

Let's talk about it: The reality of the impact of the changes from the revised human subject rules

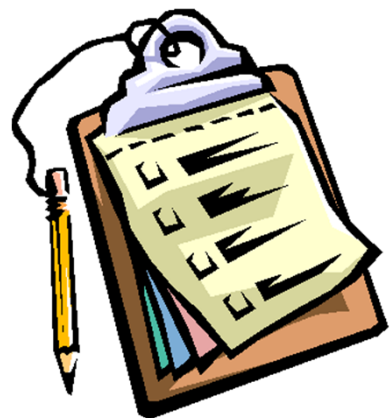
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Agenda

- Welcomed changes and unexpected pitfalls and problems
- Identify areas to improve programs
- Key resources and tools



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Poll Question 1

What sort of institution are you from?

- A. Hospital – multi-system
- B. Hospital – local/community
- C. Academic Medical Center
- D. Community based healthcare organization

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Poll Question 2

What is your level of experience with the human subjects regulations?

- A. Extensive
- B. Good working knowledge
- C. Passable but need help
- D. Minimal definitely need help

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About the University of Arizona

State's land-grant University and Academic Medical Center

- 45,918 enrolled students (35,801 undergraduate + 10,117 graduate)
- 16,523 employees and 3,212 faculty
- 2 independently accredited medical schools
- Colleges of public health, nursing and pharmacy (21 colleges total)
- \$725,000 research dollars FY20
- 3 hospitals, 2 cancer centers, and countless clinics

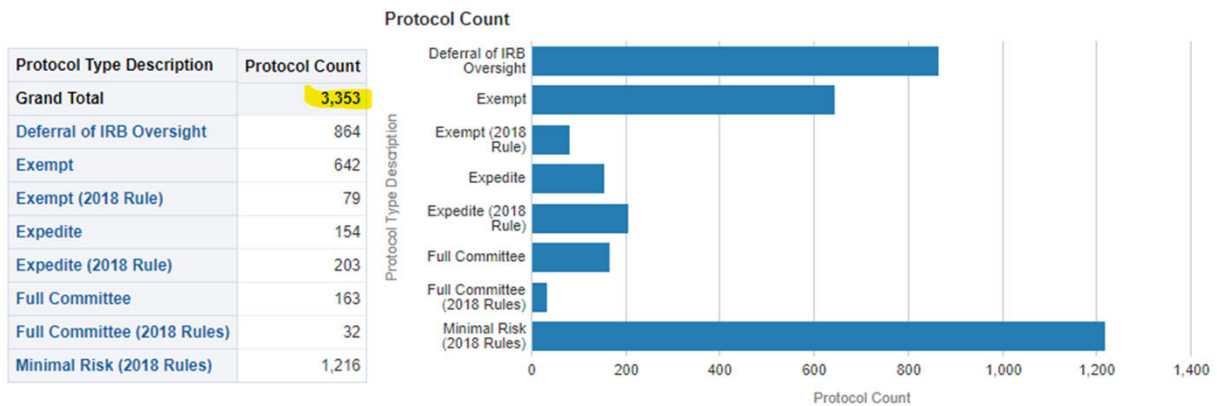
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Hospital partnerships

- 3 hospitals where academic research is overseen by UA IRB.
- Affiliations with numerous other local hospitals for UA affiliated research.
- Faculty transitioned to hospital employment with research privilege back to UA.
- Federally designated comprehensive cancer center with 2 separate locations (and two separate hospitals involved).
- Affiliation with pediatric teaching hospital.

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IRB statistics



Health Science only colleges = 1939 protocols = approx. 60% of all protocols

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Questions raised with new rule

- To transition or not
- Flexible review for non-federal
- Single IRB review
- To continuing review or not
- Limited IRB review
- Informed consent revisions
- Other items



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Transition for existing studies

- Changes allowed prior to transition for items that did not conflict with the new rule:
 - Increased data security questions for limited IRB review
 - Increased single IRB review questions
 - New consent requirements added to template
- All federally funded studies “asked” to transition starting July 2019.
 - Few exceptions allowed for studies near completion.

Resource: *Project Transition Form*

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Outcomes

- Required IT system changes to track studies pre- and post-rule.
- Required development of tools for staff and researchers to understand requirements.
- Required auditing of studies to ensure appropriate categories listed.
- Required follow up once full rule was implemented to ensure everything was captured.



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Poll Question 3

Did you wait to implement the rules or did you implement early?

- A. Implemented early
- B. Waited to implement

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Flexible review

- Large subset of social behavioral research was minimized or excluded from new rule.
- Created new Minimal Risk review bucket.
- Moved non-risky medical projects as well.
 - Blood draws above volume or frequency
 - Minimal xray or contrast use in clinical procedures
- Removed requirement to document regulatory requirements.

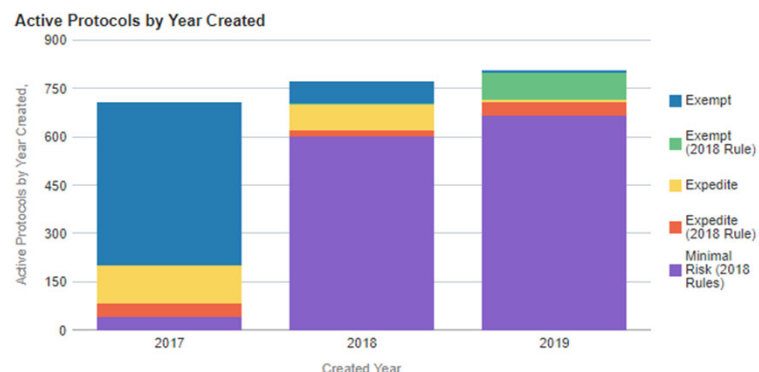
Resources: *Flexible Review guidance* and *Minimal Risk Research guidance*

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Minimal Risk reviews

We implemented **flexible** review options for non-federally funded or supported research in late 2017.

The change resulted in a HUGE shift in how we review research.



Protocol Type Description	Active Protocols by Year Created			Active Protocols by Year Created
	2017	2018	2019	
Grand Total	709	772	807	2,288
Exempt	506	67	5	578
Exempt (2018 Rule)	2	5	84	91
Expedite	118	80	8	206
Expedite (2018 Rule)	39	19	46	104
Minimal Risk (2018 Rules)	44	601	664	1,309

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Outcomes

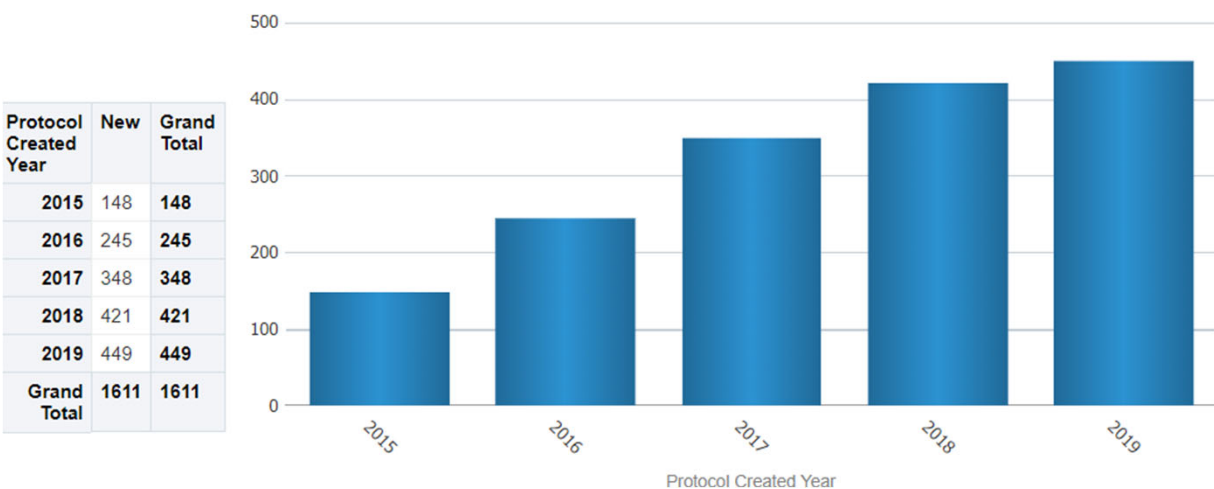
- Created dual review systems for staff and researchers to follow.
- Multiple new work instructions (WI) for staff.
- Increased education and training to explain nuances to researchers.
- New guidance documents for researchers.
- Possibility of not doing it right!
- Unexpected side effect – determinations increased.



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Requests for determination of research

All Sections



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Poll Question 4

How likely are you to implement flexible review options if you haven't already?

- A. Already have
- B. More likely
- C. Less likely
- D. Not at all

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Single IRB

One IRB for multi-site research.

- NIH policy effective January 25, 2018.
- Federal implementation January 21, 2020.
- Institutional policies must still be followed:
 - Radiation safety, COI, Institutional contracts/budget

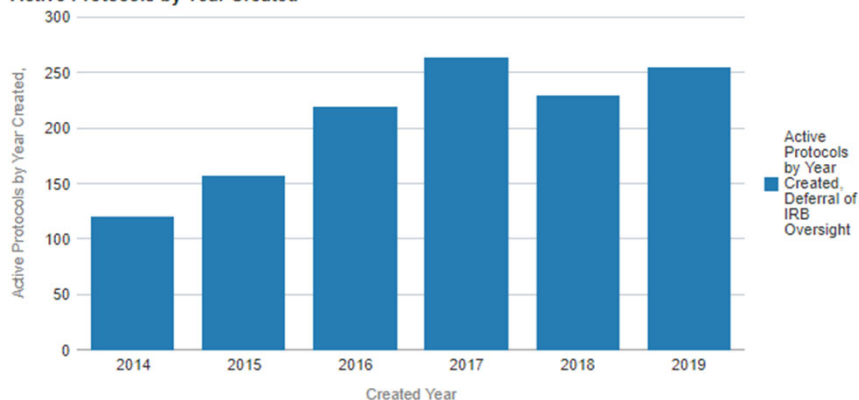
Resource: *Single IRB Review guidance and Deferral checklist*

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Single IRB review

20% increase (as part of total IRB submissions) in sIRB requests from 2014 to 2018

Active Protocols by Year Created



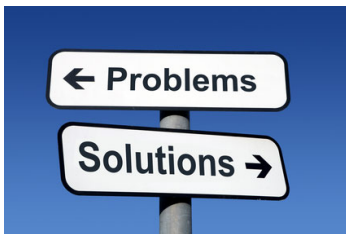
Protocol Type Description	Active Protocols by Year Created						Active Protocols by Year Created
	2014	2015	2016	2017	2018	2019	
Grand Total	121	157	219	263	229	254	1,243
Deferral of IRB Oversight	121	157	219	263	229	254	1,243

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Outcomes

CON:

- Created more work for research teams understanding nuances of different IRBs.
- Required executed contracts – each entity doing own thing.
- Negotiation of different IRB expectations.
- Requirement to verify P&Ps or AAHRPP accreditation.
- Orgs not willing to rely because of HIPAA.

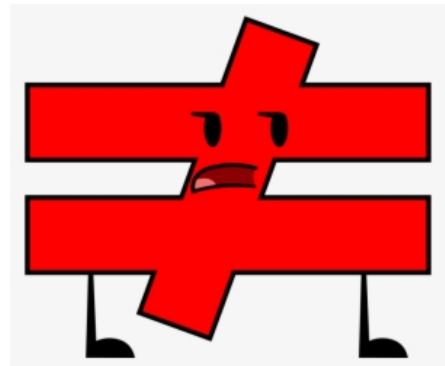


PRO:

- Ability to audit more studies.
- Some standardization of review through SMART IRB.
- Increased fee for review.

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Single IRB review



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Poll Question 5

Are you allowing studies to use the single IRB option?

- A. For all studies regardless of funding
- B. Only for federally funded studies
- C. We still require a local review even though we say we do single IRB review
- D. Not at all or very limited use of single IRB

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Continuing Reviews

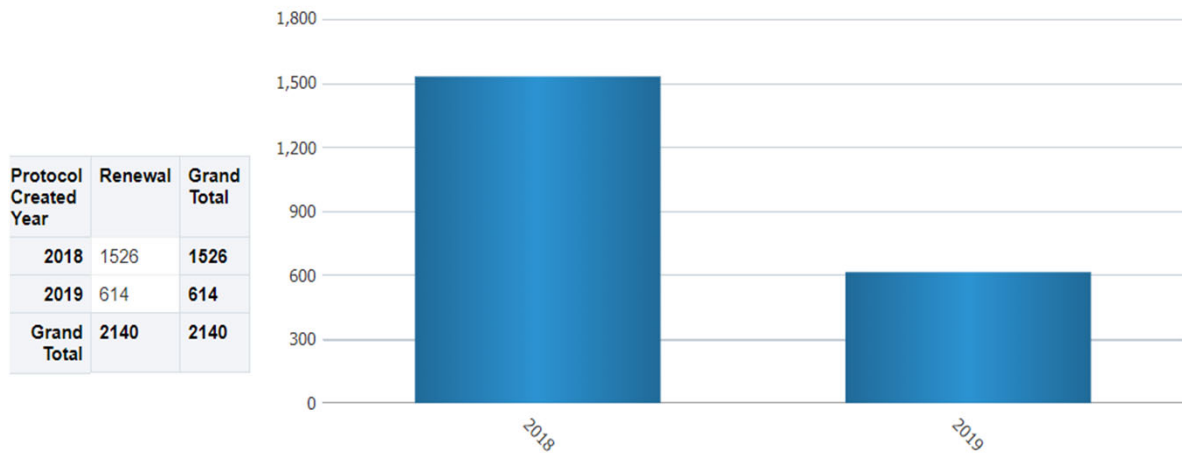
- Minimal risk projects and certain full committee projects not required to submit an annual review.
- Institutionally we already implemented flexible renewal requirement at 2 years.
 - Exceptions for bad behavior, COI concerns, special populations.

Resource: *Project Update Form*

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Renewals

All Sections



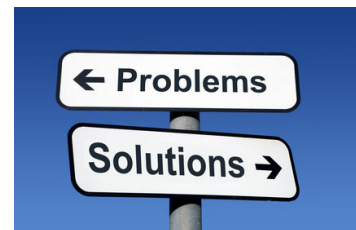
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Outcomes

- New form for researchers.
- IRB committee questioned why not seeing studies.
- Possibility of not doing it right.
 - Verify Funding!

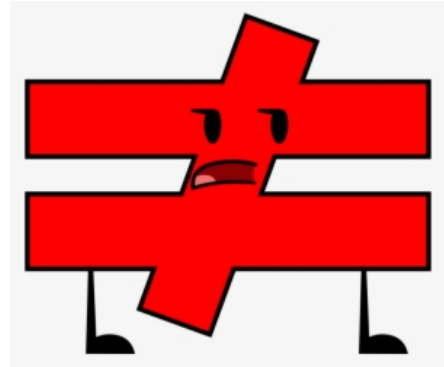
Reality is that numbers show significant decrease in overall requirement for renewals.

- Maybe too soon to tell?
 - Reportable items?



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Continuing review



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Poll Question 6

Have you changed your continuing review policy to remove the requirement?

- A. Yes for everything we can
- B. Yes with some modified type of project update check-in
- C. No but considering it
- D. Don't plan to implement

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Limited IRB review

- Required increased data security and privacy review for studies that included some risk but still exempt.
- Must be reviewed by IRB (may be a designated reviewer).

Resource: *Limited IRB Review guidance*

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Out of 79 total projects

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Outcomes

- Fear of limited review overrated.
- Increased data security and privacy questions across **ALL** research projects.
- Increased compliance with institutional policies for security/privacy.
- No noticeable change in process.
- Required other parts of institution to function better. 😊



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Limited IRB review

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Poll Question 7

Are you applying limited IRB review to everything or only those studies which need it?

- A. To everything
- B. To only those specific studies

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Informed consent revisions

- Requirement to add 'key information.'
- New required elements of informed consent.

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Outcomes

- Key information - Useful, but not.
- IRB and researcher education regarding duplication of language farther down in the ICF.
- New required elements = useful.
- Has NOT decreased length or complexity of consents.



Lots of work still
needs to be done

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Informed consent
revisions



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Poll Question 8

Do you like the new informed consent requirements?

- A. Yes very helpful to subjects
- B. Yes, but it's still complicated
- C. Not really

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Odds and Ends

- Exempt category 4 – Mostly not applicable at our institution due to Hybrid Entity status.
- Broad consent – We did not move forward with it.
- Exception from sIRB for Native American research – Already required.
- Unchecking the box on FWA – Already did.

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Key takeaways

- Overall changes were beneficial for researchers.
- Required broad organizational and operational changes.
- Required critical thinking about gaps.
- Less reporting to the feds.

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