Strategies for Rapid Implementation of Study Protocols

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Themes

- Protocol Development
- Team Building
- Study Sensitization
- IRB approval process
- SOP development
- Recruitment
- Study activation
- Study implementation

Protocol Development

- Site Level
  - Nothing happens at site level without a final protocol
  - Frequent changes in protocol hinders productivity
- Local IRBs
  - irritated by frequent ‘minor’ changes
  - Minimal or no interaction until protocol finalized
- Informed Consent Forms
  - Rapid process for localizing ICFs

Team Building I

- Assemble core team
  - Potential PI, Research Manager, Study Coordinator, Research Nurse, Data Officer, Laboratory Technician, QA/QC Officer, Community Educator & IRB Officer
- Core team drawn from ongoing studies
- Each department to review protocol and assess needs
- Weekly study meetings

Team Building II

- Core team meets to decide on client flow at the designated study site to evaluate adequacy of space
- Client flow as guide to determine team size
- Site PI and departmental heads meet to discuss
  - team chemistry & dynamics in proposed team
  - (Project policy: ≥ 25% of team should be from persons already involved in research at UNCP)
- Ensure that study team is in place at least 2 months before study commencement

IRB approval process I

- Site IRB Officer coordinates with Study PI to obtain the final copy of protocol and localized ICFs
- IRB Officer acts as liaison between translation team & PI and ensures timely translation of all documents needing translations for the IRB
- Site IRB Officer liaises with Study Coordinator to ensure that the study team is happy with all translations

IRB approval process II

- Site IRB Officer creates internal dateline for submission of documents to her office
- Site IRB Officer checks, makes copies & finalizes preparation of study documents requiring IRB submissions before actual submission
- Regular contact with IRB secretariat office on approval updates & other IRB issues

Study Sensitizations

- Aimed at sensitizing people on a planned research study
- No STUDY happens without ALL interested parties having been adequately sensitized
- Community Educators group prepare a simple brief to be used which is approved by the study team
- Interested parties include
  - UNC Project employees
  - CAB members
  - MOH institutions acting as study sites
  - Traditional/Community leaders & other stakeholders
  - Community

Study Sensitizations II

- As soon as IRB approvals received study team sets a target date for study initiation.
- Community Educators use this target to draw up itinerary for sensitizations
- Sensitization brief modified based on comments from briefing UNCP staff and CAB
- Sensitization of traditional/Community leaders & Stakeholders
- Initiation of sensitization in potential recruitment sites- eg. clinics, communities, workplaces etc. ~ 2 wks prior to study start

Study Activation

- Develop site activation checklist in addition to study activation checklist
- Constant contact on status of study preparatory activities with protocol team contact person
- Work through study activation checklist by distribution of assignments to study staff and compiling the finalized issues by Study Coordinator
  - e.g. SOPs, Data collection folder, Special purchases, etc

Study Activation II

- Timely submission of study activation documents for registration
- Datelines for assignments given to study staff quite helpful

Standard Operating Procedures (SOPs)

- Unnecessary lengthy development process which delays study implementation
- Need to recognize that each site has generic SOPs for various activities developed to harmonize activities across various networks
- Need for Study managers to STOP micromanaging these SOPs to suite specific studies within a network with little regard for how it affects work at site and within the network

Recruitment

- Decide where the potential participants are most likely to come from
- Develop strategies for getting at potential study participants once the protocol gets over to the site
- Involve others in strategy to reach target
  - CAB members,
  - potential study participants,
  - other stakeholders
- Primarily general sensitization talks/briefs targeting potential participants & referral sites

Recruitment

- Media involvement –
  - not fully exploited but may move in that direction for some studies e.g. HPTN 052, Malaria vaccine trial
- Tracking of daily events
  - enrolment rates
  - Events
- Adjustment of strategies throughout early recruitment period
  - Daily team meetings to discuss activities of the day

Study implementation – Screening/Enrolment into a Study

- Walk through study implementation activities with study staff as often as possible
- Figure out participant flow for EACH study visit
- Dry runs for study visits implementation done before actual study implementation

Study implementation – II
Screening/Enrolment into a Study

- Revision of participant flow when necessary after dry runs
- Dry runs till study staff is comfortable to conduct study visits
- Then wet runs

Thank you