UK OFFICE OF RESEARCH INTEGRITY (ORI)

QUALITY IMPROVEMENT PROGRAM (QIP)

WHAT DOES THE QIP DO?

- The UK ORI QIP was implemented to assess the strengths and weaknesses within UK's human research protection program (HRPP)

- This is achieved by evaluating existing processes, procedures, and programs in order to enhance human subject protections at UK and ensure our compliance with federal, state, and institutional regulations as well as the Association for the Accreditation of Human Research Protection Programs (AAHRPP) standards

- https://www.research.uky.edu/office-research-integrity/quality-improvement-program-human-research-protections

THE QIP COMPONENTS

- Directed on-site reviews
- Selected new study check-ins (aka Wellness Checks)
- Principal Investigator (PI) self-assessments
- Administrative assessment reviews

BREAKING IT DOWN

Outside the office:

- Directed reviews/visits
- Selected new study check-ins
- Principal Investigator (PI) self-assessments

Inside the office:

- Administrative assessments

DIRECTED VISITS

- Also known as "for cause" visits
- Requested by the **convened IRB** (or VPR or ORI Director) when there are unusual circumstances, significant risk to subjects, routine failure to comply with protocol requirements, and/or allegations or concerns about the conduct of a study. [*Typically involves Full review protocols, but expedited review protocols are also eligible*.]
- Can only be requested for protocols under that IRB's purview

DIRECTED VISITS, CONT.

- QIP team familiarizes themselves with the relevant protocol(s), the issues and concerns which led to the request, and contacts the PI to schedule the site visit
- Summary report of the visit/findings is provided to both the PI and the IRB
- The IRB reviews the report (and any response from the PI) at a convened meeting and determines whether further action is necessary

WELLNESS CHECKS

- A form of post-approval monitoring fully implemented in 2019, paused for COVID in 2020 and subsequent staffing changes, and resumed in late 2022
- Intent is to conduct an **abbreviated on-site review** designed to assist the PI and study staff with ensuring adherence to the approved protocol. This post-approval monitoring can be done for either Full or Expedited review protocols
- Targeted timeline is approximately 6-months after initial IRB approval

WELLNESS CHECKS, CONT.

- The ORI identifies and selects protocols for these visits in various ways (e.g., a risk-based approach, staff recommendations, past meeting agendas, protocols approved within a certain date range)

- Goal is to identify and reduce errors by the PI/study personnel early in the life of the study prior to the first annual renewal review (i.e., AAR/CR). This can improve human subjects protection as well as the AAR/CR submission, screening, and review processes.

WELLNESS CHECKS, CONT.

- Typically takes 1 to 4 hours depending on the complexity of the protocol, number of participants enrolled at the time, etc.

- Summary report of visit/findings provided to the PI and, if there are significant concerns or findings, the IRB

PI SELF-ASSESSMENT*

- Can be voluntarily performed by the PI/study team or the PI may be asked/directed to do it by the IRB (or VPR or ORI Director)
- Web-based self-assessment which includes questions and information regarding federal regulations, local IRB policies/procedures, and Good Clinical Practice (GCP) guidelines

- **The self-assessment tool is currently undergoing re-programming to update it and move it to REDCap*

PI SELF-ASSESSMENT, CONT.

- Results are submitted to a secure database and ORI can return suggested corrective actions for areas of improvement, if noted
- Results are not shared with the IRB unless significant deficiencies in human subjects protections are revealed or the self-assessment was directed by the IRB
- Wishlist item: we hope to eventually create an interactive version

SUMMARY OF EXTERNAL ASSESSMENTS

- IRB Directed visits:
  - Requested by the convened IRB at a meeting (not a decision by just the Chair/Vice Chair, etc.)
  - Can only be requested for protocols under that IRB's purview
  - IRB receives and discusses a copy of the report (and any PI response) at a subsequent convened meeting

SUMMARY OF EXTERNAL ASSESSMENTS, CONT.

- Wellness Checks:
  - Selected by QA/QI staff in the ORI (i.e., not the IRB)
  - IRB does not receive a copy of the visit report unless significant concerns/findings were noted

SUMMARY OF EXTERNAL ASSESSMENTS, CONT.

- PI self-assessment: (*once functional in REDCap*)
  - PI/study team completes it voluntarily
  - IRB can direct a PI to complete a self-assessment if there are concerns
  - IRB does not receive a copy of the assessment unless the IRB requested the PI do it or significant concerns/findings were noted in one completed voluntarily

INTERNAL ASSESSMENTS

- Administrative assessments:
  - Can include IRB records, IRB procedures, and program assessments for accreditation requirements (e.g., protocol documentation and processing times, meeting records/minutes, office policies/procedures, and HRPP practices)
  - Results may be reviewed with IRB Chairs, one or more of the IRBs, and/or ORI staff depending on the nature of the assessment and related findings

QUESTIONS?

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Thank you!