How RECs Can Operate Efficiently During Emergency Research: Lessons From USA RECs/IRBs

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Introduction: Why RECS are often blamed

- RECs across Africa and elsewhere have been blamed for delaying research due to various reasons:
  - Lack of procedures that facilitate expedited processing
  - Failure to accommodate requests for expediting
  - Failure to meet quorum requirements
  - Lack of urgency – the usual way.
  - Lack of familiarity with the disease under investigation.

- The Covid-19 pandemic presents an opportunity to learn and share experiences.

When Covid-19 Struck, how did your REC respond?

- Most US IRBs immediately issued some guidance
  - New methods of data collection, safety precautions (PPE) and halting of "non-essential" research.
- IRBs came up with procedures for covid-19 projects.
- GWU IRB initiated a covid-19 classification in the online submission system.
- IRB immediately started meeting online – no meeting missed.
- IRB Admins started working from home – advantage of electronic submission systems.

What was happening elsewhere?

- No guidance was provided to Investigators.
- Investigators depended on MoH guidance on lockdowns.
- Paper based IRBs went into hibernation.
- Some IRBs continued in usual mode.
- REC Admins and Chairs sought guidance from colleagues in USA and elsewhere.

As we seek to reopen…….

- Human Research Office has issued guidance on reopening
- Delegated the responsibility of granting approval to Departments and Schools:
  - Prioritization of research for both restarting and initiation (new).
  - Checking on Safety measures that have been implemented
  - Check on availability of PPE and safety awareness among teams
  - Monitoring Implementation.

Human Research Office Guidance on Re-Opening

- **NO need for IRB approval** – PIs to complete a Promptly Reportable Incident Form (PRIF).
- **NEW STUDIES** – to go through Department and School leadership for review and then submitted to the IRBs.
- Emphasis on highest safety standards for staff and volunteers
- OHR provided the tools for use by investigators:
  - Guidance on how Departments prioritize research.
  - Safety procedures to be used by research teams.
  - Informed consent addendum to be used wherever there is contact with participants.

What are the lessons learned?

- Need an SOP on processing of emergency research.
- REC systems should allow flexibility in handling priority research.
- RECs should plan ahead at all stages (halting/restarting).
- RECs should think about ongoing and new research!
- RECs should be supported by trained REC Admins and Chairs.
- Communicate timely with investigators.
- RECs are there to promote responsive research.