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**Stages of Change: Is the HMORN Ready to Consider Alternative Models
for Multicenter Research Review?**

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Background: Increasingly, research in the HMO Research Network (HMORN) entails multicenter collaborations. The federal government devised the concept of institutional review board (IRB) approval in the 1970s, when multicenter research was less common. As illustrated by a growing body of empirical literature, researchers face substantial challenges in obtaining IRB approval for multicenter studies. This has prompted the exploration of new models for research review, such as a centralized IRB or facilitated review process. One function of the HMORN's Coordinated Clinical Studies Network (CCSN) is to examine the viability of assorted strategies that could streamline IRB review.

Methods/Approach: This presentation will characterize and present various alternatives for facilitating IRB and research feasibility reviews, as synthesized from published and grey literature and augmented by interviews with IRB representatives in the HMORN. Pros and cons of each alternative will be presented in the context of the HMO Research Network, taking into account our relationships with our enrollees and healthcare delivery systems, as well as with external collaborators and external IRBs.

Results and Implications: A range of models and approaches will be considered. On one end of the continuum, research could be facilitated within the existing IRB structure by utilizing common application templates, procedures and tracking systems. Such an approach could be well-suited for certain types of multicenter studies, such as analyses of de-identified automated data. At the other end of the continuum is the creation of a centralized IRB for multisite studies that could include some or all members of the HMORN. Among the goals of the CCSN research review study team are to (1) raise awareness of the different approaches under consideration by the larger research community and their financial and administrative implications; and (2) to determine how we can continue to optimize human subject protections and improve efficiency in our multicenter research. Because of our involvement with the NIH's Roadmap initiative, our innovations in this area will improve the conduct of science in our Network and help guide similar efforts around the country.