

# Examining medical ethics through the lens of health services research

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# Support

- I am supported by two HSR&D awards including my CDA (CDA 08-281) and the SDR that funds this study on IRB efficiency and quality (SDR 11-399-1).
- Also supported by the infrastructure provided by the Center for Health Equity Research and Promotion (CHERP).

Many Thanks!

# Goals for this hour

- Share some of the findings and methods from my CDA research in order to:
  - Disseminate findings
  - Network for possible future collaborations
- Describe some of the detours I've navigated over the 5 years of the award in order to:
  - Permit others to learn from my experience
  - Solicit advice for the future

# Outline

- Career Goal: Surgical Ethics Researcher
- Research Topics:
  - Clinical Ethics: Informed Consent
  - Research Ethics: IRB efficiency and Quality
- Future Directions: Improving outcomes for frail Veterans considering elective surgery.
- Discussion

# Poll Question 1 of 3: Who is listening?

- What category best describes you?
  - Aspiring CDA applicant
  - Current CDA recipient
  - CDA graduate
  - CDA mentor
  - Other health services researcher

# Poll Question 2 of 4:

- Do you consider yourself a scientist?
  - Yes
  - No

# Career Goal: Surgical Ethics Researcher

- A bit about me...
  - General Surgeon and medical ethicist
    - Background in moral philosophy and theology
    - Episcopal priest
  - Undergraduate degree in biology and philosophy with senior essay on the ethics of sequencing the human genome
  - Graduate schools in theology and medicine
  - Surgical residency at the University of Pittsburgh
  - Postdoc fellowship in religion and medicine at Duke
  - Joined Pitt faculty in 2007, now Associate Professor
  - CDA recipient 2010-2015, full time at VA
    - Operate 1 week/month with remaining time for research

# Career Goal: Surgical Ethics Researcher

- Goal to become independent investigator with focus on surgical ethics
  - Clinical ethics is my primary concern—how to be a good (rather than just technically excellent) surgeon.
  - Research ethics is where most of the money is, and I've followed that trail of opportunity.
  - Primary Mentor: Robert Arnold
    - Internist and Palliative Care physician with research expertise in ethics, patient-physician communication and palliative care
  - Secondary Mentor: Michael Fine
    - Internist and health services researcher who co-directs the CHERP with expertise in pneumonia and disparities.
  - Surgical Mentor: Various
    - My career path is unusual, and I don't have a direct mentor to guide my career development. This has been both interesting and challenging.

# Career Goal: Surgical Ethics Researcher

- Philosophical Approach
  - No clear career path or home for an academic medical career focused on ethics
  - Health services research was the closest fit at my institution
    - Focus on overarching coordination, quality and effectiveness leads to fundamentally philosophical questions of “why?” or “for what purpose?” or “to what end?”

# Poll Question 3 of 4:

- Do you regularly interact with patients clinically?
  - Yes- surgery and its subspecialties
  - Yes- medicine and its subspecialties
  - Yes- behavioral health (MD, MSW, PhD)
  - Yes- nursing
  - No/other- Please describe via online response

# Poll Question 4 of 4:

- Do you consider yourself a moral philosopher or ethicist?
  - Yes
  - No

# Career Goal: Surgical Ethics Researcher

- Philosophical Approach (continued)
  - Critical of “standard”, procedural bioethics
    - Seek a set of rules by which any rational agent can determine the right and good course of action regardless of the content of their character.
      - Although such rules exist, they don’t provide much substantive moral guidance (e.g., they are what philosophers call “thin” accounts of moral philosophy).
    - Consensus is promised, but in seeking the least common denominator, medical ethics are evacuated of content.
  - Aristotelian virtue ethics acknowledge the critical role of character in moral deliberation and action
    - Procedural ethics cannot replace character.
    - How best to form good character (vs. good procedure)?

# Career Goal: Surgical Ethics Researcher

- Philosophical Approach (continued)
  - Practical wisdom (*phronesis*)
    - Capacity to choose the best from among multiple imperfect options
    - Learned not from books, but from experience
      - No class in ethics will ever make you practically wise
    - Embodied and transmitted by communities of practice
      - Masons know how to build walls that bear weight
      - Surgeons know how to improve health by rearranging organs
    - Messy, but satisfying
      - No pat answers; no procedural solutions; but important content
      - Technically challenging cholecystectomy vs. morally challenging conversation that shifts goals from cure to comfort.
    - All clinicians are practical moral philosophers.

# Career Goal: Surgical Ethics Researcher

- Philosophical Approach (continued)
  - The role of empirical data
    - Empirical argument not particularly suited to moral inquiry, but the analytical arguments better suited to moral inquiry are typically viewed with skepticism.
    - Empirical ethics can answer some questions through the kind of open inquiry typical of empirical methods.
    - Empirical ethics can also develop evidence to test (or support) analytical hypotheses (or conclusions).
    - My goal has been to see if I can develop data that can refine (or reform) standard bioethics to better reflect the actual moral practices on the ground.

# Clinical Ethics: Informed Consent

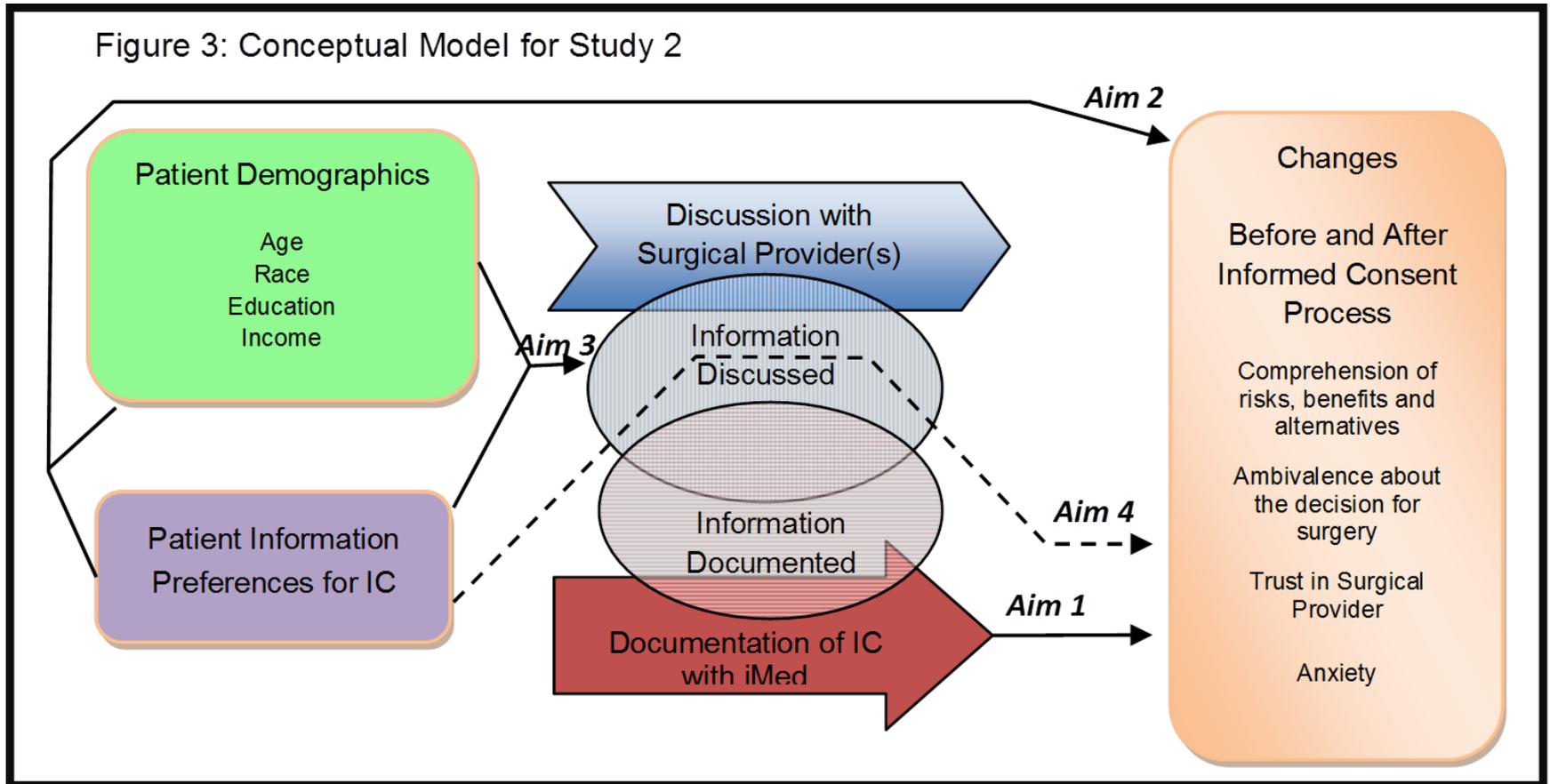
- Bedrock of standard bioethics
  - Erected against the specter of “paternalism”
  - Ritualized dogma—Almost beyond critique
- Rarely achieves its ideals (legal, ethical or administrative)
- Doesn't describe the way most of my patients actually make decisions
- Some have suggested abandoning it entirely
  - Mandatory autonomy
  - Is it about information or trust?
- Paradigm for shared decision-making, but how, precisely, is it shared?

# Informed Consent: Methods

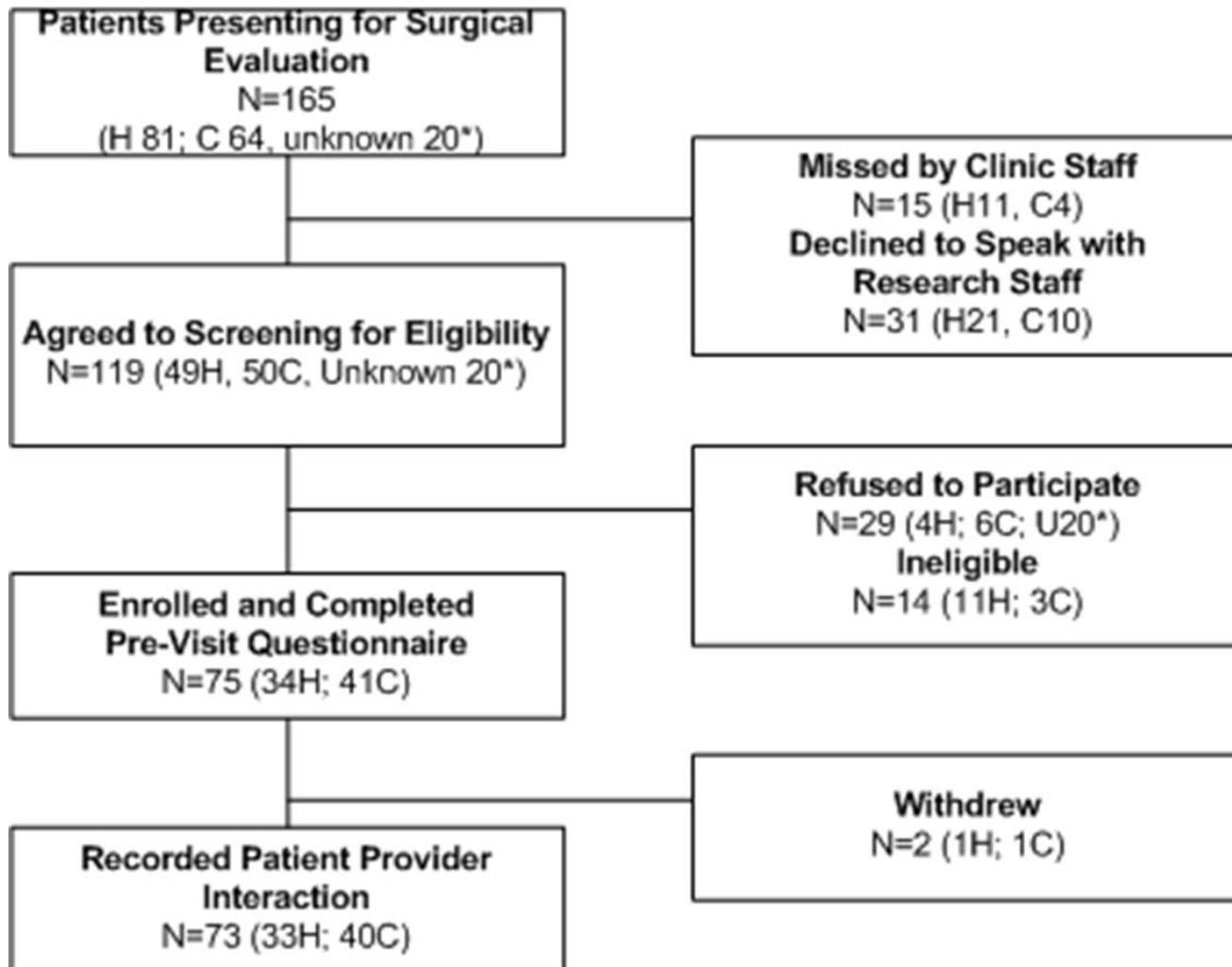
- Methods
  - Enrolled cohort of patients seeking inguinal hernia or cholecystectomy (2 most common surgeries)
  - Administered questionnaires before and after they met the surgeon(s).
  - Hung a tape recorder around their neck to capture all conversations during their clinic visit(s) until a decision for surgery was made and documented.
  - Conducted semi-structured telephone interviews with patients and providers probing attitudes and opinions about the informed consent process.

# Informed Consent: Conceptual Model

Figure 3: Conceptual Model for Study 2



# Informed Consent: Recruitment



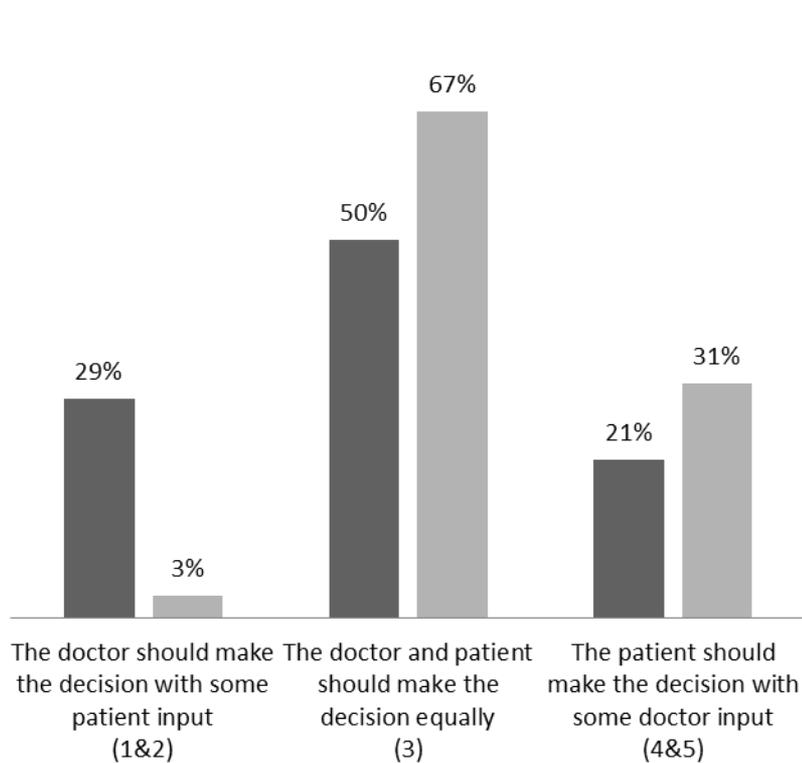
# Informed Consent: Outcomes

Outcome	Before iMed (N=38)	After iMed (N=38)	p value*
	<b>Mean±SD</b>	<b>Mean±SD</b>	
<b>Procedure-specific knowledge ‡</b>	0.50±0.20	0.60±0.18	< 0.001
<b>Understanding operation</b>	0.33±0.31	0.74±0.32	< 0.001
<b>Alternatives</b>	0.43±0.25	0.38±0.26	0.29
<b>Benefits</b>	0.66±0.29	0.76±0.25	0.02
<b>Overall risks</b>	0.50±0.27	0.60±0.21	0.002
<b>Key risks</b>	0.38±0.42	0.68±0.35	0.001
<b>Trust in the surgeon (Range 1-5)</b>	3.67±0.50	3.84±0.60	0.11
<b>Ambivalence about the decision to have surgery (Range 1-4)</b>	2.21±0.66	2.24±0.54	0.67
<b>Anxiety State (Range 1-4)</b>	1.97±0.56	1.91±0.57	0.29
<b>Decision Style (Range 1-4) †</b>			
<b>Defer Responsibility</b>		3.98±0.92	
<b>Information Seeking</b>		2.91±1.24	
<b>Deliberation</b>		3.68±0.83	
<b>Avoidance</b>		1.78±0.75	
<b>Information Seeking Preference (Range 1-5) †</b>		4.49±0.56	

# Informed Consent: Outcomes

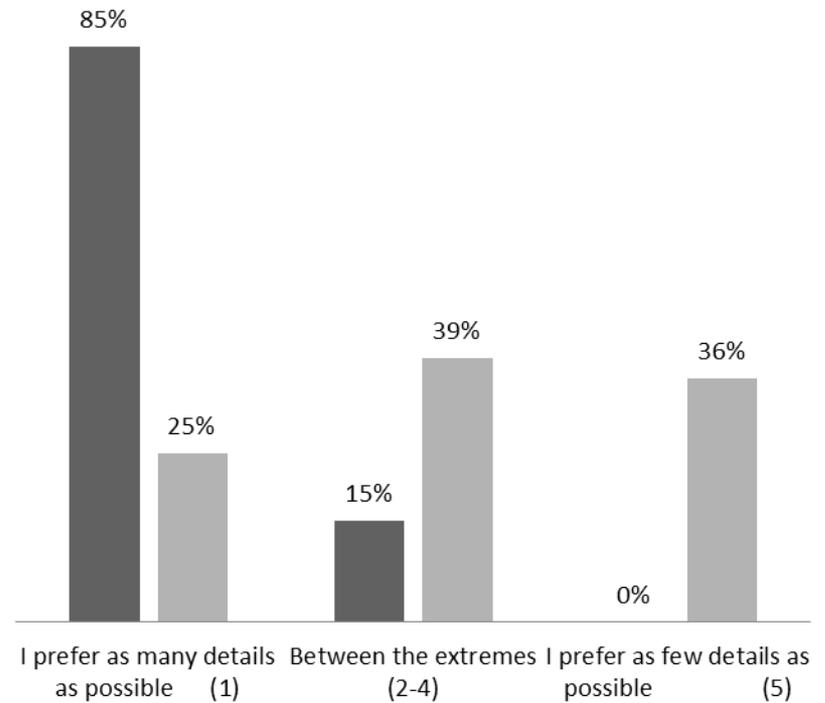
## Participation Preference

■ Before iMed (n=38) ■ After iMed (n=38)



## Information Preference

■ Before iMed (n=38) ■ After iMed (n=35)



## REMINDERS!!

- **YOU MUST GO THROUGH THE ENTIRE FORM** with patient or surrogate.
- **If the patient has a DNR order, you must discuss possible suspension of the order with the patient or surrogate when appropriate. DNR orders MUST NOT be suspended or discontinued without consent of the patient or surrogate.**
- **Ensure that all information is accurate and edit as needed.**
- **Encourage the patient or surrogate to ask questions.**
- **Confirm understanding by asking the patient or surrogate to describe the treatment/procedure in his or her own words**
- **Offer to provide a printed copy of the consent form for the patient to read before asking for a signature.**
- **Offer and provide available educational materials according to the patient's/surrogate's needs or interests.**

OK

# Informed Consent: Information Documented vs. Discussed

		iMed items documented <sup>^</sup>		iMed items discussed <sup>*</sup>		Additional items discussed <sup>†</sup>		Total items discussed <sup>‡</sup>	
		Median	Range	Median	Range	Median	Range	Median	Range
<b>Cholecystectomy (N=20)</b>									
Procedural Information	Risks	18	16-20	6	0-11	1	0-3	7	1-14
	Benefits	3	3	0	0-3	1	0-3	1	0-6
	Alternatives	3	1-3	1	0-3	1.5	0-4	2	0-6
	Indications for Procedure	6	2-6	2	0-5	1	0-3	3	0-7
	Description of Procedure	14	11-15	5	0-9	0	0-3	6	0-12
	<b>Subtotal</b>	<b>44</b>	<b>36-44</b>	<b>15</b>	<b>1-25</b>	<b>5</b>	<b>0-12</b>	<b>22</b>	<b>2-37</b>
Additional Information	Patient Experience					3	0-9	3	0-9
	Anatomy					2	0-6	2	0-6
	<b>Total</b>	<b>44</b>	<b>36-44</b>	<b>15</b>	<b>1-25</b>	<b>10.5</b>	<b>1-20</b>	<b>27.5</b>	<b>2-45</b>

- Patients and providers discussed 37% (95% CI 0.7-.067) of information documented.
- Discussions frequently included relevant details nowhere documented on the forms.
- 80% of discussions discussed at least one risk, benefit or alternative, indication for and description of the procedure.

# How did patients make decision?

- 69% decided to have surgery before meeting their surgeon
  - 47% stated that the surgeon did not influence their decision.
- Although the surgeon was an important source of information for most patients (81%), patients frequently described using information gathered before meeting the surgeon, such as other health care providers (81%) or family members (58%).
- Most (68%) patients perceived iMed as a legal formality with little influence on decision making.

# How did patients make decision?

- No distinction between learning the diagnosis and deciding to have surgery.
  - *The doctor in [city] said I had a hernia so I figured, well, I have to go to the hospital and have it fixed...As soon as I heard the word hernia, I knew that there was nothing I could do. (124)*
- The presence of disease eliminated the perception of a real choice:
  - *“There is no choice: You either have the surgery or you have this for the rest of your life...Pretty much a no brainer there...I knew right away that I had to, you know, I had to have the surgery.” (124)*

# Research Ethics: IRB Quality and Efficiency

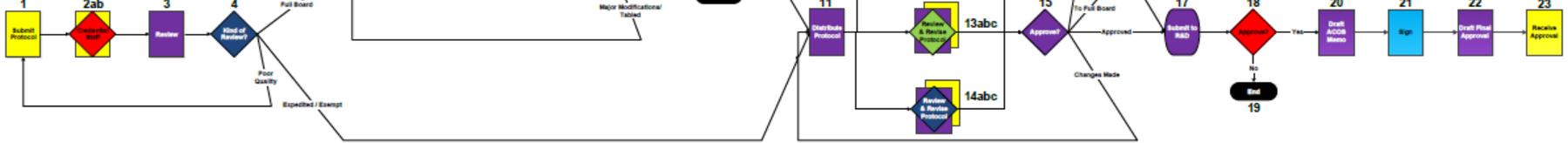
- How did I get involved?
  - Service Directed Research RFA on “Research Best Practices” released in Year 1 of my CDA.
  - Mentors recognized that I had unique skill set to compete for this award and encouraged me to apply.
  - Funded on first submission—off and running with multi-site research project, but only 2 years
  - Required me to develop completely new methods.

# IRB Efficiency and Quality

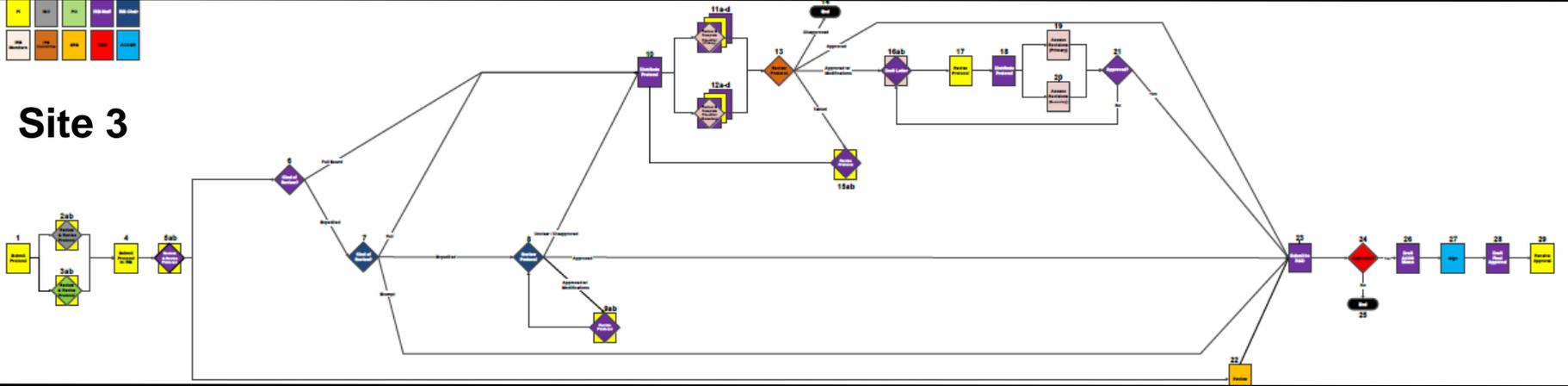
- Methods
  - Partnered with systems engineers from the Veterans Engineering Resource Center (VERC)
  - At 10 sites, including the Central IRB
    - Visited to develop site-specific process flow map of IRB review for newly submitted protocols.
    - Returned for second visit to collect the IRB documentation pertaining to a sample of up to 45 protocols from each site.
      - Abstracted data regarding review times and quality from these records.



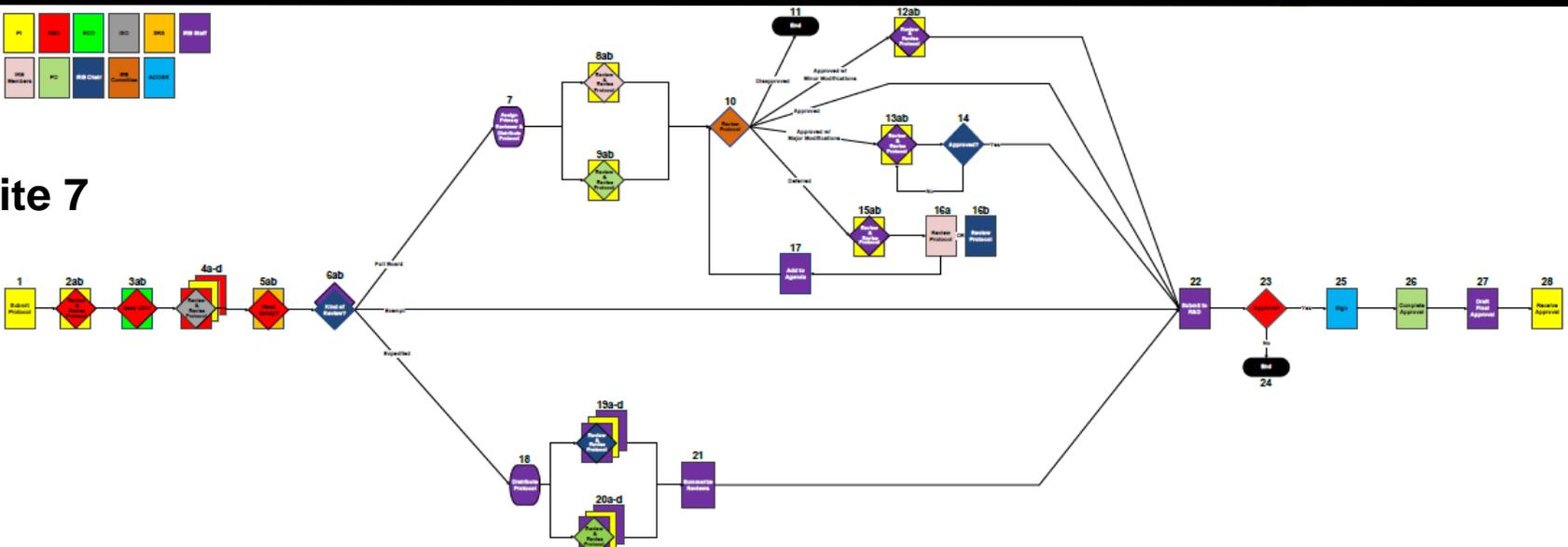
# Site 1



# Site 3

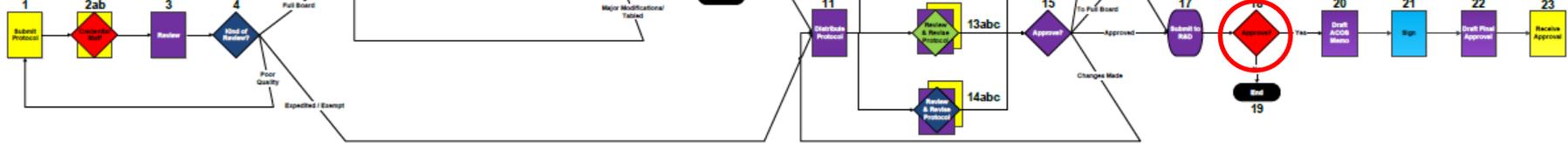


# Site 7

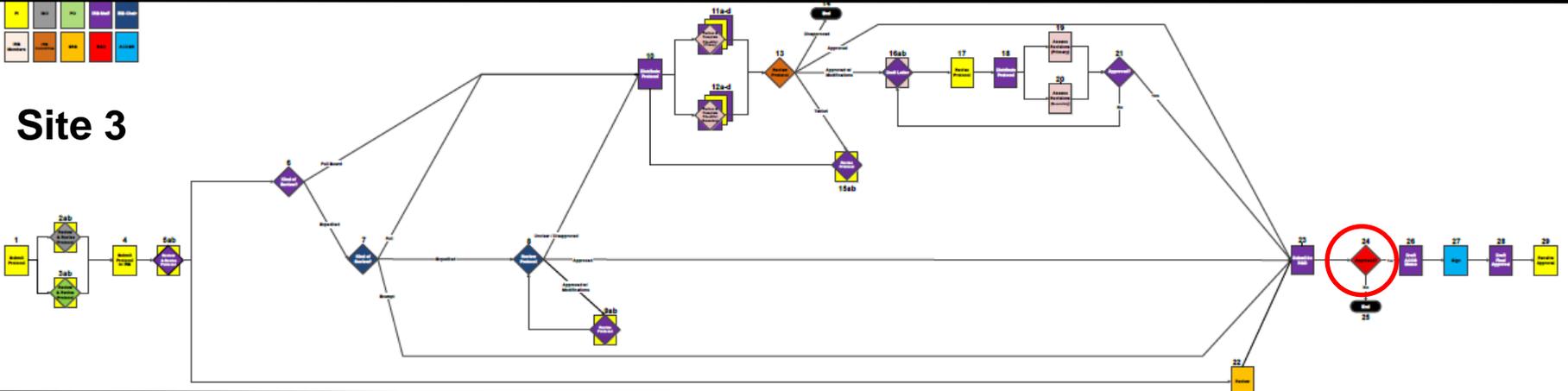




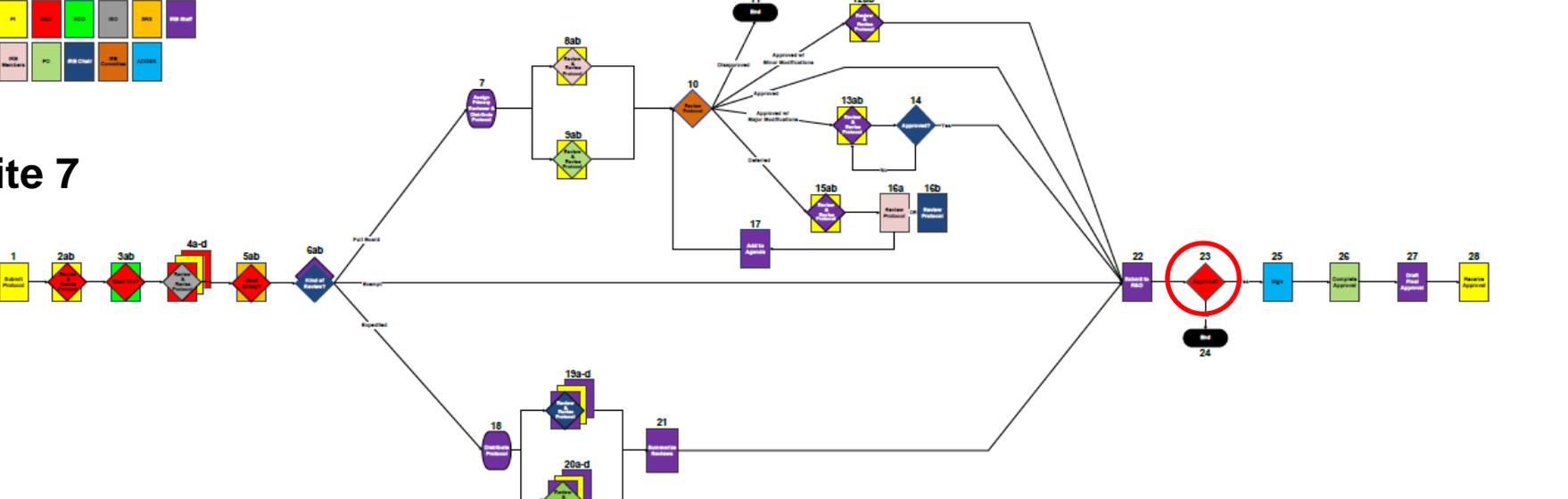
# Site 1



# Site 3

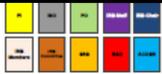
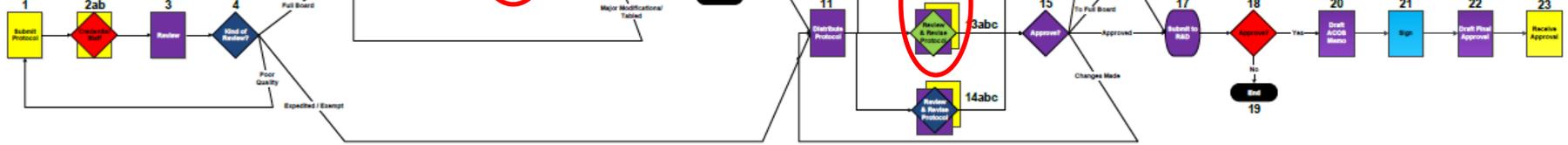


# Site 7

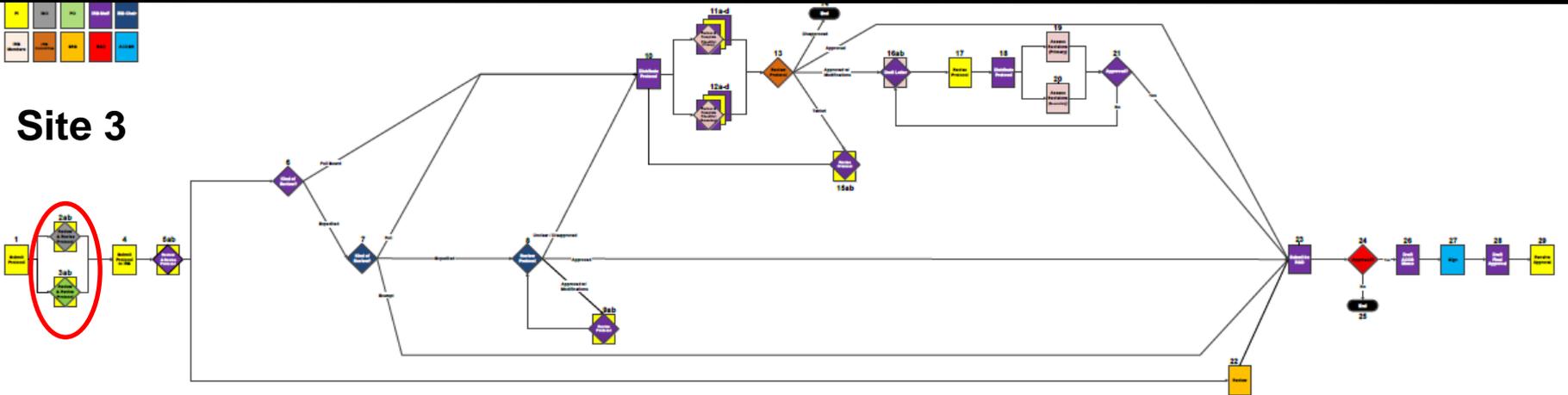




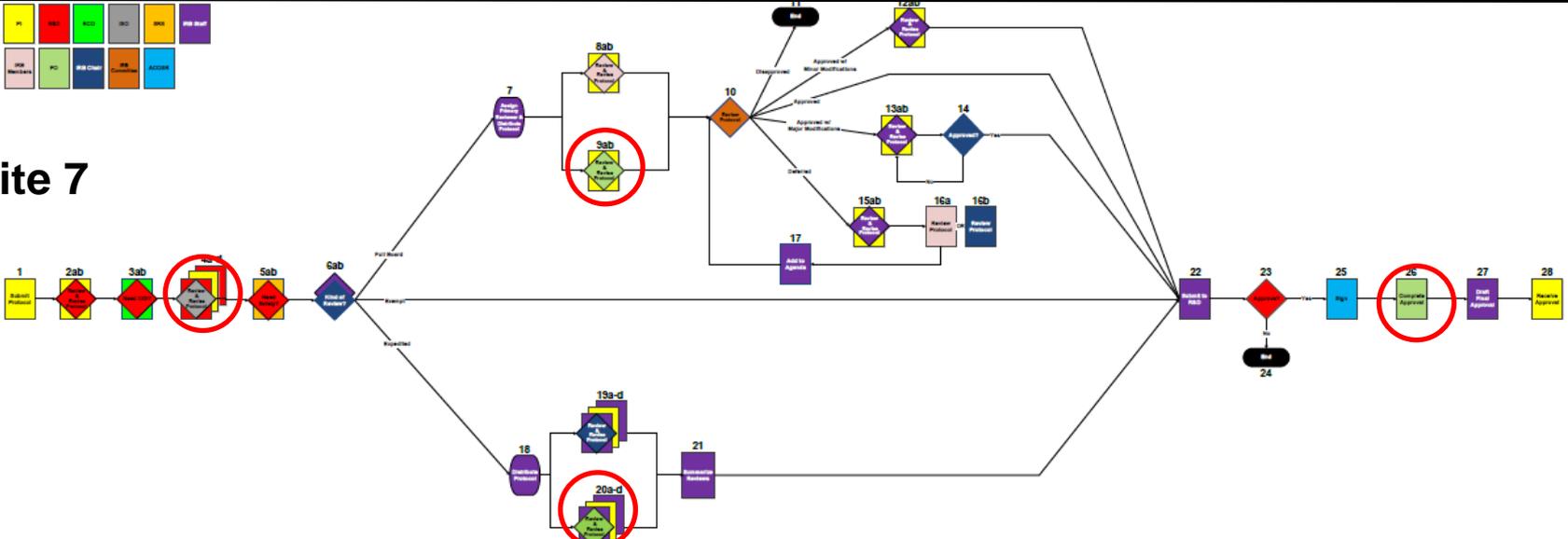
### Site 1



### Site 3



### Site 7

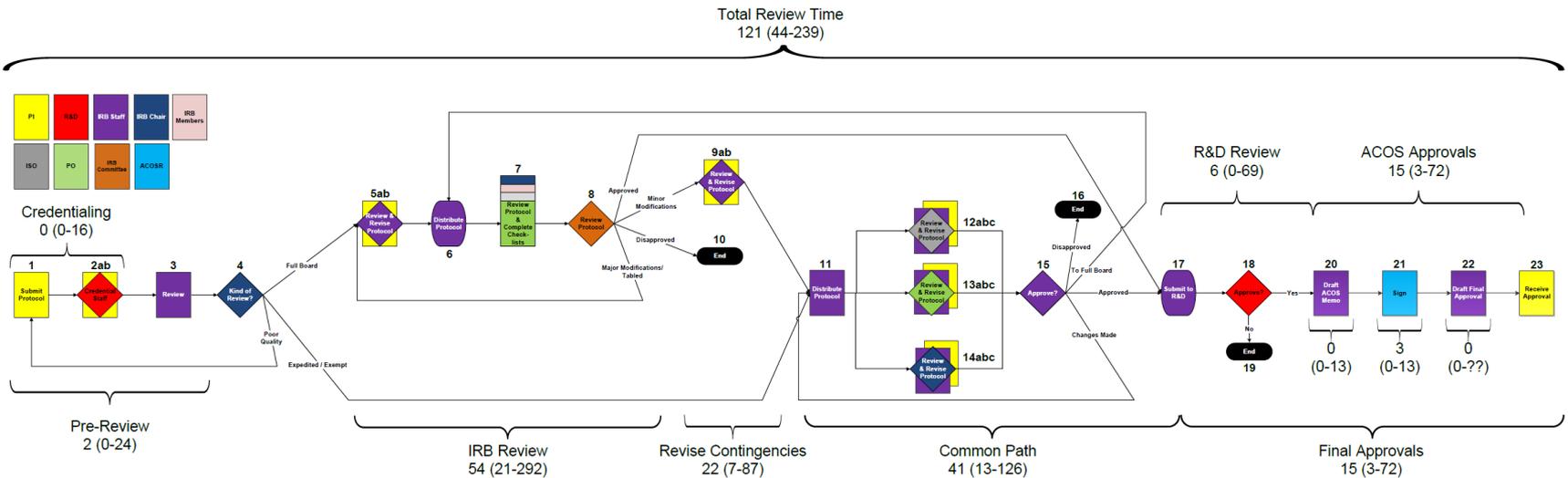


# Specific Methods

- Flow Maps
- Efficiency of IRB Review
  - Databases for tracking efficiency
  - Pilot data
- Quality Metrics
  - IRB RAT
  - Level of Review (OHRP Algorithm)
  - Common Rule Criteria
- Simulation Models
- Videoconference for facilitated brainstorming

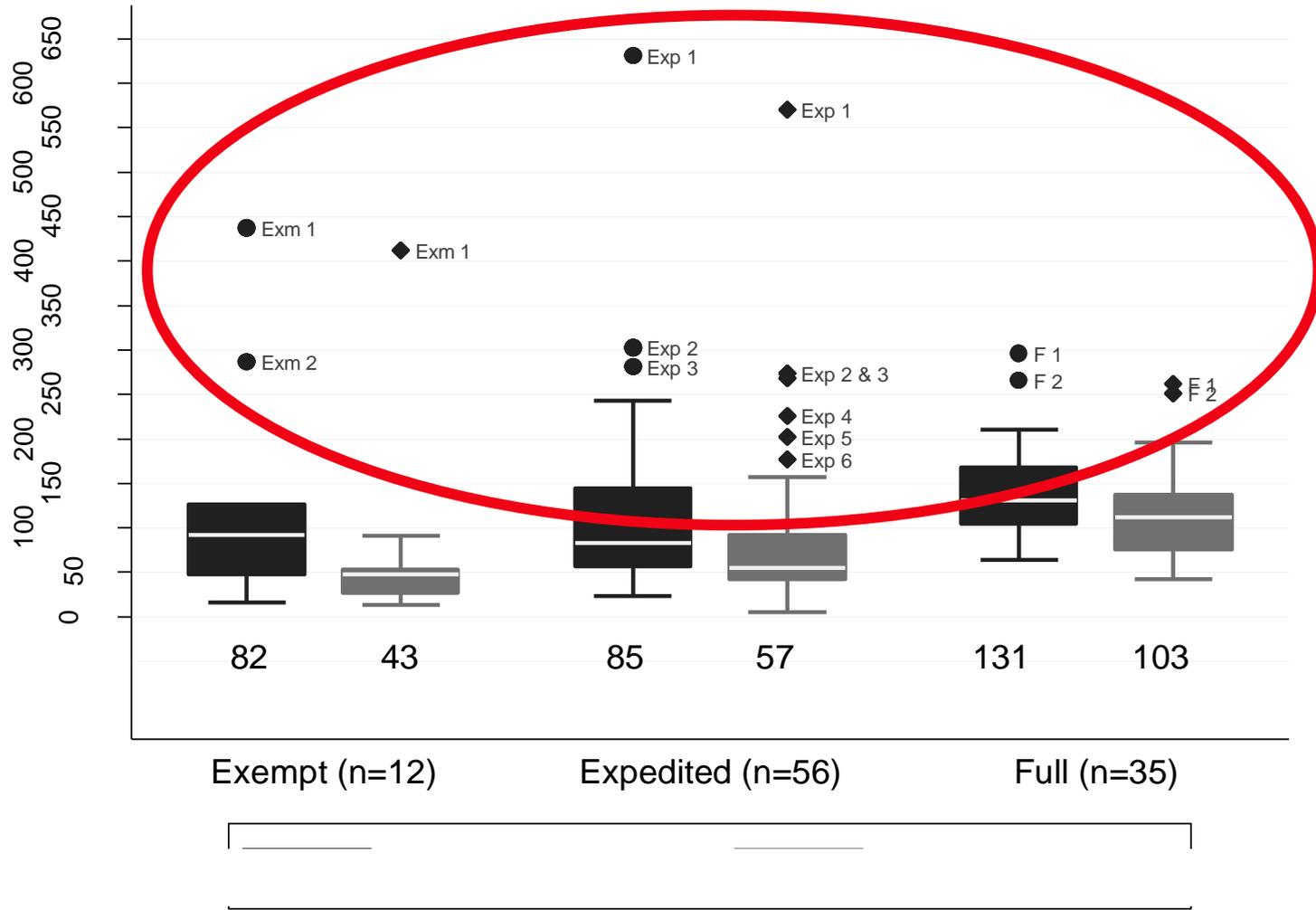
# IRB Review Times

## median calendar days (range)





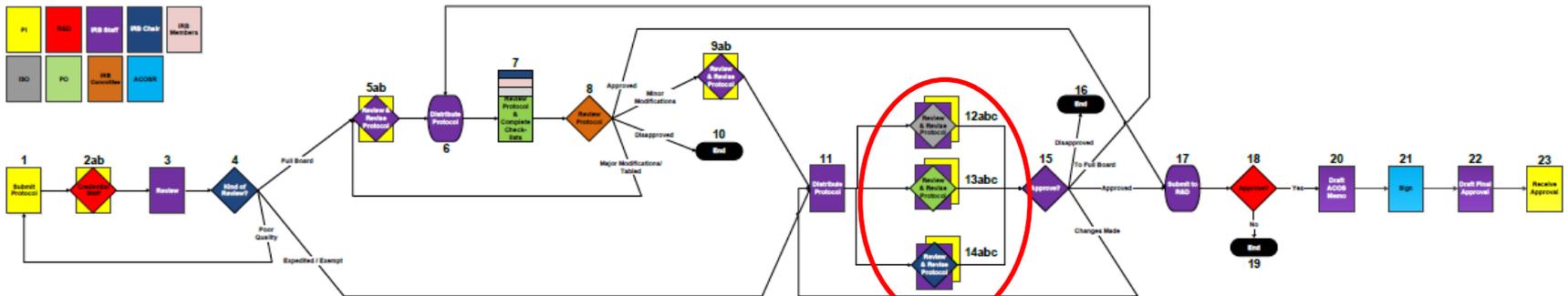
# IRB Review Times by Review Type



# IRB Review Times

## median calendar days (range)

Total Review Time  
105 (16-631)



Credentiaing  
1 (0-75)

IRB Review  
74 (5-570)

Final Approvals  
15 (0-184)

# Simulated Effect of improving ISO, PO and Chair Performance

	Actual Data		Baseline Simulation	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	median	Mean (sd)					
<b>ISO</b>	11	14.5 (16.3)	14.5 (16.3)	7 (2)	7 (1)	7 (4)	4 (1)
<b>PO</b>	8	14.4 (18.2)	14.4 (18.2)	7 (2)	7 (1)	7 (4)	4 (1)
<b>Chair</b>	8	11.7 (12.9)	11.7 (12.9)	7 (2)	7 (1)	7 (4)	4 (1)
<b>Total Time</b>	105	122.8 (87.0)	127.0 (74.3)	101.5 (58.0)	90.9 (42.0)	99.5 (52.3)	84.7 (55.2)
<b>Days Saved</b>	-	-	-	25.5 (20%)	36.1 (28%)	27.5 (22%)	42.3 (33%)

# IRB Quality: Level of Review

Level of Review Expected based on the OHRP Criteria	Level of Review Determined by the Study Sites			Total
	Full Board % (n)	Expedited % (n)	Exempt % (n)	
Full Board	48.6 (68)	.88 (1)	0.0	22.0 (69)
Expedited	47.1 (66)	93.8 (106)	10.0 (6)	56.9 (178)
Exempt	.71 (1)	4.4 (5)	75.0 (45)	16.3 (51)
Not Human Subjects Research	1.4 (2)	.88 (1)	8.3 (5)	2.6 (8)
Insufficient Information	2.1 (3)	0.0	6.7 (4)	2.2 (7)
<b>Total</b>	<b>100 (140)</b>	<b>100 (113)</b>	<b>100 (60)</b>	<b>100 (313)</b>

Kappa=0.59 (p<.001).

# IRB Quality: Level of Review

Level of Review Expected based on OHRP Criteria	Level of Review Determined by the Site 1 IRB			Total % (n)
	Full Board % (n)	Expedited % (n)	Exempt % (n)	
Full Board	100 (14)	0.0 (0)	0.0 (0)	34.2 (14)
Expedited	0.0 (0)	86.7 (13)	0.0 (0)	31.7 (13)
Exempt	0.0 (0)	13.3 (2)	100 (12)	34.2 (14)
<b>Total</b>	<b>100 (14)</b>	<b>100 (15)</b>	<b>100 (12)</b>	<b>100 (41)</b>

Some sites do very well: Kappa=0.93 (p<.001).

# IRB Quality: Level of Review

Level of Review Expected based on OHRP Criteria	Level of Review Determined by the Site 3 IRB			Total % (n)
	Full Board % (n)	Expedited % (n)	Exempt % (n)	
Full Board	26.7 (4)	0.0 (0)	0.0 (0)	8.9 (4)
Expedited	73.3 (11)	100 (15)	26.7 (4)	66.7 (30)
Exempt	0.0 (0)	0.0 (0)	46.7 (7)	15.6 (7)
Not Human Subjects Research	0.0 (0)	0.0 (0)	13.3 (2)	4.4 (2)
Insufficient Information	0.0 (0)	0.0 (0)	13.3 (2)	4.4 (2)
<b>Total</b>	<b>100 (15)</b>	<b>100 (15)</b>	<b>100 (15)</b>	<b>100 (45)</b>

Other sites not so well: Kappa=0.44 (p<.001).

# IRB Quality: Common Rule Criteria

	Not Assessed	Assessed without Explanation	Assessed With Explanation	Total	
Study Site	% (n)	% (n)	% (n)	% (n)	OR (95% CI)
<b>Total</b>	5.7 (115)	62.0 (1,244)	32.3 (649)	100 (2,008)	94.3% of Common Rule Criteria assessed
1	6.0 (14)	53.0 (123)	41.0 (95)	100 (232)	Reference
2	7.6 (17)	60.7 (136)	31.7 (71)	100 (224)	.50 (.25 - 1.0)
3	8.8 (21)	63.8 (153)	27.5 (66)	100 (240)	.37 (.19 - .75)
4	1.8 (3)	72.6 (122)	25.6 (43)	100 (168)	.66 (.31 -1.4)
5	10.5 (21)	43.5 (87)	46.0 (92)	100 (200)	1.1 (.52 -2.2)
6	1.7 (4)	36.3 (87)	62.1 (149)	100 (240)	4.1 (2.0 -8.3)
7	14.2 (17)	65.8 (79)	20.0 (24)	100 (120)	.08 (.03 -.20)
8	2.6 (6)	94.0 (218)	3.5 (8)	100 (232)	.13 (.06 - .27)
9	0.0 (0)	53.3 (64)	46.7 (56)	100 (120)	.88 (.37 - 2.1)
10	5.2 (12)	75.4 (175)	19.4 (45)	100 (232)	.27 (.14 - .55)
<b>Total</b>	5.7 (115)	62.0 (1,244)	32.3 (649)	100 (2,008)	

# IRB Quality: Common Rule Criteria

	Not Assessed	Assessed without Explanation	Assessed with Explanation	
Common Rule Criterion	% (n)	% (n)	% (n)	OR (95% CI)
1. Risk minimization	3.2 (8)	57.0 (143)	40.0 (100)	reference
2. Risk/benefit ratio	4.4 (11)	86.9 (218)	8.8 (22)	.16 (.10 - .24)
3. Equitable selection of subjects	5.6 (14)	80.1 (201)	14.3 (36)	.20 (.13 - .31)
4. Seeking informed consent	4.8 (12)	60.6 (152)	34.7 (87)	.70 (.46 - 1.1)
5. Documenting informed consent	3.2 (8)	41.8 (105)	55.0 (138)	2.4 (1.5 - 3.6)
6. Data safety monitoring	16.3 (41)	71.7 (180)	12.0 (30)	.09 (.06 - .14)
7. Protecting privacy and confidentiality	1.2 (3)	27.9 (70)	70.9 (178)	6.6 (4.2 - 10.3)
8. Safeguards for vulnerable subjects	7.2 (18)	69.7 (175)	23.1 (58)	.31 (.20 - .48)
<b>Total</b>	5.7 (115)	62.0 (1,244)	32.3 (649)	

# IRB Quality: RAT Survey

An IRB:	All Respondents	Site										
		IRB Members	1	2	3	4	5	6	7	8	9	10
		Investigators	IRB Members Investigators									
That reviews protocols in a timely fashion	X									X	X	
That is allocated sufficient resources to carry out its functions	X	X			X			X		X	X	
That gives a complete rationale for any required changes to or disapprovals of protocols	X	X										
With forms that limit duplication of requested information					X							
That provides unambiguous guidance that improves the chance of gaining IRB approval		X										
That focuses on making the informed consent process understandable to participants more than focusing on wording required by regulation			X									
That is as concerned with facilitating research as it is with protecting participants' rights		X	X									
That views itself as an investigator's ally rather than as a hurdle to clear												
That works with investigators to find mutually satisfying solutions whenever disagreements exist												
That offers protocol-specific consultation that improves the chance of gaining IRB approval												
That focuses on protecting human subjects more than enforcing regulatory compliance												
That provides model language for consent documents suitable for a diversity of research methods												
That is open to reversing its earlier decisions (i.e., is willing to consider investigator appeals)												
That conducts a consistent analysis of potential benefits weighed against potential risks before making decisions		X										
Whose members are very knowledgeable about IRB procedures and federal policy	X	X	X							X		
Whose members who do not allow personal biases to affect their evaluation of protocols	X	X	X	X						X		
Whose members do not hold biases against particular research topics or methods	X	X	X	X								
That maintains accurate records	X	X	X			X				X	X	
That avoids making decisions based on an inappropriate aversion to risks												
That can reliably distinguish exempt and expedited research from research requiring the evaluation of a fully convened IRB committee	X	X									X	
That conducts a competent and complete review of protocols	X											
That treats investigators with respect	X	X		X						X		
That ensures that at least one member of the review board is knowledgeable about the topics and methods of submitted protocols	X	X										
Whose members are highly experienced investigators												
Whose Chair is an experienced investigator										X		
That views protection of human participants as its primary function	X	X	X		X		X		X	X		
That takes timely and appropriate action whenever scientific misconduct is alleged	X	X			X				X		X	

# Future Directions

- January 2014 (Year 3.5 of CDA): What next?
  - Informed Consent
    - Recapitulate methods in multiple sites, adding colon cancer (more complex decisions)
    - Focus proposal on modifying iMed to improve process:
      - Provide document at time of diagnosis/referral
      - Create toggle boxes to let surgeons pick details they discussed
    - No support from VA National Center for Ethics in Health Care (owns iMed, and in leadership transition)
    - Mentors not convinced that outcomes of interest were sufficiently aligned with VA or HSR&D priorities—fear it would be a difficult sell to HSR&D study sections
    - Conclusion: Defer

# Future Directions

- January 2014 (Year 3.5 of CDA): What next?
  - IRB Efficiency and Quality
    - RFA intended for multiple cycles was withdrawn
    - No clear commitment from Central Office to continue research from operations budget
    - Very clear guidance that IRB research would not fit in existing portfolio of HSR&D funding priorities.
    - Not my primary interest anyway.
    - Conclusion: Abandon
  - Need to develop more compelling focus: frailty.

# Elective Surgery among the Frail

- Mentors advised finding a clinical context with higher stakes decisions than “just” hernia or gallbladder.
- Long noted perverse phenomena in surgical ICU where patients made CMO after risky surgeries without sufficient buy-in.
- Question: How to get patients, surrogates, surgeons, intensivists and nurses on the same page?
- New collaborator: Jason Johanning, Omaha VAMC
  - He had a QI mentality that synergized with systems engineering
  - Started screening surgical patients for frailty with the suggestion of improved survival
  - Lacked statistical sophistication that I could provide
  - Shared interest in palliative care as a mechanism for improved perioperative decision making
  - Analyzed results together

# Omaha Frailty Screening Initiative

**Table 1: Change in mortality at different time horizons before and after implementing the FSI**

	30-Day Mortality			180-Day Mortality			360-Day Mortality		
	Before FSI	After FSI	Total	Before FSI	After FSI	Total	Before FSI	After FSI	Total
<b>Overall</b>	84 1.6%	26 0.7%	110 1.2%	223 4.2%	38 1.1%	261 3.0%	317 6.0%	37 1.4%	354 4.4%
<b>Non-Frail</b>	60 1.2%	15 0.4%	75 0.9%	176 3.5%	21 0.7%	197 2.4%	249 4.9%	20 0.8%	269 3.6%
<b>Frail</b>	24 12.2%	11 2.7%	35 5.8%	47 23.9%	17 4.5%	64 11.1%	68 39.9%	17 5.7%	85 17.2%
<b>Total N</b>	5275	3743	9018	5275	3367	8642	5275	2709	7984

Differences between mortality before and after implementing the FSI were tested using Pearson Correlation. Differences were significant at every time horizon, and in every group (frail, non frail, and overall) at levels of  $p < .001$ . At 30 days, 6.7% (n=603) were frail. At 180 days, 6.7% (n=578) of the sample was frail. At 360 days 6.2% (n=494) were frail.

- 9018 patients had surgery from 2007-2014
- Overall 30-day mortality fell from 1.6% before implementing the FSI to 0.7% after implementation ( $p < 0.001$ ).
- Mortality improved in non-frail (1.2% to 0.4%,  $p < 0.001$ ), and frail patients (12.2% to 2.7%,  $P < .001$ ) with the greatest improvement among the frail.
- The improvement in survival for frail patients was further magnified at 180 days [23.9% to 4.5% ( $p < 0.001$ )] and 360 days [39.9% to 5.7% ( $p < 0.001$ )].
- Multivariate models controlling for age and frailty demonstrate the odds of 180-day survival increased after implementing FSI (OR 3.360, 95% CI 1.776-6.359), and the increase was greatest among the frail (OR 7.503, 95% CI 4.081-13.795).

# PEACEFUL-ESI

PAtient-Centered CarE for the FraiL—Elective Surgery Intervention

- Intervention
  - Screen for frailty in patients scheduled for elective surgery
  - Notify surgeons of frailty-specific risks,
  - Alert anesthesia and critical care to optimize perioperative treatment plans
  - Require preoperative palliative care consultation to clarify goals and document limits of buy-in
- Pragmatic, stepped wedge, randomized controlled trial testing PEACEFUL-ESI in 32 surgical services among 795 frail Veterans scheduled for elective surgery at 3 tertiary care VAMCs to
  - Test the impact on mortality, quality of life, quality of health care, length of stay and living situation (independent vs. assisted)
  - Test the impact on the quality of the surgical decision-making process
  - Measure the impact on the rate of surgical intervention and explore its relationship to patient preferences for non-operative management.

# Questions/Comments?

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