ATTACHMENT J

SSLA— In-depth telephone interviews with Researchers

SOCIETAL STAKEHOLDER LEVEL OF ANALYSIS (SSLA)

INTERVIEW PROTOCOL FOR RESEARCHERS

**Description of the Protocol**

The purpose of the in-depth stakeholder telephone interviews is to collect information on the three primary domains of interest—knowledge and skills, attitudes and beliefs, and behaviors and experiences—in an effort to understand what processes stakeholders use to engage in CER. The interviews will also follow up on issues raised in other data collection activities. We will collect this information from each *key* stakeholder group—those that are directly involved in CER decision-making or are CER users, including: (1) physicians, (2) consumers/patients, and (3) health care organizations. We will also collect this information from each *additional* stakeholder group—those that contribute to and use CER but are not directly involved in point-of-care decision making, including: (4) employer/payers, (5) researchers and (6) developers of innovation. This will allow us to examine differences in CER-relevant knowledge and skills, attitudes and opinions, and behaviors and experiences held by various stakeholder groups. We will use the data we collect from the telephone interviews to help answer SSLA evaluation questions as well as inform other levels of analysis. (Please see the stakeholder-specific section of the draft approach for more detail.)

The expectation is that we will conduct 8 to 10 interviews for each of the 6 stakeholder groups, for a total of up to 60 hour-long interviews.

For the researcher interviews, we will recruit biomedical, translational, clinical trial researchers, as well as other researchers.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990- . The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer

The total burden of this interview protocol is 10 hours.

**I. GENERAL INTRODUCTION** (<5 minutes)

 We appreciate you taking the time to speak with us today. Before we begin, let me introduce myself and tell you a little bit about the work we are conducting for the Office of the Assistant Secretary for Planning and Evaluation (ASPE), which is part of the Department of Health and Human Services. My name is \_\_\_\_\_\_\_\_\_, and I work for an independent policy research firm called Mathematica Policy Research (Mathematica). *[If note taker, introduce him/her as well.]*

 We are helping ASPE learn more about what people know and think about comparative effectiveness, which is often called CER for simplicity. I will use this term, CER, during our discussion today as well. To do this, we are interviewing people from key stakeholder groups, including clinical researchers, to hear about your opinions and experiences with CER. We obtained your name from [insert name of sampling frame]. Your participation today is voluntary and our discussion is private. We will combine your answers with those of others to develop a broad overview of perspectives regarding comparative effectiveness research.

The results of our discussion will be synthesized in a final report and only general themes that emerge from our discussions will be reported. We will not attribute specific comments or quotes to named individuals without permission and your individual answers will be kept private to the extent permitted by law. Only the Mathematica evaluation team will have access to individually identifiable information.

 We expect this discussion to take about an hour.

 Before we begin, do you have any questions?

**II. BACKGROUND QUESTIONS** (5 minutes)

 First, I would like to ask you a few questions about your research background.

 1. Please describe your training (economist, public health, etc.)?

 2. Please tell me about your research area and the number of years you’ve worked in this area?

 3. Can you please provide a couple of examples of recent research you have or are conducting?

 4. What print, online, or other resources do you most frequently use to inform your research or to stay informed on important topics/issues related to your work?

 - For print/publication resources—(e.g., PubMed, Nexis, Google, specific publications)?

 - Other—(e.g., conferences, websites of specific professional or research organizations)?

**III. GENERAL KNOWLEDGE ABOUT CER** (10-15 minutes)

 Now, I would like to discuss comparative effectiveness research (CER).

 **A. Awareness/Understanding of CER**

 1. [Awareness]: Have you heard of comparative effectiveness research (CER) or patient-centered outcomes research?

 - *If yes, could you describe it in your own words? (And give an example?)*

 *[Give AHRQ Definition:* ***Comparative effectiveness research is a type of health care research that compares the results of one approach for managing a health problem to the results of other approaches****. Comparative effectiveness usually compares two or more types of treatment, such as different drugs, for the same disease. Comparative effectiveness also can compare types of surgery or other kinds of medical procedures and tests.]*

 2. [Awareness]: Different people interpret definitions differently. What would you say the definition I read for CER means, in your own words?

 3. Please describe some recent examples of CER:

 4. [Awareness]: Do the terms “comparative effectiveness research” and “patient-centered outcomes research” mean the same thing to you or do they mean something different?

 - *If they are different*, *is one more positive or negative than the other? Why do you think that?*

 **B. Knowledge/Understanding of CER**

 [Knowledge] [Attitudes]: I would also like to ask you about some specific aspects of comparative effectiveness research and how important these are for improving health care.

 1. How important is it that this kind of research responds to the information needs of patients, providers, and other decision makers? Why or why not?

 2. How important is it that this kind of research examines effectiveness of interventions for different types of patients? For example:

* + - **Probe:** Should it examine effectiveness for different age groups? Why or why not?
		- **Probe:** Should it examine effectiveness for different ethnicities and races? Why or why not?

 3. How important is it that this kind of research examines a range of interventions? For example:

* + - **Probe:** Should it examine medications? Why or why not?
		- **Probe:** Should it examine procedures like surgical and screening procedures? Why or why not?
		- **Probe:** Should it examine medical and assistive devices and technologies? Why or why not?
		- **Probe:** Should it examine behavioral change strategies such as strategies to help patients monitor their own conditions? Why or why not?

 4. How important is it that this kind of research examines a range of health-related outcomes (for example, looking at clinical outcomes but also patient satisfaction outcomes)? Why or why not?

 5. Could you please rank these four aspects of comparative effectiveness research by how important they are to you (1= most important, 4=least important)?

**IV. KNOWLEDGE, ATTITUDES, BEHAVIORS REGARDING ELEMENTS OF COMPARATIVE EFFECTIVENESS RESEARCH** (15 – 20 minutes)

 I would also like to talk to you about your ability to use the new developments in CER.

 1. [Behavior]: Are you involved in doing CER in your work?

* + - **Probe:** for examples: conducting CER projects, teaching topics in CER, reviewing CER work conducted by others? If yes, can you give an example?

 **A. Methods**

 1. [Awareness] Are you familiar with any methods for conducting comparative effectiveness research?

- *If yes*, which ones? Any new ones?

*[Give one or two examples: An example of CER methods includes:*

*1)*

*And*

*2)]*

*- If no, provide examples: Examples of two different kinds of methods used for this type of research are randomized controlled trials and an analysis of existing data from electronic databases.*

- *Describe the uses, advantages and disadvantages of these CER methods in the conduct of research:*

 2. [Self-Efficacy]: On a scale of 1 to 10, how confident are you with your ability to use these research methods for CER? Can you give an example?

3.[Attitudes]: What are your thoughts about different methods (i.e. study designs or analytic approaches) being developed for conducting comparative effectiveness research?

 *If answered yes to involvement in CER work:*

 4. [Behaviors]: How often do you use CER methods in your work? Can you give an example?

 **B. Databases for Using CER**

1. [Awareness]: Are you familiar with any large databases that can be used for conducting comparative effectiveness research?

- *If yes*, which ones? *Any new and/or enhanced/expanded databases?*

*[Give one or two examples: An example of CER databases includes:*

*1)*

*And*

*2)]*

*- If no, provide examples: an example of CER databases include merging all payer claims or linking payer data with electronic health record information*

 2. [Self-Efficacy]: On a scale of 1 to 10, how confident are you with your ability to use research data infrastructure/databases developed for CER? Can you give an example?

 3. [Attitudes]: What are your thoughts about databases that should be included in conducting comparative effectiveness research?

* + - **Probe:** What about new and/or enhanced/expanded databases being developed?

 4. [Behaviors]: How often do you use new or enhanced/expanded databases or other CER data infrastructure in your work? Can you give an example?

 **C. CER Training Curricula and Programs**

 1. [Attitudes]: What are your thoughts about new CERtraining curricula developed for preparing future comparative effectiveness research investigators?

* + - **Probe:** For examples: continuing education credits, annual meetings of specialty societies, conferences (such as a session or workshop covering CER)?

2. [Attitudes]: What are your thoughts about the preparation for future comparative effectiveness research careers of recent graduates of CER training programs?

*If answered yes to involvement in CER work:*

 3. [Behaviors]: Do you use CER training programs or curricula in your work? Can you give an example?

- If yes, how often?

**V. GENERAL ATTITUDE TOWARD CER** (5-10 minutes)

 [Attitude]: Now that we have discussed the different elements and possible uses of comparative effectiveness research, I would like to ask you more generally about what you think of this type of research.

 1. What are your thoughts on how CER might affect health care in the US?

 2. What are your thoughts on how greater provider use of CER in clinical decision-making might affect health care in the US?

 3. What are your thoughts on how greater patient use of CER in clinical decision-making might affect health care in the US?

 4. What are your thoughts on how greater use of CER by health plans or other payers might affect health care in the US?

**VI. WRAP UP** (<5 minutes)

 Are there any other thoughts about CER that you would like to add in the time we have left?

 *(Check with note taker to see if anything was missed or if s/he has follow-up questions.)*

Thanks for taking the time to speak with us. Your comments have been very helpful.