IRB COMPLIANCE MONITORING PROGRAM ANNUAL REPORT 2024

Institutional Review Board and Human Subjects Office

CONTEXT

The primary goals of the Compliance Program are to:

1. Assess human subjects research for compliance with federal regulations and institutional policies through:
   a. an independent review of the HawkIRB application and associated research materials;
   b. a personal interview with the Principal Investigator and affiliated research team members, as applicable; and
   c. online questionnaires approximating the in-person review.

2. Provide researchers one-on-one and group educational opportunities regarding human subjects research; and

3. Facilitate communication between the IRB/Human Subjects Office and researchers at the University of Iowa.

The Compliance Program is currently staffed by the Compliance Manager, one full-time Senior IRB Compliance and Education Specialist, and one full-time IRB Compliance and Education Specialist who conduct the reviews and provide information about the educational resources that are provided by the Human Subjects Office.

COMPLIANCE PROGRAM STAFF

The Compliance Program team has been fully staffed since 2023. The Compliance Manager (CM) was hired in January 2022. In October 2022 the team added a Senior Compliance and Education Specialist (Sr. CES), and one additional full-time Compliance and Education Specialist (CES), joined the program in July 2023.

COMPLIANCE MONITORING EVENTS

The IRB Compliance Program conducts several types of pre- and post-approval monitoring of human subjects research. The following table defines these event types in brief. Routine audits of IRB-03 studies are conducted by the VA Research Compliance Officer.

Table 1: Types of Compliance Monitoring

Title/Acronym	Definition
CT.gov	Review of studies in need of assistance and education in order to comply with CT.gov requirements.
Directed	IRB Chair or Director requests monitoring, usually for a specific reason and to investigate possible non-compliance of researchers.
DoD	Involves research supported or conducted by the Department of Defense or one of its components.
Exempt	Monitoring of exempt approved studies; conducted via Qualtrics surveys.
FDA/EMA	A monitor attends during a Food & Drug Administration or European Medical Association inspection at UI.
IND/IDE/HGT	Investigational New Drug/Investigational Device Exemption/Human Gene Transfer
Internal Audit	Audit conducted by UI Internal Audit (not IRB Compliance Program).
PAM & Ed	Post-Approval Monitoring & Education for open human subjects research at UI.
PARR	Post-Approval Responsibilities Review
PARR-IDE	Post-Approval Responsibilities Review for Investigational Device Exemption
SPI-FA	Monitoring of studies conducted by a Student Principal Investigator having a Faculty Advisor; conducted via Qualtrics surveys.
Umbrella	Required monitoring of studies in which a single investigator submits one IRB application to cover multiple sub-studies with a common hypothesis.
By Request	A voluntary monitoring visit conducted at the request of a Principal Investigator
IDHHS	Audit conducted by the Iowa Department of Health and Human Services
EPIC	Monitoring of UIHC EPIC system and studies

Calculation of Percentage of Open Studies Monitored in 2024

Total Number of AAHRPP Open Studies as of 12/31/23 4403

136 Studies Monitored in 2024
4403 AAHRPP Studies

= 3.08% of Open Studies Monitored in 2024

Year	AAHRPP Open Studies	Studies Monitored	% of Open Studies Monitored
2023	4502	102	2.3%
2022	4533	53	1.2%
2021**	4419	39	0.88%
2020**	4467	63	1.4%

**Compliance monitoring halted due to the COVID pandemic during the bulk of the 2020-2021 calendar year.

Distribution of monitoring events per Compliance Program Staff Member is documented in Table 2 below.

Table 2: Total Events in 2024 by Staff Member: On-Site Monitoring

		CM	Sr. CES	CES	Event Total	% of Total
Type of Event	PARR	1	3	2	6	10%
	PARR - IND	-	-	-	-	-
	IDHHS	1	-	-	1	1.5%
	Pam & Ed	6	14	11	31	49%
	Directed	11	3	1	15	24%
	FDA	3	1	-	4	6%
	CT.gov	1	-	-	1	1.5%
	Umbrella	-	5	-	5	8%
	Total Events	23	26	14	63	
	% of All	**37%**	**41%**	**22%**	**100%**	**100%**

Table 3: Total Events in 2024 by Staff Member: Monitoring via Survey

	CM	Sr. CES	CES	Event Total	% of Total
SPI-FA	17	20	36	73	100%
Exempt*	-	-	-	-	-
Total Events	17	20	36	73	100%
% of All	**23%**	**28%**	**49%**	**100%**	**100%**

*The Exempt application was under significant revision in 2021 and went live in 2023. Monitoring has been on hold while the research community adjusts to the new process.

Table 4: Total Events by Type of Event, 2020 – 2024 **Add lines for FDA and IDHHS**

		2020	2021	2022	2023	2024
Type of Event	PARR	8	3	0	2	6
	PARR-IND	0	0	0	1	0
	PARR-IDE	0	0	0	0	0
	IND/IDE/HGT	0	4	1	0	0
	PAM & Ed	14	6	2	31	31
	Directed	5	1	8	11	15
	SPI-FA	30	18	16	52	73
	Exempt	0	0	0	0	0
	DoD	1	3	0	0	0
	Internal Audit	0	0	26	2	0
	Umbrella	4	2	0	0	5
	By Request	0	2	0	0	0
	CT.gov	0	0	0	0	1
	Yearly Total	**62**	**39**	**53**	**99***	**131****

*There were an additional 3 monitoring events in 2023 (2 FDA audits; 1 IDHHS audit)
**There were an additional 5 monitoring events in 2024 (4 FDA audits; 1 IDHHS audit)

Figure 1 below illustrates the number of monitoring events completed by year since 2020

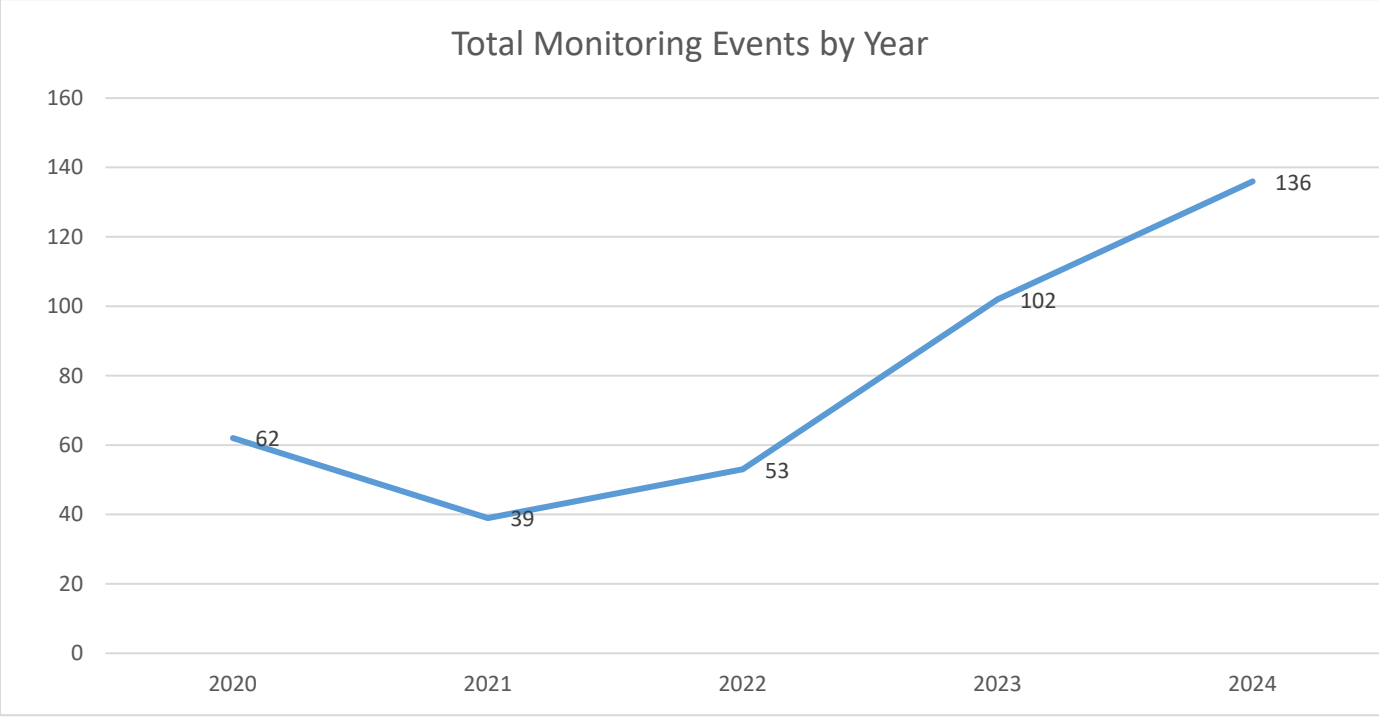

Table 5: Total Monitoring Event Type by Board Type: 2022 – 2024

		Number of Studies per Board per Year					
		IRB - 01			IRB-02		
		2022	2023	2024*	2022	2023	2024*
Type of Visit	PARR	0	2	6	0	0	0
	PARR-IND	0	1	0	0	0	0
	PARR-IDE	0	0	0	0	0	0
	IND/IDE/HGT	1	0	0	0	0	0
	PAM & Ed	2	30	29	0	1	2
	Directed	3	9	10	1	2	2
	SPI-FA	6	22	37	10	30	36
	DoD	0	0	0	0	0	0
	Not in HawkIRB	0	0	0	1	0	0
	IDHHS	0	1	1	0	0	0
	FDA/EMA	0	0	3	0	0	0
	Exempt	0	0	0	0	0	0
	Umbrella	0	0	4	0	0	1
	CT.gov	0	0	1	0	0	0
	Total # by Board	13	65	91	14	34	41

***** Four additional visits were under commercial/external IRBs.

Table 6: Total Number of Reports Reviewed by IRB Chair of Record 2024

		01 Chair 1	01 Chair 2	01 Chair 3	01 Chair 4	01/02 Chair	02 Chair 1	02 Chair 2	01 Chair 5	02 Chair 3	Total
Type of Study	PARR		3	1		1			1		6
	PARR - IND										0
	IND/IDE/HGT										0
	Pam & Ed	1	6	4		10	1	1	8		31
	Directed		2	2	1	5	1		3	1	15
	SPI-FA		16	17			9	4		27	73
	CT.gov			1							1
	FDA/EMA Site Inspection					4					4
	IDHHS					1					1
	Umbrella		1	3						1	5
	Total Events	1	28	28	1	21	11	5	12	29	136
	% of Total	<1%	21%	21%	<1%	15%	8%	4%	9%	21%	100%

MONITORING FINDINGS

As part of the monitoring process, the Compliance and Education Specialist enters findings from the visit into HawkIRB. Table 7 below illustrates the number of findings in HawkIRB by category in 2024.

Table 7: 2024 Monitoring Findings by Category **Breakout specific findings**

Finding Type	Number	Percent of Total
Findings noted with HawkIRB Application and Attachments	104	52%
Findings addressed internally; no required action for PI	2	1%
Findings noted with conduct of study or investigator oversight	1	0.5%
Findings noted with the HSO	2	1%
Findings noted with the IRB	1	0.5%
Findings with IRB Determinations	1	0.5%
No Finding	70	35%
Findings noted with Documentation and/or Process of Consent	9	4.5%
Information learned at monitoring visit	5	2.5%
Information learned via communication with PI	2	1%
Other findings noted with study	3	1.5%
TOTAL	**200**	**100%**

Figure 2: Monitoring Findings for the HawkIRB Application, by Section

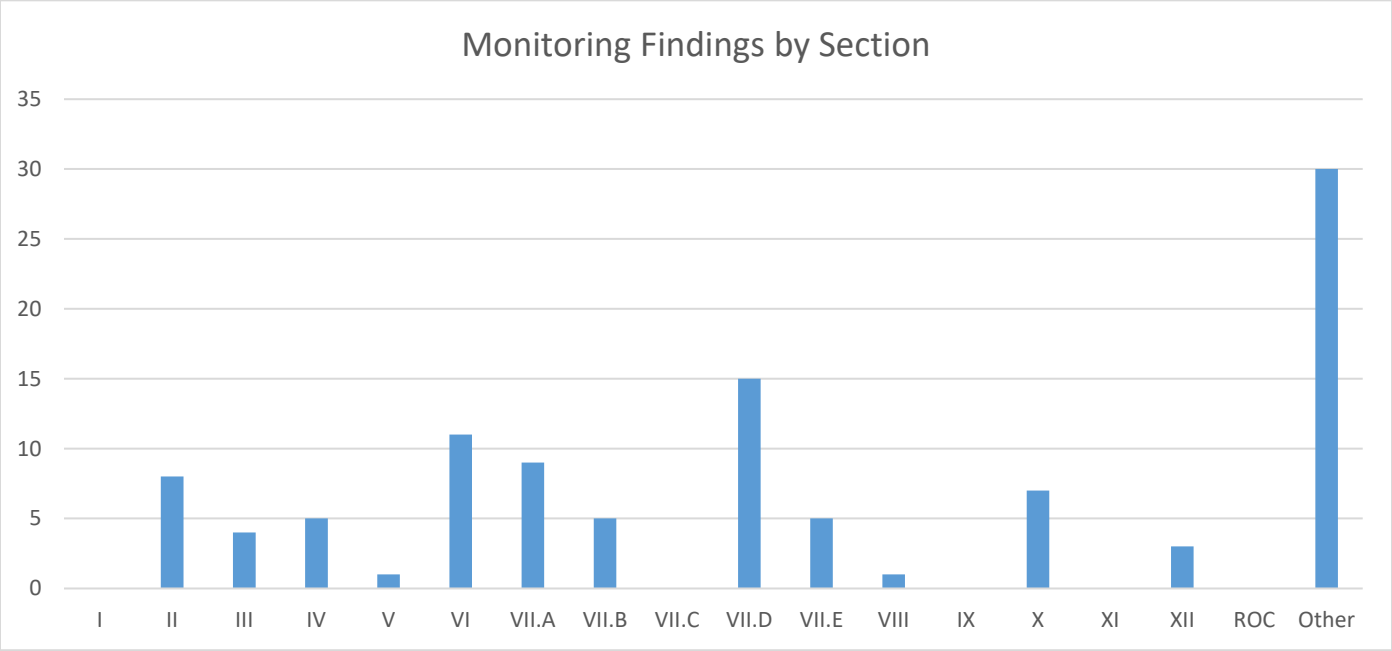

Table 7 illustrates the frequency of findings per study. Studies without findings are not represented.

Total Findings	Number of Studies	Percent of Studies
No Findings	70	51%
1 or 2 findings	40	29%
3 or 4 findings	19	14%
5 or 6 findings	5	4%
7 or 8 findings	1	1%
9 or 10 findings	1	1%
11 or 12 findings	0	0
13-16 findings	0	0
Total	136	100%

COMPLIANCE INITIATIVES

During 2024, Compliance Program team members undertook a number of special projects to improve internal work processes or education for the research community.

Table 9. 2024 Accomplishments and Key Contributors

Project in Brief	**Key Contributors**
Updated Compliance Educational Handouts to be current	Compliance Manager, Sr. IRB Compliance and Education Specialist
Created educational tool for web-based survey research	Compliance Manager
Created educational tool for research involving student educational records	Compliance Manager
Updated content for new Human Subjects Office website	Compliance Manager, IRB Compliance and Education Specialist
Revised SPI-FA SOP and surveys	Sr. IRB Compliance and Education Specialist

Project in Brief	Key Contributors
Presentation: Clinical Trials Investigator Training Program (Reporting and Compliances), May 2024	Compliance Manager
Presentation: Monthly IRB Efficiency Initiative Update (Web-based Survey Research Educational Tool), August 2024	Compliance Manager
Presentation: Conducting Research Involving Student Records: How to Ensure Compliance, October 2024	Compliance Manager

COMPLIANCE PROGRAM STAFF DEVELOPMENT

Members of the Compliance Program participated in a variety of professional development opportunities in 2024. These included webinars and trainings on a variety of relevant topics from AAHRPP, PRIM&R, WCG, Advarra, and OHRP. All members of the Compliance Program completed PRIM&R's two-part webinar series, Exploring FDA Regulations. The Compliance Manager also attended Health Care Compliance Association's Healthcare Research Compliance Academy in September and is now Certified in Healthcare Research Compliance (CHRC). The Senior IRB Compliance and Education Specialist is a Certified Clinical Research Coordinator (CCRC). The Compliance Manager and Senior IRB Compliance and Education Specialist completed training for eReg and EDC platforms. The Senior IRB Compliance and Education Specialist completed the HawkAI training series.

COMPLAINTS AND CONCERNS

There were 15 complaint and concern investigations documented in 2024. The table below summarizes the types of complaints and the HSO response. There were four more complaints than recorded in 2023. Currently, this information is maintained in an Excel spreadsheet; however, our goal in the future is to incorporate the complaint and concern tracking into HawkIRB.

Table 10. 2024 Complaints and Concerns Investigated

Complaint Type	Total	HSO Response
HIPAA	1	Study was monitored; no findings
PI Oversight	3	All 3 studies were monitored; all were referred to the IRB-01 Executive Committee for potential noncompliance
Recruitment*	3	2 studies were monitored, of these, 1 was referred to the IRB-01 Executive Committee for potential noncompliance
Procedures**	7	3 studies were monitored; no significant findings. 3 studies were resolved by communication with research team; 1 study was resolved in consultation with IRB-02 Chair, UI Registrar, and UI General Counsel
Other	1	Issue was resolved internally with no monitoring

* One study had 2 separate complaints

**Examples of procedures included the following:
Concerns regarding compensation
Concern regarding sharing of potentially FERPA protected data
Concern regarding costs of participation

CONCLUSION

The Compliance Program had a successful year in 2024. We increased the number of monitoring events we completed and resumed monitoring of Umbrella projects. We accomplished several large-scale projects and participated in numerous professional development activities. We contributed to the overall mission of the Human Subjects Office by developing new educational tools and participating in several presentations to the research community, as well as staffing Office Hours, and monitoring the HSO email inbox. We are looking forward to increasing the number of monitoring events we conduct in 2025, as well as expanding the scope of the program to include increased monitoring of IND, IDE, and controlled substance studies, and a more in-depth monitoring process for clinical trials.