

Human Subjects Protection Program

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THE UNIVERSITY OF ARIZONA
Research
Innovation & Impact



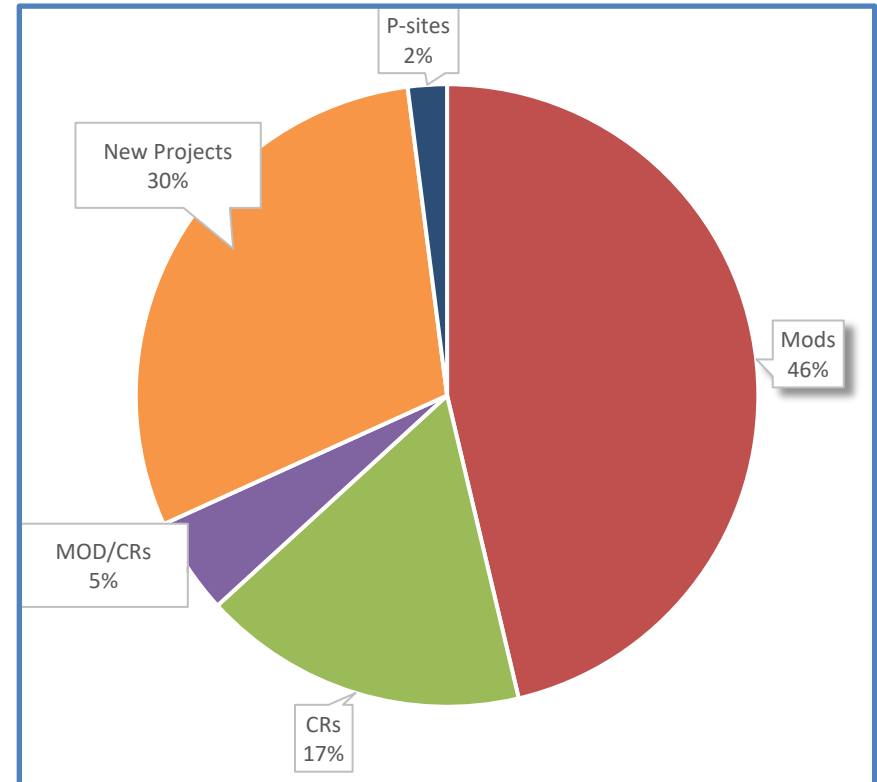
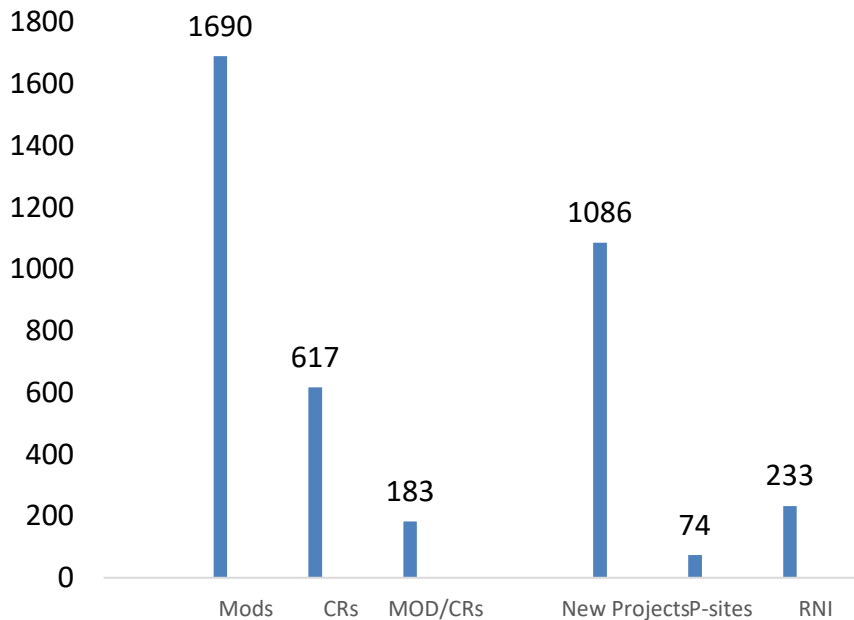
2022 RECAP

- 2022 was the first full year of using the eIRB electronic submission platform. eIRB training is ongoing and it is incorporated into our regular training activities.
- We successfully implemented EDGE Learning into eIRB for increased campus visibility to training records.
- We experienced staffing changes including three (3) new hires and two (2) promotions, which required time/effort investment into staff training. We continue to work on a comprehensive training plan in order to accommodate future staff changes.
- Researcher education about the IRB process, ethics and regulations, vulnerable populations, etc. also increased. We implemented several workshops in addition to continued targeted training, office hours and study team meetings.
- We strengthened the post-approval monitoring QAQC program and launched not-for-cause routine audits. We conducted two (2) external audits and two (2) internal audits.
- We revised the Customer Satisfaction Survey and launched a new Training/Education Input Survey in order to solicit feedback from the research community which allows us to better serve their needs. We are using this data driven input to design future training.

3,883 NC items were reviewed in 2022.

2022 Non-Committee (NC) Workload

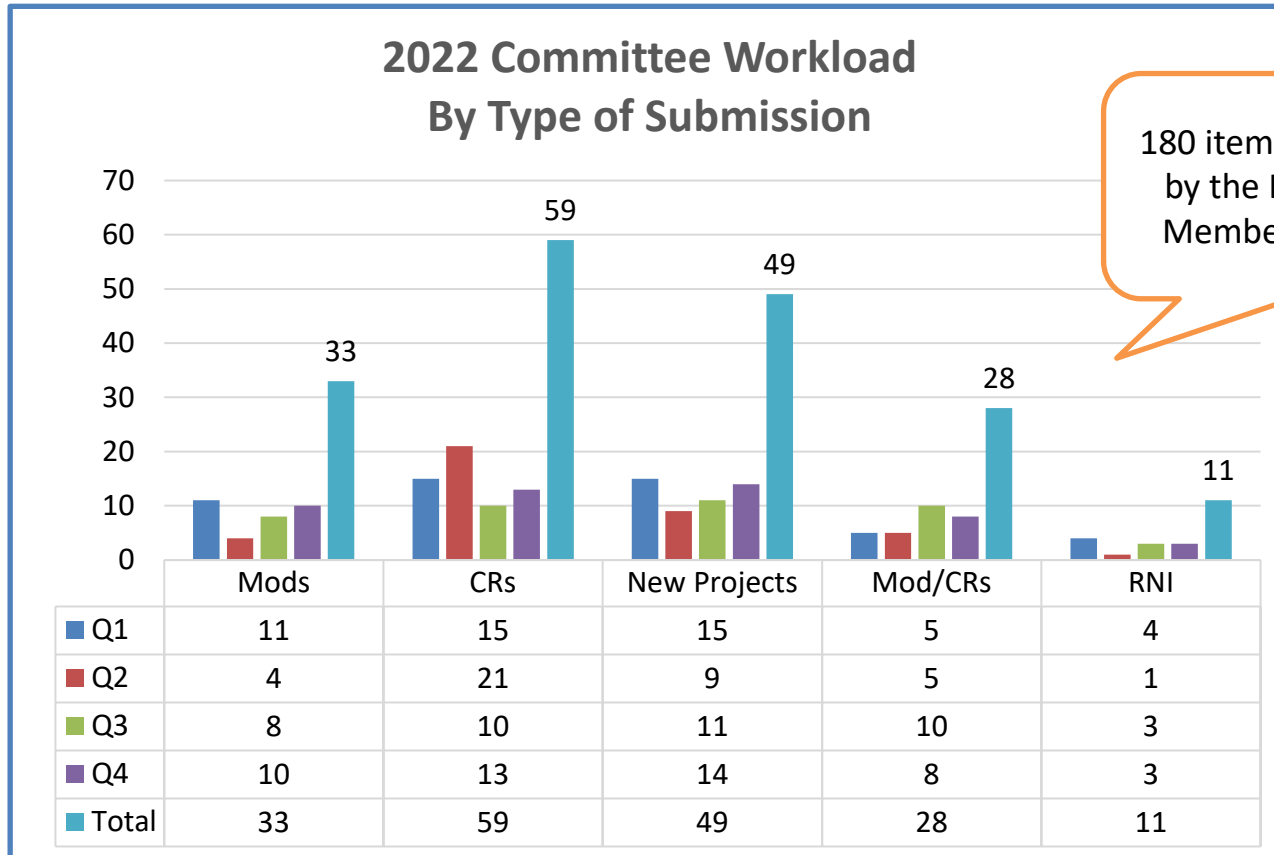
2022 Non-Committee Workload by Submission Type



- Modifications represented the majority of Non-Committee submissions.
- New Projects were the second largest group.
- We also absorbed regulatory oversight for 74 P-sites.
- In addition, we also received 141 External Updates.



2022 Committee Workload

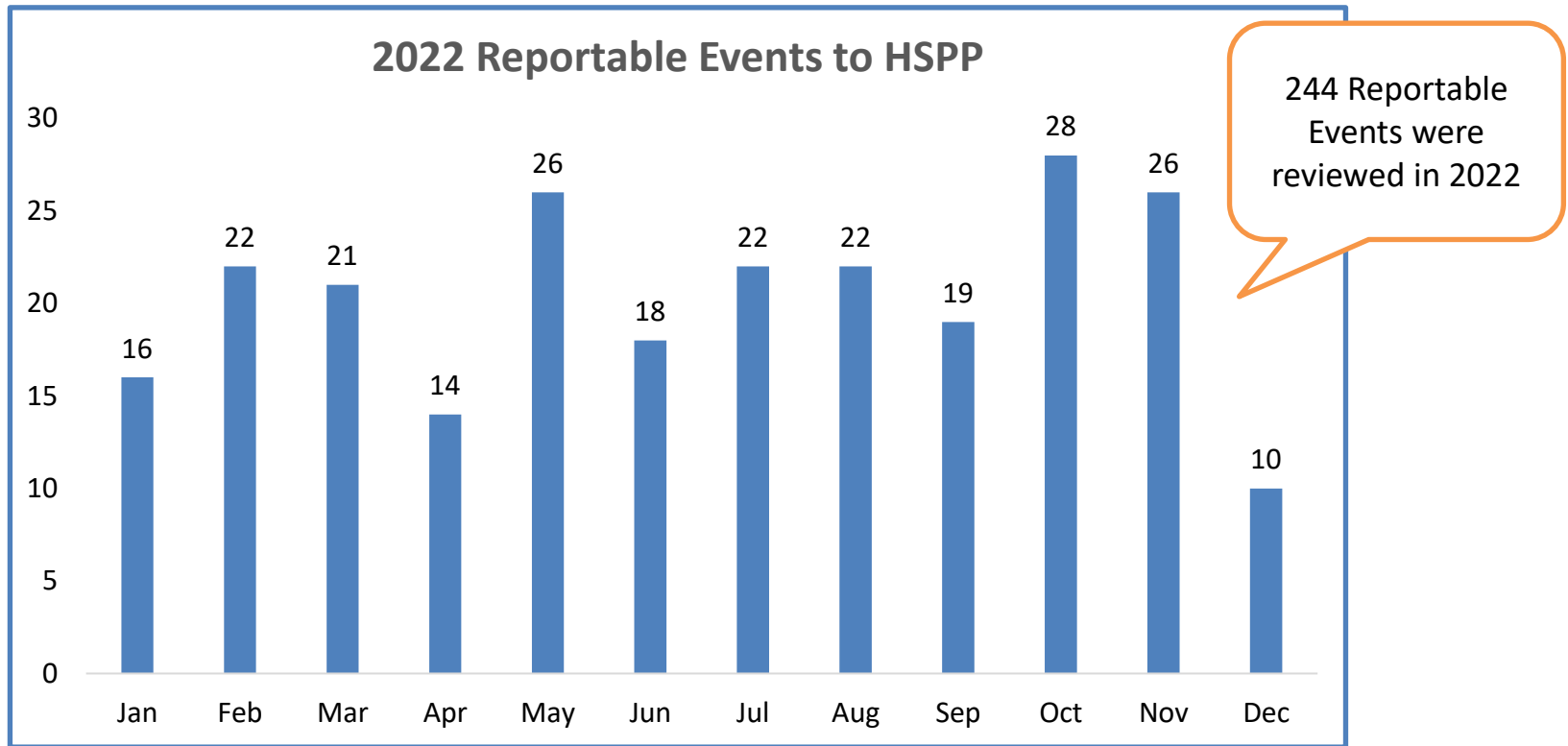


180 items were reviewed by the IRB Committee Members during 2022

5 RNIs were reviewed at multiple FC meetings

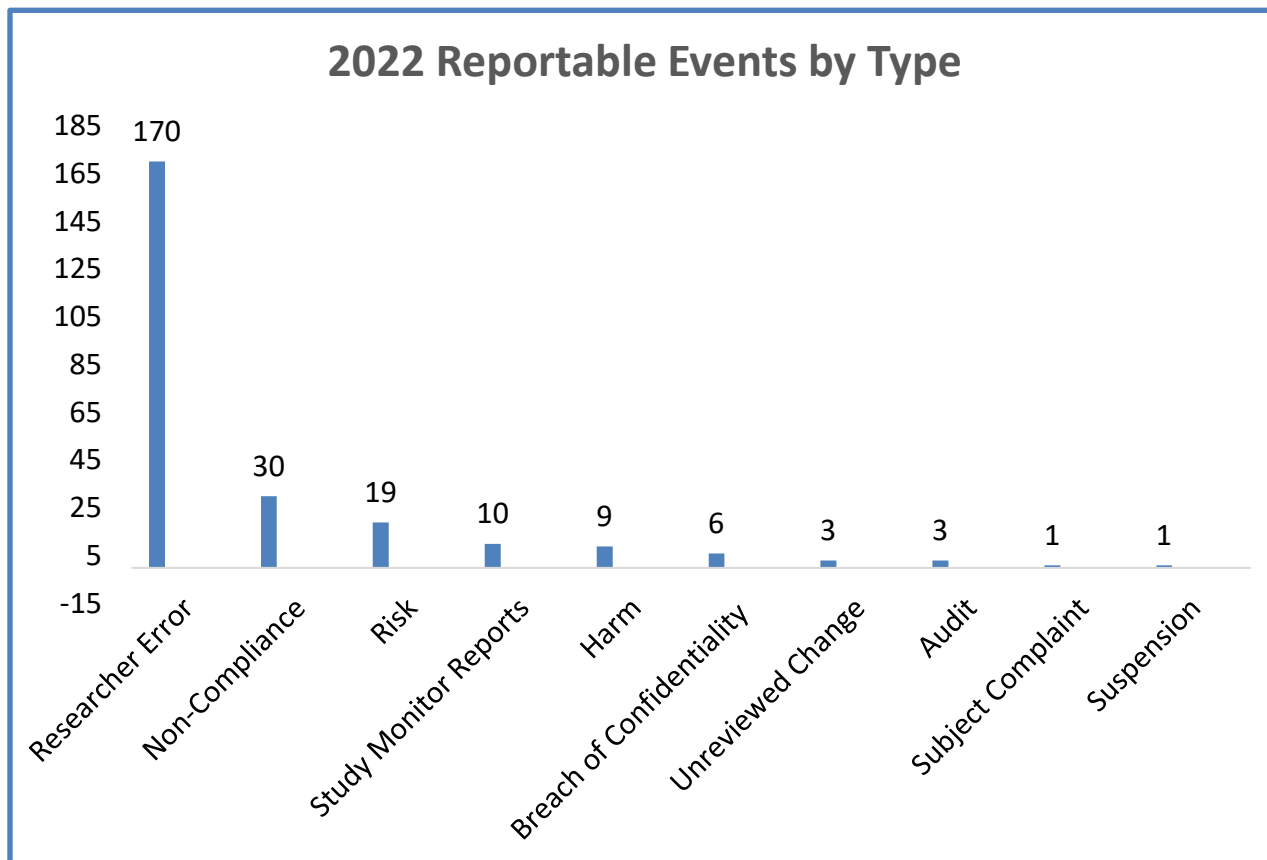
- Continuing Reviews represented the majority of Full Committee (FC) submissions.
- New Projects were the second largest submission type reviewed by FC.
- MODs (33) were the third highest category with MOD/CR (28) came in fourth.

Reportable New Information (RNI) in 2022



- Reported events are reviewed by the IRB Committee or by a single IRB Chair based on level of risk.
- Reportable events may also be a Notify IRB, which do not require IRB Committee or Chair review.
- Out of the 244 Reportable Events, 11 (~5%) were reviewed by Full Committee.

Types of Reportable Events



Researcher error: Failure to follow the protocol due to the action or inaction of the investigator or research staff.

Non-compliance: with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.

Risk: Information that indicates a new or increased risk, or a safety issue. Any changes significantly affecting the conduct of the research.

Harm: Any harm experienced by a subject or other individual that, in the opinion of the investigator, is unexpected and at least probably related to the research procedures.

- RNIs can have more than one item checked for RNI Type in eIRB.
- Researchers Error continues to be the most checked category.
- Non-Compliance (i.e., Protocol Deviations) came in 2nd.

11 RNIs
were reviewed by
Full Committee



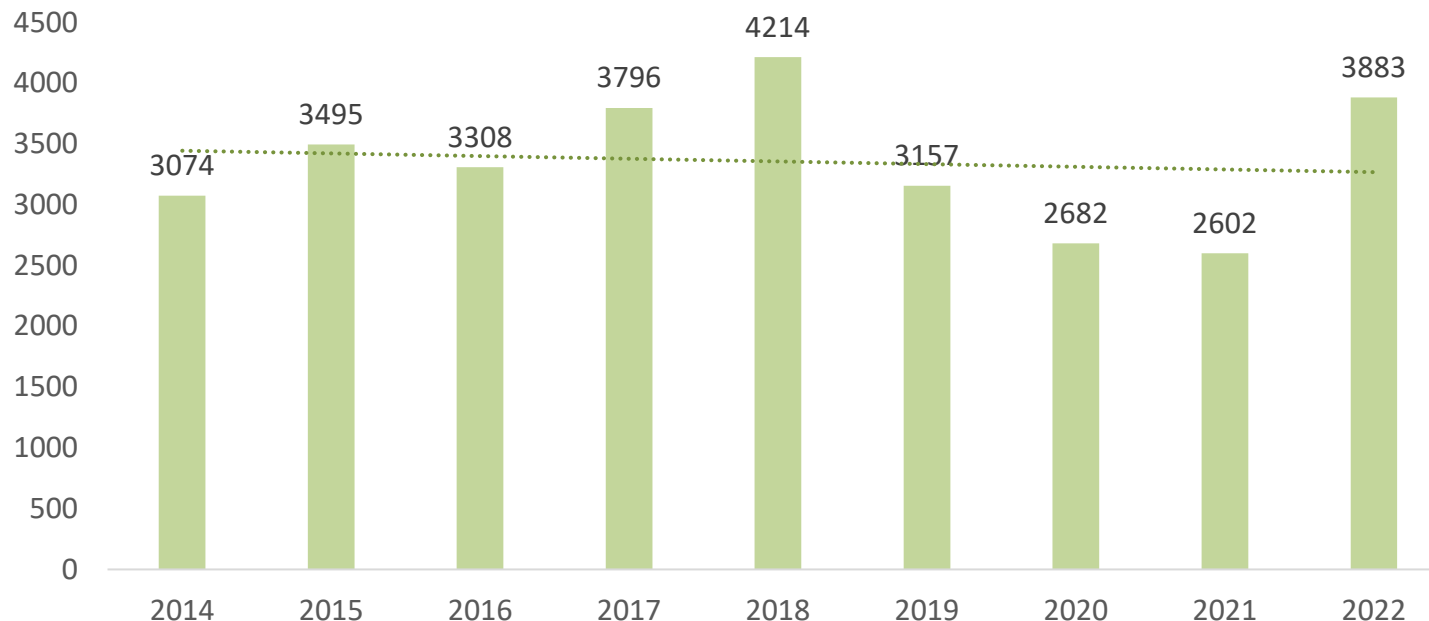
Reportable Events to Federal Agencies

There were no events reported to federal/regulatory agencies during 2022.



Historical Non-Committee Workload

Non-Committee Submissions 2014-02022

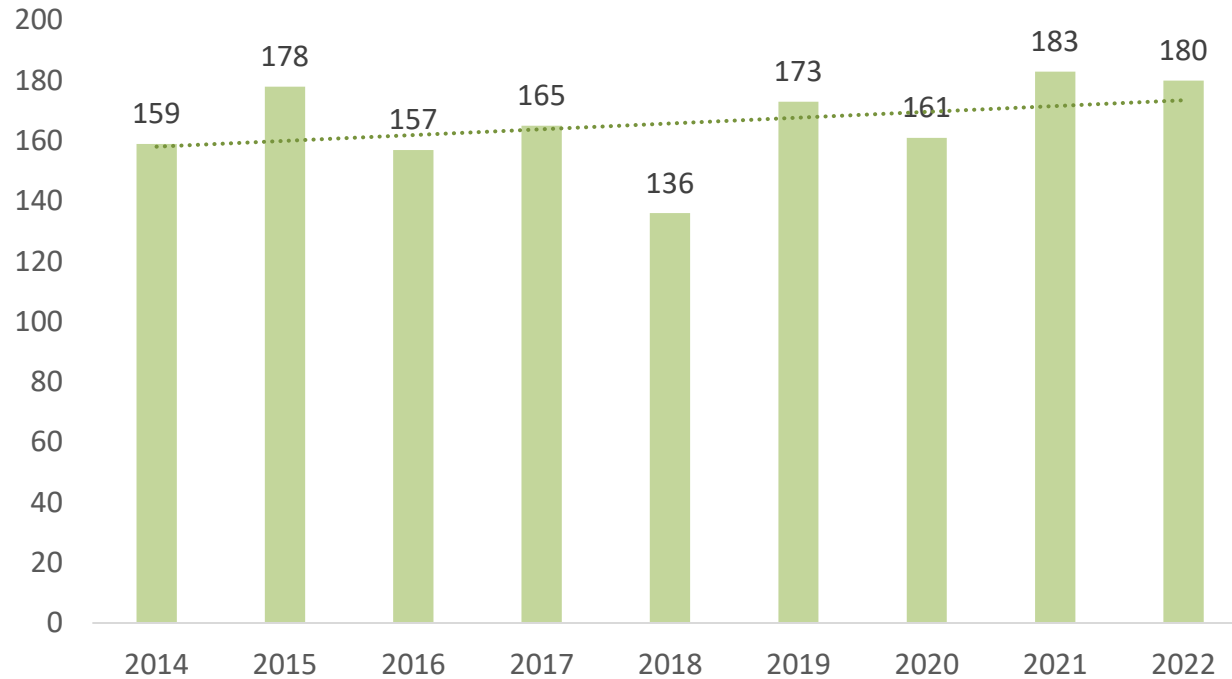


- The 2022 Non-Committee workload **increased about 49%** compared to 2021. This is indicative of a continued increase in total submission volume.
- Since simple changes and renewals for Minimal Risk 2018/Exempt protocols is no longer needed the current non-committee workload contains more complex submissions that may require additional processing time.
- Multisite submissions may require reliance's and additional processing time by reviewers. About 30% of Deferrals and about 81% of P-sites need Institutional Agreements (IA's).



Historical Full Committee Workload

Historical Full Committee Workload
2014-2022

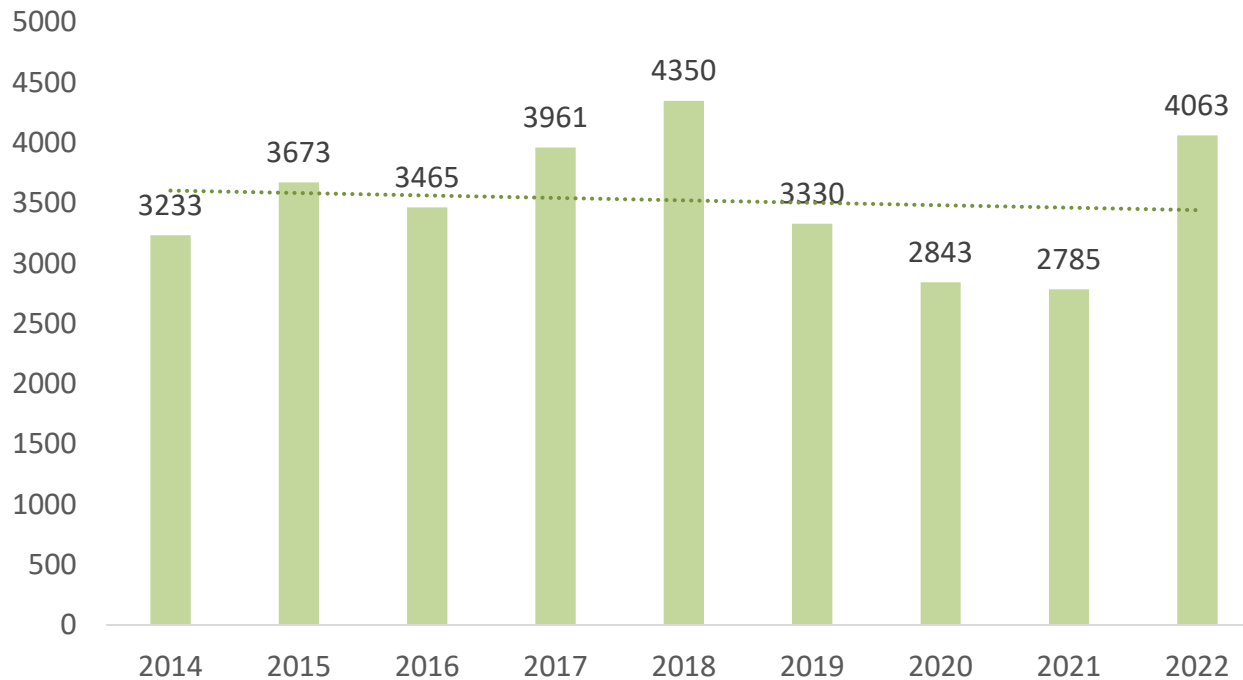


- For the second year in a row, we **maintained a 12% increase** in Full Committee submissions compared to 2020.



Historical Workload Totals

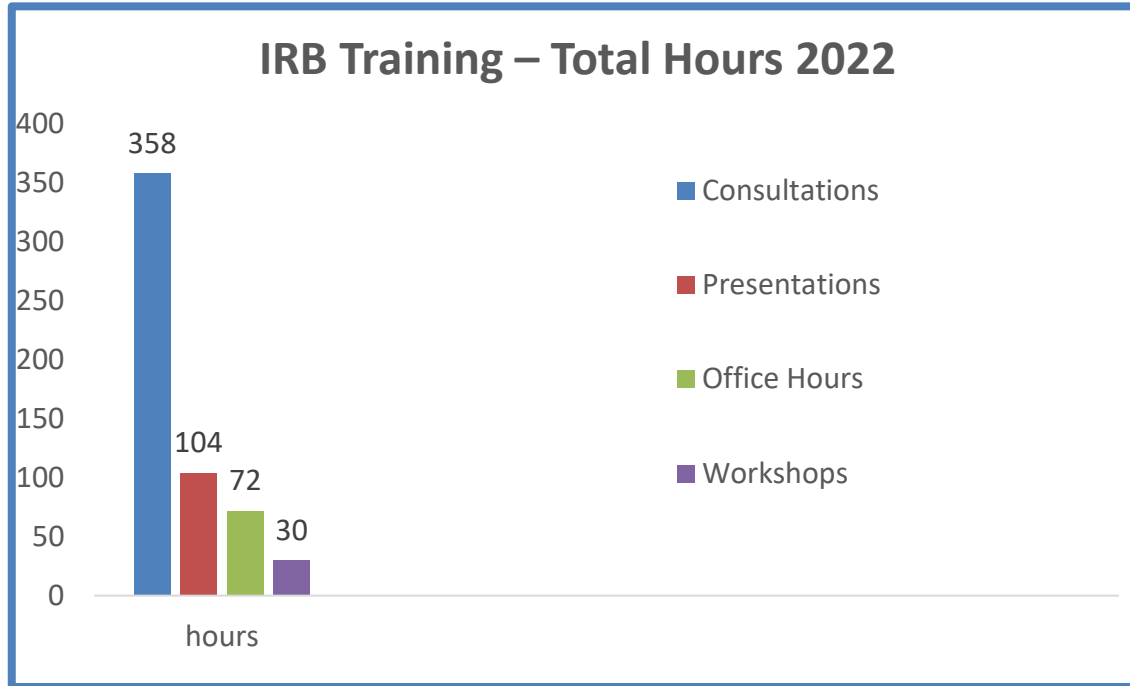
Historical Workload 2014-2022



- We experienced a **46% increase in total workload** compared to last year.
- The total workload was higher than the prior three (3) years. This indicates that the UA is continuing to expand its human subject's research activities.



Education, Training & Outreach in 2022



- **Consultations:** meetings between the HSPP staff and researchers (staff effort varies).
- **Presentations:** HSPP staff present on IRB topics, including eIRB.
- **Office Hours:** Biweekly virtual office hours for researchers to bring any IRB related questions (~2-3 staff members).
- **Workshops:** Topic specific lecture with an interactive component (up to 90 min ~ 2 staff members)

Over 544 staff hours were spent on these activities in 2022, which is a significant increase since 2019.
~47% increase compared to 2021
~83% increase compared to 2020

Multiple staff members participated in most Education & Outreach events.

- Consultations took approximately 358 staff hours.
- Presentations took approximately 104 staff hours.
- Office Hours took approximately 72 staff hours (121 people attended).
- The 10 Workshops took approximately 30 staff hrs to present (368 people attended).

Additional Education, Training & Outreach in 2022

- Presentations during staff meetings, periodic staff training, webinars, and new staff training were conducted as needed (29 training events took place in 2022).
- Preparing for presentations (i.e., creating /updating slides, etc.).
- Weekly Listserv announcements are sent to the research community.
- Committee Meetings are held twice a month. We conducted training at 3 Committee meetings, plus IRB members are trained on an ongoing basis. The meetings take about 1-2 hours and several staff members including IRB Coordinators and HSPP leadership are in attendance.
- Exempt Reviewer Training is conducted once per year, and support to the Exempt reviewers is offered as needed.
- Over 2,000 questions were answered through the departmental email account in 2022. The majority of questions were related to IRB submissions, study updates, eIRB, and multisite collaborations.





2023 Goals

The HSPP hopes to attain the following goals in 2023:

- Implement eIRB Version 10.5 upgrade, and provide education for staff, IRB and the research community.
- Focus on staff retention, education and QI/QC.
- Prepare for AAHRPP Re-Accreditation.
- Recruit and train new HSPP staff & IRB Committee members.
- Continue education and outreach opportunities:
 - Integrate Workshops and HSPP training with interdepartmental efforts in order to consolidate efforts and maximize time. Focus on more targeted training.
 - Continue to improve and expand the training plan for new HSPP staff, IRB Chairs, and Committee Members.
 - Increase continuing education opportunities for HSPP staff.
 - Expand effort tracking to better assess time devoted to various efforts.
- Continue to expand the HSPP Quality Assurance Program:
 - Conduct at least one (1) routine audit per quarter and alternate between types of studies to include both Biomedical and Social/Behavioral.
 - Conduct staff audits.
- Update the HSPP Website to make it more user friendly.
- Incorporate DEI into UA affiliated research projects. Provide DEI outreach and present DEI guidance to the research community. New policy requiring translation of study documents into non-English language set to go-live in 2024.

