

# FLEX at Oregon State University

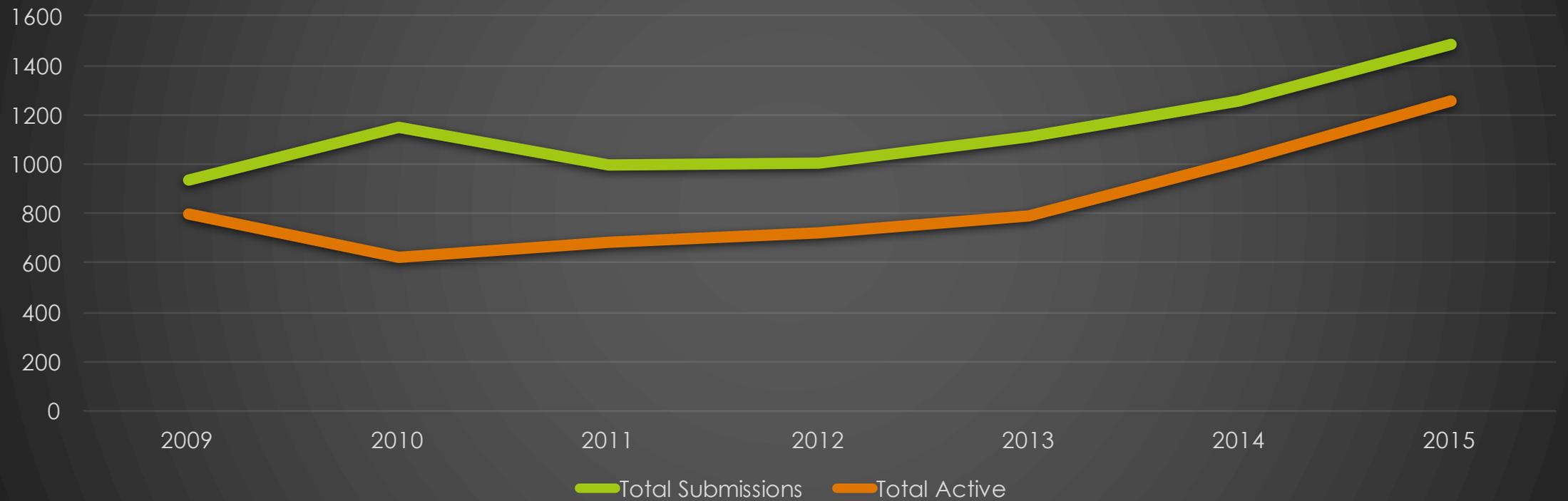
Changing landscape of policy approval process

# Leadership Transitions

VPR	1	1, <b>2</b> ,3	3	3	3	3,4	4,5	5	5
IO	1	2	<b>3</b> ,4	4	4	4, <b>3</b>	<b>3</b>	<b>3</b> ,5	5
DIR	1	1	1, <b>2</b>	<b>2</b>	<b>2</b> ,3	3	3,4	4	
AVPR									1
	2009	2010	2011	2012	2013	2014	2015	2016	2017

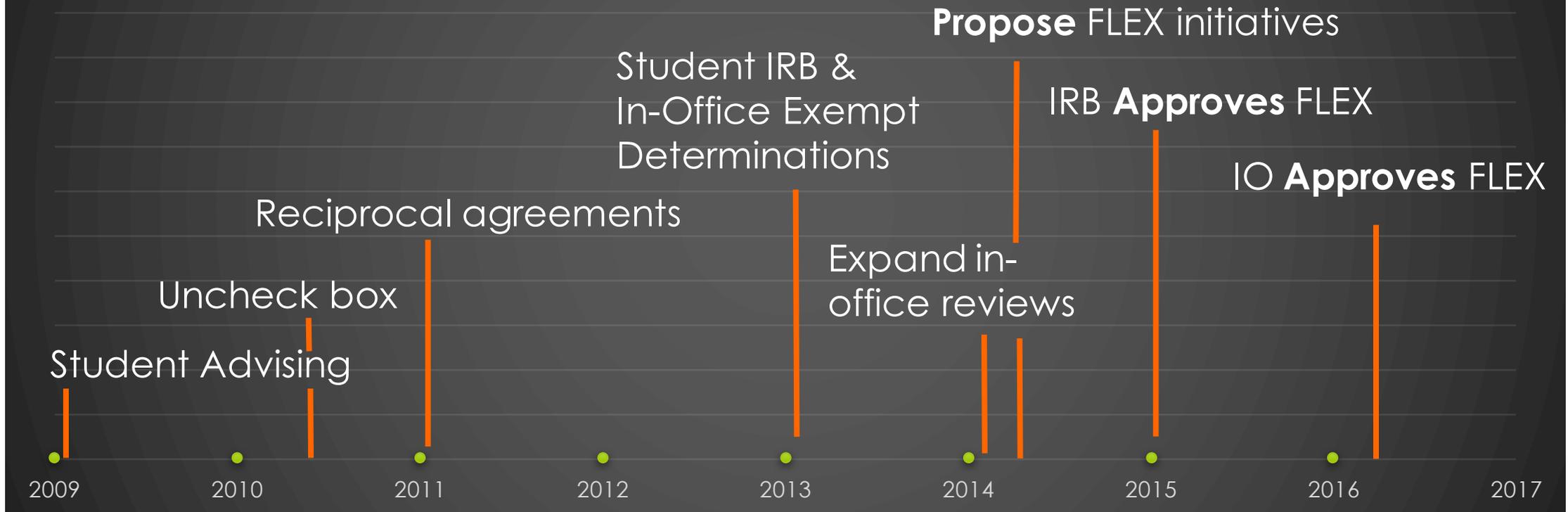
Leadership Transitions									
VPR	1	1,2,3	3	3	3	3,4	4,5	5	5
IO	1	2	3,4	4	4	4,3	3	3,5	5
DIR	1	1	1,2	2	2,3	3	3,4	4	
AVPR									1
	2009	2010	2011	2012	2013	2014	2015	2016	2017

## All Submissions and Active Studies



LEADERSHIP TRANSITIONS									
VPR	1	1-2	2-3	3	3	3-4	4-5	5	5
IO	1	2	3-4	4	4	4-3	3	3-5	5
DIR	1	1	1-2	2	2-3	3	3-4	4	
AVPR									1
	2009	2010	2011	2012	2013	2014	2015	2016	2017

# Initiatives



# FLEX Initiatives

- Flex eligibility
- Two additional exempt categories – Flex A & B
- Up to 3 year approval for expedited cat. 3-7
- Reasonable safeguard standard for pregnant women
- Reasonable safeguard standard for parental consent

## Training initiatives...

- ▣ HRPP staff training
- ▣ IRB member competencies & self assessment
- ▣ GRAD 522: IRB Prep Course

# Member Competency Matrix

	KNOWLEDGE			SKILLS			VALUES		
Competency	Board Policies & Procedures	Board Mission & Vision	History & Current Events in Research Ethics	Time Management & Discipline	Critical Reading & Quality of Response	Problem Solving	Consistency & Equity in Evaluation	Conflict of Interest	Engagement & Participation
ASPIRATIONAL MEMBER	<ul style="list-style-type: none"> <li>Understands and appreciates the increased scrutiny involved in federal oversight</li> <li>Acknowledges intentionality in the flexibility of design in regulations</li> <li>Demonstrates capacity to follow through stepped processes</li> <li>Manages changes in administrative procedure with flexibility</li> <li>Accurately interprets policies, and communicates productively</li> <li>Actively seeks clarity regarding ambiguous policies, corrects misinformation</li> </ul>	<ul style="list-style-type: none"> <li>Understands mission and vision, and can effectively articulate to diverse constituents</li> <li>Recognizes the limits of the board's mission, and holds self and colleagues accountable to appropriate scope</li> <li>Regarding board scope, reflects thoughtfully on role in evaluating research design</li> <li>Actively dispels misconceptions regarding board mission and vision</li> </ul>	<ul style="list-style-type: none"> <li>Demonstrates knowledge of seminal historical events in the fruition of Institutional Review Boards</li> <li>Understands and can articulate to diverse constituents why the IRB was created, and the relevance of the IRB today</li> <li>Actively and independently engage in continuing education; keeping up on emerging issues in human subject research oversight</li> </ul>	<ul style="list-style-type: none"> <li>Regarding review tasks and administrative correspondence, responds on or before assigned deadlines</li> <li>Articulates workload capacity openly and honestly</li> <li>Demonstrates realistic expectations of what can be accomplished in relation to institutional workload</li> <li>Actively seeks support and resources to meet procedure deadlines</li> <li>When necessary, quickly communicates extenuating circumstances to IRB staff</li> </ul>	<ul style="list-style-type: none"> <li>Consistently provides revisions and notes which add to, revise, or omit the pre-review recommendations drafted by office staff</li> <li>Employs expertise and specialized content knowledge in the review of IRB applications</li> <li>Drafts detailed and comprehensible stipulations for researchers</li> <li>Demonstrates the appropriate use of time and detail in application review</li> </ul>	<ul style="list-style-type: none"> <li>Acknowledges limits of expertise, and seeks resources and referrals as needed, resisting the urge to infer or assume in the absence of knowledge</li> <li>Actively reaches out and collaborates with fellow board members to gain clarity or resolve issues</li> <li>Comfortably connects with the office staff for consult</li> <li>As PI and/or mentor, intentionally works to improve quality of IRB submissions under their direction</li> </ul>	<ul style="list-style-type: none"> <li>Reflects thoughtfully on role in evaluating research design</li> <li>Reviews and participates in board functions with consistency regardless of individual interests, values, and politics.</li> <li>Actively mediates personal and professional biases</li> <li>Demonstrates commitment to self-evaluation and introspection</li> </ul>	<ul style="list-style-type: none"> <li>Openly communicates individual, departmental, and institutional relationships, interests, etc.</li> <li>Openly communicates relationships which may pose conflict of interest, and takes responsibility for maintaining transparency</li> <li>Understands when to recuse oneself from meetings and reviews</li> <li>Acknowledges that commitment to objectivity does not guarantee objectivity, and may still need to recuse one's self</li> </ul>	<ul style="list-style-type: none"> <li>Serves actively as a liaison to home department, and as a resource for colleagues</li> <li>Actively engages in meetings and discussions, having thoroughly prepped with advance reading</li> <li>Poses questions, and elicits discussion</li> <li>Creates pathways for IRB to build relationships across the institution</li> <li>Expands networks and spans boundaries in support of the IRB mission and vision</li> <li>Participates in working groups, including committees with the central office</li> <li>Attending all meetings, with few exceptions</li> </ul>
DEVELOPMENTAL TOOLS	<ul style="list-style-type: none"> <li>CE at board meetings</li> <li>Annual Retreats</li> <li>SOPs</li> <li>Website</li> </ul>	<ul style="list-style-type: none"> <li>Operating Plan</li> <li>Annual Retreats</li> <li>Practice/Mock Reviews</li> <li>Annual review of IRB data and analytics, for board and campus scopes</li> </ul>	<ul style="list-style-type: none"> <li>CE at board meetings</li> <li>Sharing relevant literature over email:</li> <li>Blogs</li> <li>News sources</li> <li>Journal Articles</li> <li>Website</li> </ul>	<ul style="list-style-type: none"> <li>Detail expectations in orientation: Clearly communicated potential and variability of workload</li> <li>Identify options for reviewers experience barriers to timely completion</li> <li>Friendly reminders from office staff</li> <li>Annual feedback regarding average time of review</li> </ul>	<ul style="list-style-type: none"> <li>Orientation &amp; Shadow Reviews</li> <li>Practice/Mock Reviews</li> <li>Annual Retreats</li> <li>Friendly reminders from IRB Chair &amp; Administrator</li> <li>Little Red Book</li> </ul>	<ul style="list-style-type: none"> <li>Detail expectations in orientation</li> <li>Provide reminders during board meetings</li> <li>Co-develop and maintain an inventory of board member expertise for quick reference</li> </ul>	<ul style="list-style-type: none"> <li>Primary and secondary reviewer pairs</li> <li>Facilitation from IRB Chair and fellow board members, addressing issues of mission creep</li> <li>To create a frame of reference, incorporate reflections from similar studies in the review process [Upon Request]</li> <li>Review "Coordinator Picks" during IRB Meetings</li> </ul>	<ul style="list-style-type: none"> <li>Detail expectations in orientation</li> <li>Annual COI Disclosures</li> <li>SOPs</li> <li>Little Red Book</li> <li>CE at Board Meetings</li> </ul>	<ul style="list-style-type: none"> <li>Mentoring by senior members</li> <li>Role modeling</li> <li>Board meeting facilitation techniques</li> <li>Creating a safe space for asking questions and sharing perspectives</li> <li>Field trips to research sites</li> </ul>
NEW MEMBER	<ul style="list-style-type: none"> <li>No prior knowledge expected</li> </ul>	<ul style="list-style-type: none"> <li>Some level of interest</li> <li>Knows where to find information</li> </ul>	<ul style="list-style-type: none"> <li>CITI Training Competencies</li> </ul>	<ul style="list-style-type: none"> <li>Articulates capacity to meet basic expectations to IRB Chair and/or Administrator</li> </ul>	<ul style="list-style-type: none"> <li>Content knowledge in a relevant research area to the IRB</li> </ul>	<ul style="list-style-type: none"> <li>Open to collaboration and feedback</li> </ul>	<ul style="list-style-type: none"> <li>Knowing bias is a thing.</li> <li>Acknowledges the reality and implications of bias</li> </ul>	<ul style="list-style-type: none"> <li>Initial Disclosure</li> </ul>	<ul style="list-style-type: none"> <li>Attends minimum number of meetings interpreted through SOPs</li> <li>Invites dialogue</li> <li>Demonstrates civility</li> <li>Broad interest in OSU research activities</li> </ul>

# GRAD 522 - Preparing a Submission for IRB Review

- ▣ 1 credit, 2 hour workshop every other week
- ▣ IRB Admin and Dir of Student Affairs Research
- ▣ Pre reqs
  - ▣ CITI
  - ▣ Methods course
  - ▣ PI sign-off on topic

# GRAD 522 – Learning Outcomes

- Demonstrate understanding of the importance of protecting human subjects
- Draft submission-ready application materials
- Constructively evaluate the research proposals of peers
- Practice productively engaging with mentor

# What didn't work...

- ❑ Too many initiatives at one time
- ❑ SOP sections that don't stand alone
- ❑ Freaking out

## What did work...

- ▣ Limiting number of people in approval process
- ▣ Creating a safe environment for staff to make mistakes
- ▣ Helping staff to embrace chaos
- ▣ Being fast to failure
- ▣ Taking advantage of published policies and practices