

Telling a story – manuscripts

MTN Regional Meeting
Laboratory Breakout 2016

Have an idea?

- Is there a gap in the information available?
- Do you have a testable hypothesis?
- What testing / data analysis is needed?

- Ancillary study – investigations that are not described in the original protocol
- Data request – data is available, but need to crunch the numbers.

Write it up!

- Develop your hypothesis / study design and talk with the LC, SCHARP, and FHI360 folks familiar with that study.
- As you fill-in the ancillary concept / data request application (<http://www.mtnstopshiv.org/node/5647>), please keep-in mind logistical considerations.

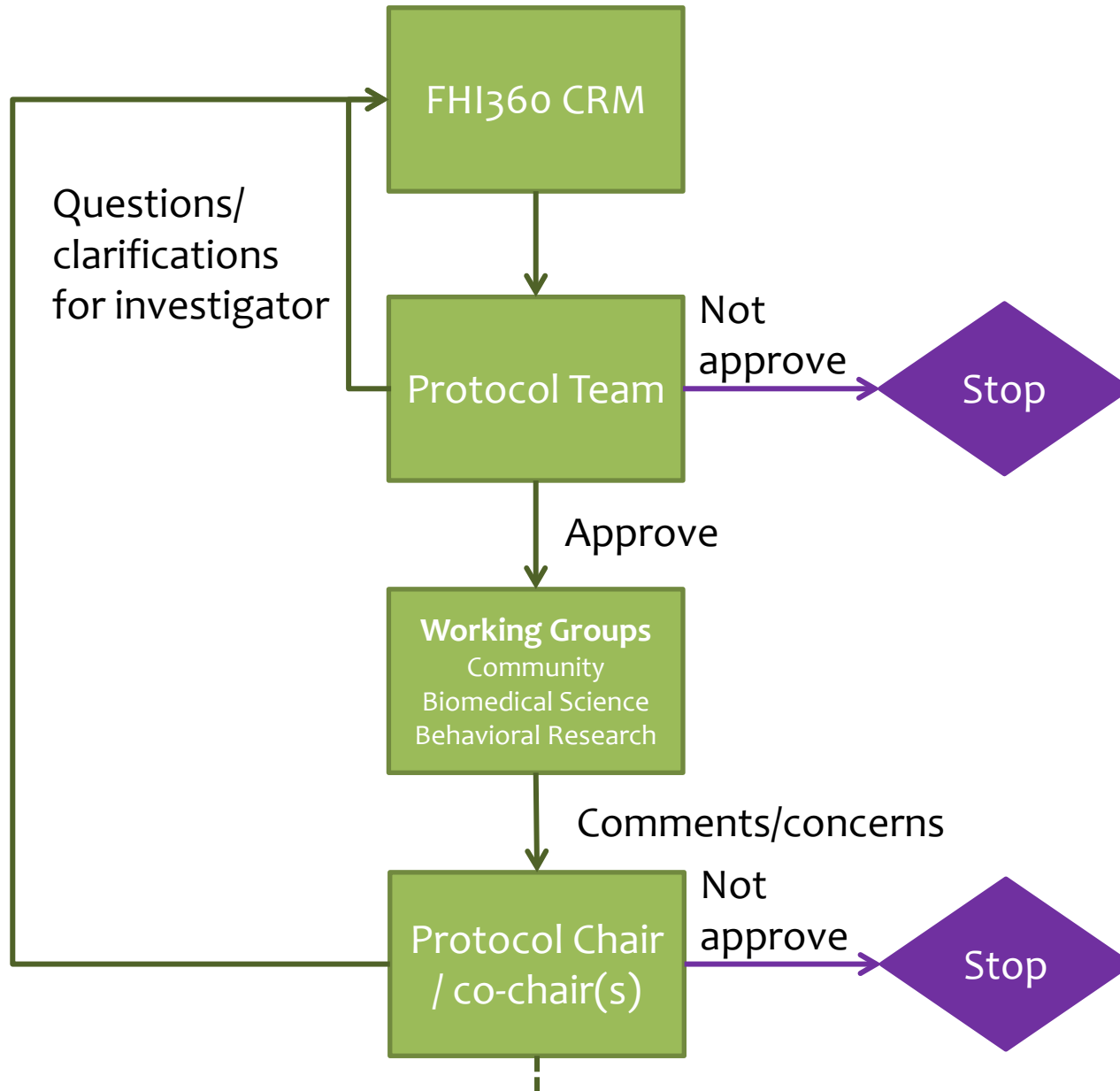
Logistics

- What types of samples are available from which visits? Review Study protocol and SSP first.
- Do your ethics committees need to approve your proposal?
- Will I only be analyzing data or will I need samples?
- Will I use samples only from my site or should I expand to include other sites?
- How will I identify samples needed for my concept? Talk with SCHARP.
- Will samples need to be shipped?
- How will shipping, testing, and other aspects of my concept be funded?
- How will the data be analyzed?

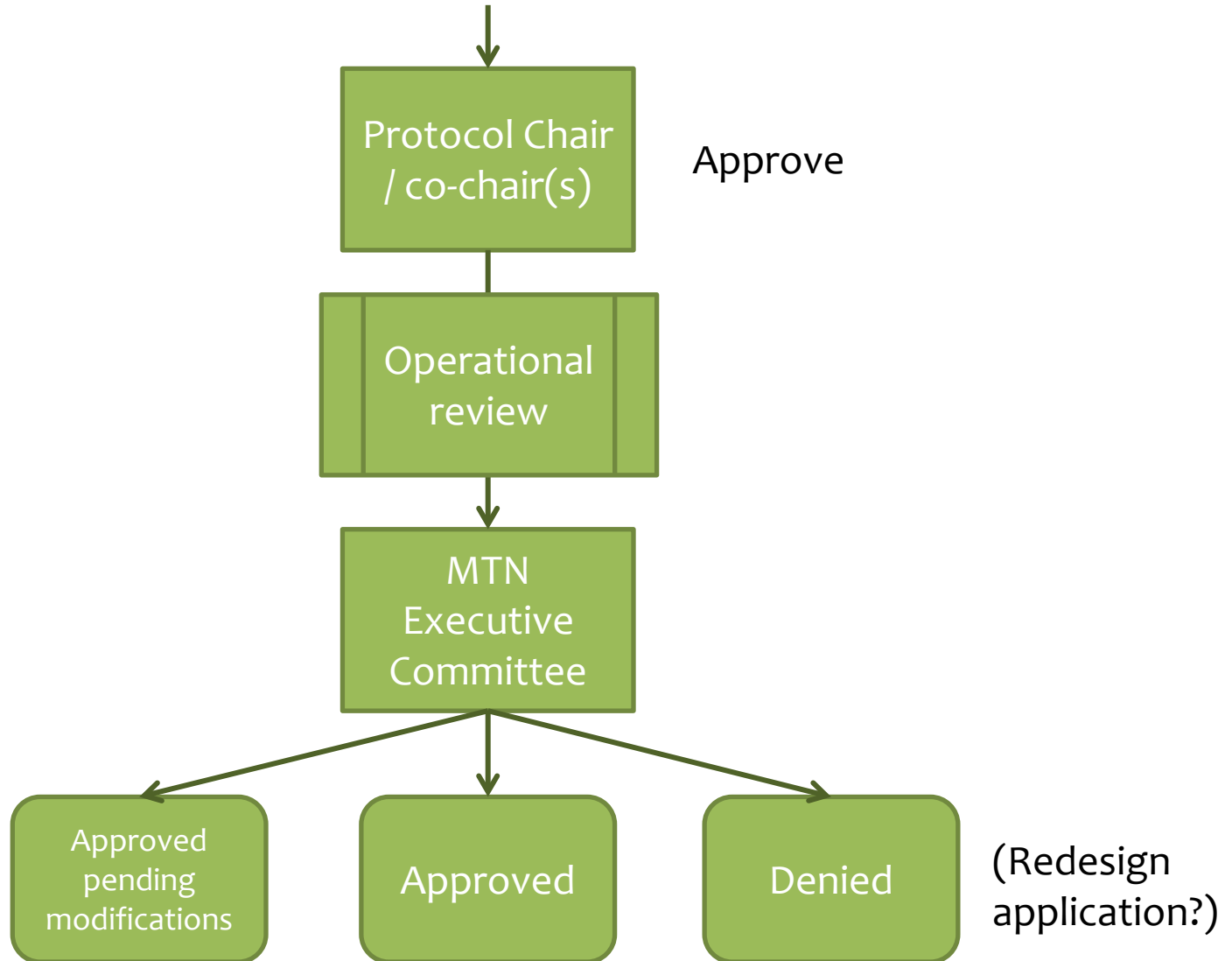
Your concept

- Make sure your application addresses all elements and is clearly written.
- Once ready, send your form, and any additional information, to the FHI 360 Clinical Research Manager (CRM) for that study to start the approval process.

Approval process



Approval process



Investigator informed of the outcome.

Don't delay

- Novel findings need to be written up well and quickly...
- ... otherwise others will publish them.

OR

- ... the information will no longer be relevant.
- MTN leaders are applying for a Fogerty Global Health Fellowship to work with you on developing publications – funded in 2018?

Once your paper is written

- Send the draft to the CRM for review by collaborators and protocol publication committee(s).
- Consider the feedback
 - Make edits as necessary or
 - Explain why they're not needed.
- After protocol team approval, paper needs to be cleared by MTN Manuscript Review Committee (MRC).

Submit to a journal

- Outcomes:
 - Provisionally accepted pending rebuttal
 - Rejected
- Regardless should have valuable comments.
- Resubmit – don't quite!
- Once accepted, notify the MTN MRC and make sure you obtain the PMCID number.

Congratulations!