

**Global Network for Women's and Children's Health Research**  
**Common Protocol Review Criteria**  
10/2005

1. Intervention addresses a leading cause of morbidity and/or mortality in pregnant women and their infants in the developing world. In mothers, this includes eclampsia, post-partum hemorrhage, and infections. Infections include puerperal sepsis, complications of abortion or episiotomy, or co-morbidities and/or complications related to HIV and other STIs, TB, and /or malaria. Malnutrition and environmental exposures are also of interest. In infants, this includes low birth weight or small for gestational age, asphyxia, neonatal sepsis, pneumonia, malnutrition and diarrhea.
2. A public health intervention, preferably community-based. The intervention must have a major impact on population health and apply to a large percentage of the population of interest. Generally interventions that do not involve hospital-based technology are preferred.
3. Intervention must be evidence-based (there must be a substantial rationale for the success of the proposed intervention), e.g., oxytocin has been demonstrated to be effective in preventing postpartum hemorrhage in the hospital. An intervention to demonstrate that oral misoprostol is equally effective would be of interest.
4. Ideally the intervention and/or application should be both evidence-based and innovative (applies the intervention in a new setting or with a new population or by different levels of personnel), e.g., auxiliary nurse midwives or traditional birth attendants can use oral misoprostol (rather than injectable oxytocin) effectively to prevent post-partum hemorrhage among women delivering in the community (rather than in hospitals), and using an innovative drape to quantify blood loss.
5. The intervention must conform to NIH and FDA guidelines concerning safety for pregnant women and infants.
6. The protocol must represent a collaborative effort between a US PI and an SFI or affiliates, i.e., an investigator at the U.S. site other than the PI can work with the PI and the SFI and his/her group to develop a protocol, OR an investigator at the SFI's site can work with the SFI and the U.S. PI to develop a protocol, OR investigators at the US and SFI sites can work with their respective PIs to develop a protocol. SFIs and their institutional colleagues can and should take the lead as appropriate.
7. The intervention should enhance research infrastructure and build capacity.
8. The intervention and the infrastructure should be sustainable. If the trial results are positive and the appropriate groundwork has been laid with the Ministry of Health and local professional communities, the intervention should have a high likelihood of adoption.

9. The problem should be common to at least three Global Network sites and a minimum of three GN sites should participate. The three cooperating sites do NOT have to be identified until the final protocol is in development.
10. The common protocol can test an intervention that is currently funded as an individual Global Network protocol. The Global Network can also participate in trials developed by other groups, e.g., WHO.
11. The intervention can be system-based; it can seek to modify practices among health care providers, e.g., a hospital-based intervention to increase active management of the third stage of labor.
12. The intervention should attempt to minimize the burden placed on patients and communities in terms of time and inconvenience.
13. A recruitment goal of 18 months is recommended.

In addition to the above criteria, reviewers are urged to take into account the review criteria used by the Gates Foundation:

- **builds:** discovery, product development, and research trials of new and improved health technologies
  - represents a discovery or invention of a health technology to solve problems for which we currently lack effective approaches
  - applied research and research trials for health technologies which will ultimately benefit developing country populations
  - modification of effective health technologies for use in developing countries to increase affordability, usability, and acceptability
- **proves:** operational research and demonstration projects to assess effectiveness of new and improved health interventions in developing countries
  - field testing of new health technologies and other interventions to determine their effectiveness in developing countries
  - large-scale demonstrations of previously field-tested health interventions to determine feasibility and cost-effectiveness of implementation
  - demonstration of innovative implementing mechanisms to accelerate disease elimination and/or eradication
- **sustains:** human capacity mechanisms, implementation mechanisms, policy and analysis to sustain prove health interventions in developing countries and support global health issues
  - mechanisms to mobilize human, organizational, and financial resources for implementation of health interventions in developing countries
  - research and analysis to provide evidence for decision-making and evaluation in global health
  - advocacy to increase the awareness, level of activity, and prioritization of global health issues.