**IRB COMPLIANCE MONITORING PROGRAM ANNUAL REPORT 2023**

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:
	1. an independent review of the HawkIRB application and associated research materials;
	2. a personal interview with the Principal Investigator and affiliated research team members, as applicable; and
	3. 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 expanded to three full-time staff in 2023. One additional full-time Compliance and Education Specialist joined the program in July 2023 (3A). The Compliance Manager was hired in January 2022 (5A). A full-time Senior Compliance and Education Specialist joined the team in October 2022 (4A).

**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 2023** |

Total Number of AAHRPP Open Studies as of 12/31/23 4502

102 Studies Monitored in 2023

**= 2.3% of Open Studies Monitored in 2023**

4502 AAHRPP Studies

|  |  |  |  |
| --- | --- | --- | --- |
| **Year** | **AAHRPP Open Studies**  | **Studies Monitored** | **% of Open Studies Monitored** |
| 2022 | 4533 | 53 | 1.2% |
| 2021\*\* | 4419 | 39 | 0.88% |
| 2020\*\* | 4467 | 63 | 1.4% |
| 2019 | 4126 | 153 | 3.7% |

\*\*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 2023 by Staff Member: On-Site Monitoring**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  | 5A | 4A |  | 3A | Event Total | % of Total |
| **Type of Event** | PARR | 1 | 1 |  | - | 2 | 4% |
| PARR - IND | 1 | - |  | - | 1 | 2% |
| IDHHS | 1 | - |  | - | 1 | 2% |
| Pam & Ed | 4 | 26 |  | 1 | 31 | 65% |
| Directed | 10 | 1 |  | - | 11 | 23% |
| FDA | 2 | - |  | - | 2 | 4% |
| Umbrella | - | - |  | - | - | 0 |
|   | Total Events | 19 | 28 |  | 1 | 48 |  |
|   | **% of All** | **40%** | **58%** |  | **2%** | **100%** | **100%** |

**Table 3: Total Events in 2023 by Staff Member: Monitoring via Survey**

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  | 5A | 4A |  | 3A | Event Total | % of Total |
| SPI-FA | 4 | 42 |  | 6 | 52 | 100% |
| Exempt\* | - |  |  | - | - | - |
| Total Events | 4 | 42 |  | 6 | 52 | 100% |
| **% of All** | **8%** | **80%** |  | **12%** | **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, 2019 – 2023**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  | **2019** | **2020** | **2021** | **2022** | **2023** |
| **Type of Event** | PARR | 16 | 8 | 3 | 0 | 2 |
| PARR-IND | 1 | 0 | 0 | 0 | 1 |
| PARR-IDE | 0 | 0 | 0 | 0 | 0 |
| IND/IDE/HGT | 3 | 0 | 4 | 1 | 0 |
| PAM & Ed | 22 | 14 | 6 | 2 | 31 |
| Directed | 19 | 5 | 1 | 8 | 11 |
| SPI-FA | 39 | 30 | 18 | 16 | 52 |
| Exempt | 43 | 0 | 0 | 0 | 0 |
| DoD | 2 | 1 | 3 | 0 | 0 |
| Internal Audit | 0 | 0 | 0 | 26 | 2 |
| Umbrella | 2 | 4 | 2 | 0 | 0 |
|  | By Request | 0 | 0 | 2 | 0 | 0 |
|  | EPIC | 6 | 0 | 0 | 0 | 0 |
|  | **Yearly Total** | **153** | **62** | **39** | **53** | **99\*** |

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

**Figure 1 below illustrates the number of monitoring events completed by year since 2019**

**Table 5: Total Monitoring Event Type by Board Type: 2019 – 2023**

|  |  |  |
| --- | --- | --- |
|   |   | **Number of Studies per Board per Year** |
|   |  | **IRB - 01** | **IRB-02** |
|   |   | **2021** | **2022** | **2023** | **2021** | **2022** | **2023** |
|   | PARR | 3 | 0 | 2 | 0 | 0 | 0 |
| **Type of Visit** | PARR-IND | 0 | 0 | 1 | 0 | 0 | 0 |
| PARR-IDE | 0 | 0 | 0 | 0 | 0 | 0 |
| IND/IDE/HGT | 4 | 1 | 0 | 0 | 0 | 0 |
| PAM & Ed | 6 | 2 | 30 | 0 | 0 | 1 |
| Directed | 1 | 3 | 9 | 0 | 1 | 2 |
| SPI-FA | 0 | 6 | 22 | 18 | 10 | 30 |
| DoD | 1\* | 0 | 0 | 0 | 0 | 0 |
| Not in HawkIRB  | 0 | 0 | 0 | 0 | 1 | 0 |
| IDHHS | 0 | 0 | 1 | 0 | 0 | 0 |
|   | FDA/EMA | 0 | 0 | 0 | 0 | 0 | 0 |
|   | Exempt | 0 | 0 | 0 | 0 | 0 | 0 |
|   | Umbrella | 2 | 0 | 0 | 0 | 0 | 0 |
|  | By Request | 2 | 0 | 0 | 0 | 0 | 0 |
|  | WIRB/External | 0 | 1 | 0 | 0 | 2 | 2 |
|   | Total # by Board  | 19 | 13 | 65 | 18 | 14 | 34 |

**\*** Two additional DoD visits were under IRB-03.

**Table 6: Total Number of Reports Reviewed by IRB Chair of Record 2023**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | IRB-01 (Chair 1) | IRB-01 (Chair 2) | IRB-01 Chair (3) | IRB-01 Chair (4) | IRB-01/IRB-02 Chair (5) | IRB-02 (Chair 6) |  | IRB-02 (Chair 7) | IRB-01 (Chair 8) | IRB-02 (Chair 9) | Total |
| **Type of Study** | PARR | 1 |  |  |  | 1 |  |  |  |  |  | 2 |
| PARR - IND |  |  |  |  |  |  |  |  | 1 |  | 1 |
| IND/IDE/HGT |  |  |  |  |  |  |  |  |  |  | 0 |
| Pam & Ed | 8 | 1 | 5 | 1 | 1 |  |   | 1 | 14 |  | 31 |
| Directed | 1 |  | 3 |  | 3 |  |  | 1 | 2 | 1 | 11 |
| SPI-FA | 14 |  | 8 |  |  | 10 |  | 2 |  | 18 | 52 |
| DoD |  |  |  |  |  |  |  |  |  |  | 0 |
| Exempt |  |  |  |  |  |  |  |  |  |   | 0 |
| FDA/EMA Site Inspection |  |  |  |  | 2 |  |  |  |  |  | 2 |
| Umbrella |  |  |  |  |  |  |  |  |  |  | 0 |
|  | **Total Events** | 24 | 1 | 16 | 1 | 7 | 10 |  | 4 | 17 | 19 | 99 |
|   | **% of Total**  | 24% | 1% | 16% | 1% | 7% | 10% |   | 4% | 17% | 20% | 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 2023.

**Table 7: 2023 Monitoring Findings by Category**

|  |  |  |
| --- | --- | --- |
| Finding Type | Number | Percent of Total |
| Findings noted with HawkIRB Application and Attachments | 91 | 52% |
| Findings noted with conduct of study or investigator oversight | 3 | 2% |
| Findings noted with the HSO | 12 | 7% |
| Findings noted with the IRB | 1 | 0.5% |
| No Finding | 47 | 26% |
| Findings noted with Documentation and/or Process of Consent | 9 | 5% |
| Information learned at monitoring visit | 6 | 3% |
| Information learned via communication with PI | 4 | 2.5% |
| Other findings noted with study | 3 | 2% |
| **TOTAL** | **176** | **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 | 53 | 54% |
| 1 or 2 findings | 26 | 26% |
| 3 or 4 findings | 11 | 11% |
| 5 or 6 findings | 7 | 7% |
| 7 or 8 findings | 1 | 1% |
| 9 or 10 findings | 0 | 0 |
| 11 or 12 findings | 0 | 0 |
| 13-16 findings | 1 | 1% |
| **Total** | 99 | 100% |

**COMPLIANCE INITIATIVES**

During 2023, Compliance Program team members undertook a number of special projects to improve internal work processes or education for the research community.

**Table 9. 2023 Accomplishments and Key Contributors**

|  |  |
| --- | --- |
| **Project in Brief** | **Key Contributors** |
| Updated Compliance Educational Handouts to be current  | 5A, 4A |
| Created educational tool for electronic informed consent | 5A, 4A |
| Updated content for new Human Subjects Office website | 5A, 3A |
| Revised SPI-FA SOP and surveys  | 4A |

|  |  |
| --- | --- |
| **Project in Brief** | **Key Contributors** |
| Presentation: FDA Site Inspection Guidance Document, February 2023 | 5A |
| Presentation: Hot Topics and Updates, March 2023 (Informed consent documentation and recordkeeping) | 5A |
| Presentation: Unlocking the Mystery of IRB Compliance, September 2023 | 5A, 4A |
| Presentation: Hot Topics and Updates, October 2023 (Electronic Consent and Checklist) | 5A |
| Presentation: Human Subjects Research in the UIHC, November 2023 | 5A |
| IRB Connection Articles: March, October, November, December 2023 | 5A |

**COMPLIANCE PROGRAM STAFF DEVELOPMENT**

Members of the Compliance Program participated in a variety of professional development opportunities in 2023. These included webinars and trainings on a variety of relevant topics from AAHRPP, PRIM&R, WCG, Advarra, and OHRP. The Compliance Manager also attended AAHRPP’s Annual Conference (virtual), and the UI Learning and Development’s eight-week supervisor training series (Practical Applications of Supervisory Skills, Engaging Yourself). The Compliance Manager is also a member of the Research Compliance Network and serves as a member of one of its working groups.

**COMPLAINTS AND CONCERNS**

There were 11 complaint and concern investigations documented in 2023.  The table below summarizes the types of complaints and the HSO response. There were five more complaints than recorded in 2022.  Currently, this information is maintained in an Excel spreadsheet; however, our goal in the future is to incorporate the C/C tracking into HawkIRB.

|  |  |  |
| --- | --- | --- |
| **Complaint Type** | **Total** | **HSO Response** |
| PI Oversight | 2 | Both studies were monitored; one of these was referred to IRB-01 Executive Committee for potential noncompliance |
| Recruitment | 4 | 3 studies were monitored, of these, one was referred to IRB-01 Executive Committee; 1 study submitted a modification |
| Procedures\* | 5 | 1 study was monitored and referred to IRB-02 Chair\*\*; 1 study has monitoring pending; 2 studies were resolved by communication with research team |

\*Examples of procedures included the following:

Concerns regarding compensation

Concern regarding sharing of data outside of research team

Concern regarding study questionnaire

 \*\*Study had 2 separate complaints

**CONCLUSION**

The Compliance Program had a successful year in 2023. We nearly doubled the number of monitoring events we completed. We added a new full-time member to our team, and successfully completed their onboarding and training. We accomplished several large-scale projects and participated in numerous professional development activities. We are looking forward to increasing the number of monitoring events we conduct in 2024, as well as expanding the scope of the program.