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