Glossary of Terms from Appendix 1 of FOA DP10-003

American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. No. 111-5): Signed into law by President Obama on February 17, 2009. ARRA includes measures to modernize our Nation's infrastructure, enhance energy independence, expand educational opportunities, preserve and improve affordable health care, provide tax relief, and protect those in greatest need. Four hundred million dollars were allocated to the Health and Human Services Office of the Secretary for CER.

Cluster randomized trials: Groups of subjects, such as patients in a general practice or tenants in a housing scheme, are randomly allocated to the experimental or a control intervention.[1]

Comparative effectiveness research: Comparative effectiveness research is the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in "real world" settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

- To provide this information, comparative effectiveness research must assess a comprehensive array of health-related outcomes for diverse patient populations and sub-groups.
- Defined interventions compared may include medications, procedures, medical and assistive devices and technologies, diagnostic testing, behavioral change, and delivery system strategies.
- This research necessitates the development, expansion, and use of a variety of data sources and methods to assess comparative effectiveness and actively disseminate the results.

Complex (public health) interventions: Complex interventions are widely used in the health service, in public health practice, and in areas of social policy such as education, transport and housing that have important health consequences. Conventionally defined as interventions with several interacting components, they present a number of special problems for evaluators, in addition to the practical and methodological difficulties that any successful evaluation must overcome.[1]

Federal Coordinating Council for Comparative Effectiveness Research (FCC): Authorized by the American Recovery and Reinvestment Act (ARRA), the FCC helps coordinate research and guide investments in comparative effectiveness research (CER) funded by the ARRA. FCC does not recommend clinical guidelines for payment, coverage or treatment. FCC considers the needs

of populations served by federal programs and opportunities to build and expand on current investments and priorities.

FCC Prioritization Criteria for Comparative Effectiveness Research:
The criteria for scientifically meritorious research and investments are:
1) Potential impact (based on prevalence of condition, burden of disease, variability in outcomes, costs, potential for increased patient benefit or decreased harm),

2) Potential to evaluate comparative effectiveness in diverse populations and patient sub-groups and engage communities in research,

3) Uncertainty within the clinical and public health communities regarding management decisions and variability in practice,

4) Addresses need or gap unlikely to be addressed through other organizations,

5) Potential for multiplicative effect (e.g., lays foundation for future CER such as data infrastructure and methods development and training, or generates additional investment outside government)

Individually randomized trials: Individuals are randomly allocated to receive either an experimental intervention, or an alternative such as standard treatment, a placebo or remaining on a waiting list. Such trials are sometimes dismissed as inapplicable to complex interventions, but there are many variants of the basic method, and often solutions can be found to the technical and ethical problems associated with randomization.[1]

Institute of Medicine (IOM): The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiasedunbiased and authoritative advice to decision makers and the public. Established in 1970, the IOM is the health arm of the National Academy of Sciences, which was chartered under President Abraham Lincoln in 1863. Nearly 150 years later, the National Academy of Sciences has expanded into what is collectively known as the National Academies, which comprises the National Academy of Sciences, the National Academy of Engineering, the National Research Council, and the IOM.

IOM Priorities for Comparative Effectiveness Research: Committee on Comparative Effectiveness Research Prioritization, Institute of Medicine (IOM). Initial National Priorities for Comparative Effectiveness Research. 2009. National Academies Press. Washington DC.

Minority and underserved populations: Ethnic/racial minority groups include African-American, American Indian and Alaska Native, Asian American and Pacific Islander, and Hispanic. Underserved populations include, but are not

limited to, the homeless, migrant workers, the unemployed or working poor, the elderly, veterans, the mentally ill, people who have disabilities, or other vulnerable groups.

N-of-1 designs: Individuals undergo interventions with the order or scheduling decided at random; This design can be used to assess between and within person change, and to investigate theoretically predicted mediators of that change.[1]

Observational designs: A design where there is no manipulation of the factor of interest. An observational design can take many forms, but the simplest design mimics the results of an experiment or quasi-experiment.[2]

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the five core review criteria, and additional review criteria (as applicable for the project proposed).

People with disabilities: According to the Americans with Disabilities Act, The term "disability" means, with respect to an individual (A) A physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) A record of such an impairment; or (C) Being regarded as having such an impairment.

Preference trials and randomized consent designs: Practical or ethical obstacles to randomization can sometimes be overcome by the use of non-standard designs. Where patients have very strong preferences among treatments, basing treatment allocation on patients' preferences, or randomizing patients before seeking consent, may be appropriate.[1]

Quasi-experimental designs: A study in which the factor of interest has been manipulated but for which randomization has not been used. These designs may involve one-group comparisons, multiple-group comparisons, or a combination of these.[2]

Scalability: The implementation of research findings (i.e. effective public health interventions) translated into public health programs, practice, and policy in states and communities throughout the country in a time- and cost-efficient manner.

Stepped wedge designs: May be used to overcome practical or ethical objections to experimentally evaluating an intervention for which there is some evidence of effectiveness, or which cannot be made available to the whole population at once. It allows a randomized controlled trial to be conducted without delaying roll-out of the intervention. Eventually, the whole population

receives the intervention, but with randomization built into the phasing of implementation.[1]

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[1] Medical Research Council. Developing and evaluating complex interventions: new guidance. London, 2008. http://www.mrc.ac.uk/complexinterventionsguidance; see also Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. "Developing and evaluating complex interventions: the new Medical Research Council guidance." *British Medical Journal* 2008:337;a1655; http://www.bmj.com/cgi/content/full/337/sep29_1/a1655

[2] For detailed definitions, see Kleinbaum DG, Kupper LL, Morgenstern H. *Epidemiologic research: principles and quantitative methods.* New York: John Wiley and Sons, 1982.