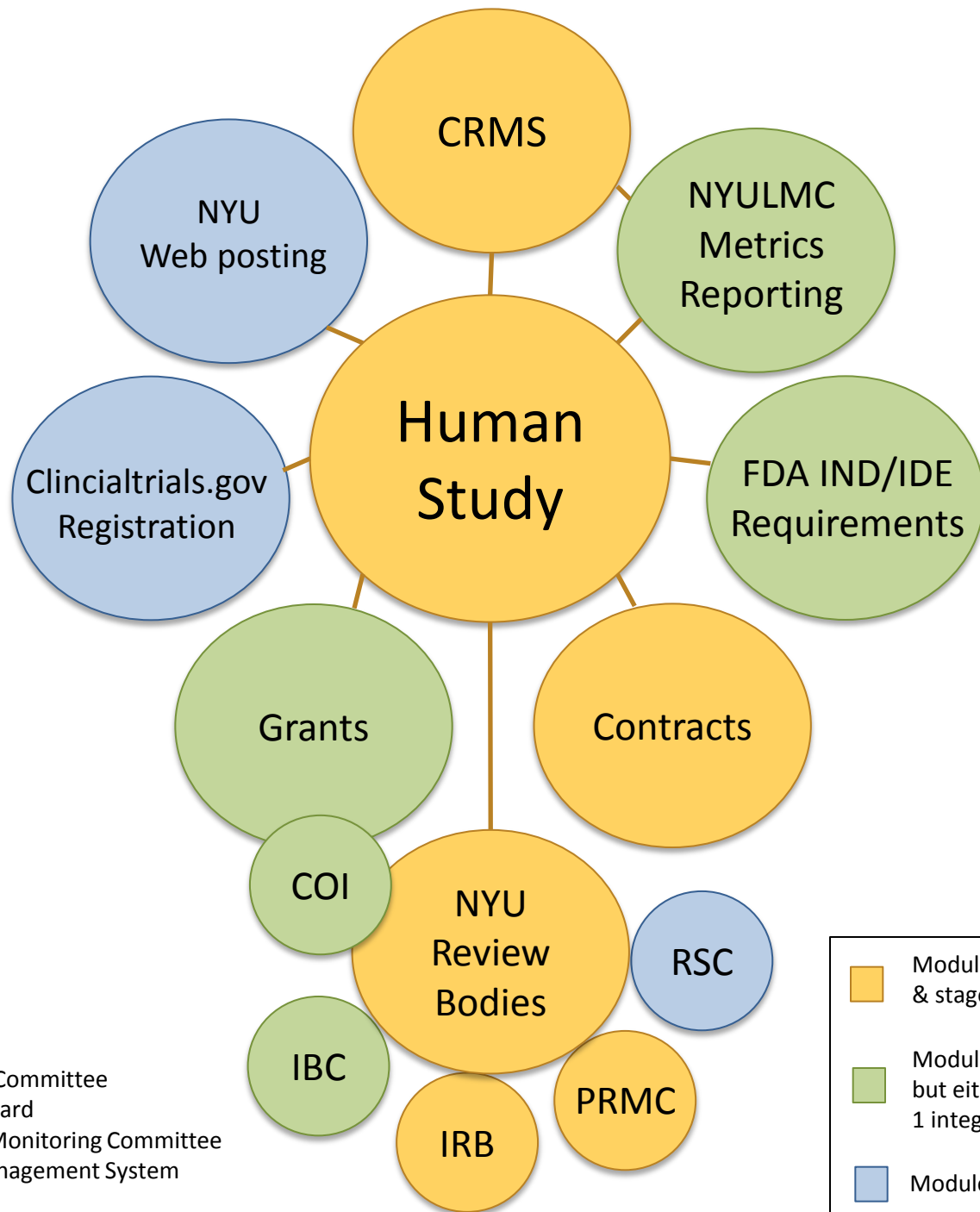
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COI: Conflict of Interest  
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<span style="color: yellow;">■</span>	Module/functionality in place & stage 1 integration completed
<span style="color: lightgreen;">■</span>	Module/functionality in place but either none or only early stage 1 integration
<span style="color: lightblue;">■</span>	Module/functionality not yet in place

# Summary

- **Enterprise strategy/vision** – the overarching roadmap
- **Importance of study team perspective** as a driver to user interface
- **Evaluate readiness** for implementing the enterprise vision
  - *Sr. Leadership support*
  - *Shared ownership - operational and IT owners*
  - *Common language about “integration”*
  - *Standardizing common data sets (persons, organizations, drugs, etc.)*
- **Project team organization**
  - *Key “command and control” structure for implementation*
  - *Supports co-ownership model (operations + IT)*
  - *Relies on and supports cross-department collaboration*

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## New Study

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## New Agreement

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Clear

Advanced

Export

ID	Name	<input checked="" type="checkbox"/> Status	Related IRB Study	Related CRMS Study
s14-00429	Example Study	Draft		
s14-00585	Test Case - GJF	Discarded		
s14-00481	_Research Project - Mon Dec 2 12:50:58 EST 2013	Discarded		

⏪ < 1 to 3 of 3 > ⏩

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Studies > Example Study

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## Current Status






**Draft**

Edit Study


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## My Activities...

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## OCT Actions

-  [Create CRMS Submission](#)

## Study: Example Study (s14-00429)

**Principal Investigator:** [Gregg Fromell](#)  
**Study Purpose:** [Treatment](#)  
**Responsible IRB:** [NYU School of Medicine](#)  
**Version:** 0.0  
**Update Explanation:**  
**Brief Description** [view](#)

Related Submission Link	Status	Current?
IRB:		<input type="checkbox"/>
CRMS:		<input type="checkbox"/>
Ancillary Review	Update On Status	
PRMC:	N/A	
RSC:	Required	
IBC:	N/A	
ESCRO:	N/A	
COI:	Required	

### Study Submissions

Study Documents

Related Agreements

Study Contacts/Personnel

History Log

Data for IRB

### Related submissions

Filter by  ID    [Advanced](#)

No data to display.

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
**Draft**

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IBC:	N/A	
ESCRO:	N/A	
COI:	Required	

Study Submissions

**Study Documents**

Related Agreements

Study Contacts/Personnel

History Log

Data f

**Associated Agreements:** 

**IRB Documents:**

**Protocol:** [Protocol\\_Demo\\_2013-10-10.docx\(0.01\)](#)

**Consent Forms:**

name	description
<a href="#">Consent_Demo_2013-10-10.docx</a>	

**Assent Forms:**

name	description
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


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CRMS:		<input type="checkbox"/>
Ancillary Review	Update On Status	
PRMC:	N/A	
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


Data for IRB

**Related Agreements:**


ID	Name	Created By	Document	Status	Selectica Status
a00001778	<a href="#">Inbound project funding/support - SANOFI-AVENTIS US INC - Fromell</a>	Gregg Fromell	<a href="#">CTA_Demo_2013-10-10.docx(0.01)</a>	Prepare Submission	1



**My Activities...**

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-  [Discard Study](#)
-  [Log Public Comment](#)
-  [Manage Agreements](#)
-  [View Legacy Documents](#)

**OCT Actions**

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**Create Agreement**

[Create...](#)

**Create Sub-Study**

[Create...](#)

**Brief Description** [view](#)

PRMC: N/A  
 RSC: Required  
 IBC: N/A  
 ESCRO: N/A  
 COI: Required

- [Study Submissions](#)
- [Study Documents](#)
- [Related Agreements](#)
- [Study Contacts/Personnel](#)
- [History Log](#)
- [Data for IRB](#)

**Principal Investigator:**

Gregg Fromell

**Study Departmental Administrator:**

Anny Fernandez

**Study Team Contacts:**

Contact Other Contact For Details

There are no items to display

**Team Sub Investigators:**

First Name	Last Name	Employer	Title
Elan	Czeisler	Science Operations & Transform	Dir-Institutional Review Board
Jean	Gatewood	Science Operations & Transform	Dir-Clinical Trials

**Research Coordinators:**

Name	Department	Phone	E-mail
Lenide Geffrard	Office of Science & Research		geffr101@nyumc.org
Ronnie Landis	Office of Science & Research		landir01@nyumc.org

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

**Draft**

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Continue >>

## General Information


1.0

\* **Principal Investigator:** Gregg Fromell   

1.1

**Administrative Department:** Office of Science & Research 

2.0

\* **Official Study Title:** 

Example study

3.0

\* **Brief Title:**  

4.0

**Acronym Title:**  


5.0

\* **Primary Focus of Study:** 

*Interventional research*

Drug, device, behavioral, surgical or other medical intervention.

5.0

**\* Primary Focus of Study:** 

*Interventional research*

- Drug, device, behavioral, surgical or other medical intervention.
- Mechanistic or physiologic study in humans.
- Expanded access.

*Non-interventional research*

- Biospecimen research.
- Research on human data sets.
- Survey research.
- Observational research.
- Enrollment screening protocol.

*Special Cases*

- Research evaluating educational practices or educational tests.
- Taste/food quality evaluation.
- Evaluation of public benefit or service programs.

Clear

6.0


**\* Study Purpose:** 

- Treatment
- Prevention
- Diagnostic
- Supportive Care

**8.1 NYU Investigator is the Protocol Author or contributed in a significant way to the Study Design or Study Plan:**


Yes  No [Clear](#)

**9.0 Ancillary Study:**

Yes  No [Clear](#) 

**10.0 \* Cancer-related Research:**  Yes  No [Clear](#) 

**11.0 \* Genetic Testing:**  Yes  No [Clear](#) 


**12.0 CTSI resources will be used in this study:**  Yes  No [Clear](#) 

**13.0 \* Multi-site Study?**  Yes  No [Clear](#)

**Is NYU Investigator the Study Chair?**  Yes  No [Clear](#)

**NYU is the clinical coordinating center:**  Yes  No [Clear](#)

**NYU is the data coordinating center:**  Yes  No [Clear](#)

**External DSMC Used:**  Yes  No [Clear](#) 

**14.0 \* IRB Overseeing Study at NYU site:**

NYU School of Medicine

BRANY

Other (Specify)

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Example study


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\* **Brief Title:**  

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**Acronym Title:**  

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\* **Primary Focus of Study:** 

- Interventional**      Drug, device, behavioral, surgical or other medical intervention.
- Interventional**      Mechanistic or physiologic study in humans.

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## General Information

1.0	<b>* Principal Investigator:</b> <input type="text"/>	<p><b>01 - General Information</b></p> <ul style="list-style-type: none"> <li>- 1.1) Initial Study Information</li> <li>- 1.2) Study Personnel</li> </ul> <hr/> <p><b>02 - Funding Sponsorship Information</b></p> <ul style="list-style-type: none"> <li>- 2.1) Sponsor</li> </ul> <hr/> <p><b>03 - Study Design</b></p> <ul style="list-style-type: none"> <li>- 3.1) Interventional Research</li> <li>- 3.1.1) Interventional Research Continued</li> </ul> <hr/> <p><b>04 - Subject &amp; Analysis Information</b></p> <ul style="list-style-type: none"> <li>- 4) Subject &amp; Analysis Information</li> </ul> <hr/> <p><b>05 - Locations</b></p> <ul style="list-style-type: none"> <li>- 5) Locations</li> </ul> <hr/> <p><b>06 - Sponsor/Institution/IRB/EC Information</b></p>	
1.1	<b>Administrative Department:</b> <input type="text"/>		
2.0	<b>* Official Study Title:</b> <input type="text" value="Example study"/>		
3.0	<b>* Brief Title:</b> <input type="text" value="Example Study"/>		
4.0	<b>Acronym Title:</b> <input type="text"/>		
5.0	<b>* Primary Focus of Study:</b> <input checked="" type="radio"/> <input type="radio"/>		
	<input checked="" type="radio"/> <b>Interventional</b> Drug, device, behavioral, surgical or other medical intervention.		
	<input type="radio"/> <b>Interventional</b> Mechanistic or physiologic study in humans.		



## General Information

<b>1.0</b>	<b>* Principal Investigator</b>		
<b>1.1</b>	<b>Administrative Department</b>		
<b>2.0</b>	<b>* Official Study Title:</b>	<input type="text" value="Example study"/>	
<b>3.0</b>	<b>* Brief Title:</b>	<input type="text" value="Example Study"/>	
<b>4.0</b>	<b>Acronym Title:</b>	<input type="text"/>	
<b>5.0</b>	<b>* Primary Focus of Study:</b>	<ul style="list-style-type: none"> <li><input checked="" type="radio"/> <b>Interventional</b>      Drug, device, behavioral, surgical or other medical intervention.</li> <li><input type="radio"/> <b>Interventional</b>      Mechanistic or physiologic study in humans.</li> <li><input type="radio"/> <b>Interventional</b>      Expanded access.</li> <li><input type="radio"/> <b>Non-Interventional</b>      Biospecimen research.</li> <li><input type="radio"/> <b>Non-Interventional</b>      Research on human data sets.</li> <li><input type="radio"/> <b>Non-Interventional</b>      Survey research.</li> </ul>	

- 2.1) Sponsor

-----  
**03 - Study Design**

- 3.1) Interventional Research
- 3.1.1) Interventional Research Continued

-----  
**04 - Subject & Analysis Information**

- 4) Subject & Analysis Information

-----  
**05 - Locations**

- 5) Locations

-----  
**06 - Cancer Institute: PRMC Information**

- 6) Cancer Institute: PRMC Information

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**07 - Uploads**

- 7) Uploads



Save | Exit | Hide/Show Errors | Print... | Jump To: - 3.1.1) Interventional Research Continued

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## Study Design - Interventions

1.0

### Drug Interventions:

Add

Name	Manufacturer	FDA Approved
Update	ENOXAPARIN	yes

Delete

2.0

### Biologic Interventions:

Add

Name	Manufacturer	FDA Approved
There are no items to display		

3.0

### Botanical & Dietary Supplement Interventions:

Add

Drug	Other Name
There are no items to display	

4.0

### Device Interventions:

Add

Name	Other Name	FDA Approved Device	IDE Number
There are no items to display			

5.0

### Radiation Interventions:

Add

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Create New Study

Create...

My Inbox

**My Studies**

My Agreements

ID	Name	State	Created Date	Modified Date
S13-00045	Mechanisms Of Retinal Neurodegeneration and Visual Pathway Axonal Loss in MS	Open	11/8/2013 11:27 AM	3/27/2014 12:25 AM
S13-01229	NYU Langone Concussion Center Registry	Open	11/8/2013 11:27 AM	5/22/2014 8:38 AM
S13-00297	Rapid Sideline Screening Tests for Sports-Related Concussion	Submitted	11/8/2013 11:27 AM	5/12/2014 4:38 PM
S13-01255	Visual Structure and Function in Contact Sport Athletes	Submitted	11/8/2013 11:27 AM	3/6/2014 3:50 PM
S13-00742	The New York City Collaborative Regional Coordinating Stroke Center	Submitted	11/8/2013 11:27 AM	11/11/2013 6:09 PM
s14-01121	King-Devick (K-D) Test Performance in the Pediatric Population	Submitted	4/24/2014 9:51 AM	5/14/2014 4:07 PM
s14-01122	King-Devick (K-D) Test Performance in the Pediatric Population	Withdrawn	4/24/2014 9:52 AM	4/30/2014 5:09 PM

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# Results of Poll #4

## QUICKPOLL

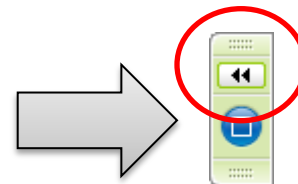
### Which statement best describes your research IT development resources?

Poll Results (single answer required):

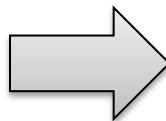
Research application development reports to Research	23%
Research application development reports to central IT	39%
Application development reports to both Research and IT	30%
We don't have any research application development resources	2%
Don't know	7%

# Questions: Using the GoToWebinar Toolbar

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Questions

Questions Log

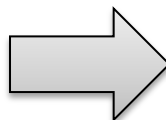
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Enter a Question in this dialog area at any time.



# Webinar Next Steps



- A copy of the webinar recording will be available next week (you will receive an automatic email)
- All questions will be answered in the summary Q&A available next week
- Results of the polling questions will be included

# Contact Us



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