

Ideas to Improve Clinical Research

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Things to Consider

- Standardized consent and contract language.
- Short form approach (AAMC/OHRP)
- Redesign text in Phase 1 and most Phase 2 trials to make a clinical response the clear primary objective. (medicare)

Things to Consider

- Create metrics around the process (NCI and Institution)
- Share metrics with cooperative groups
- Provide comparative metrics to local organization.
- Reduce non-value-added steps, consolidate valuable steps (Lean Six Sigma)

Things to Consider

- Conduct all processes in parallel (not series) at NCI, cooperative groups and investigative site.
- Ask for minor change in CFR that would allow expedited study approval and review of consent language at secondary sites once an accredited IRB has given approval.

Things to Consider

- Underpayment for trials will erode enthusiasm and all processes.
- Opening too many trials – tide goes out and sinks all ships.
- High volume recruitment of under-financed trials is not sustainable.
- Growing tension between cancer and non-cancer with regard to volunteerism, fair distribution of institutional support for trials.