

**Developing a Self-Management Tool for  
Individuals with Systemic Lupus Erythematosus (SLE)**

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**Supporting Statement Part B**

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**B. Supporting Statement B**

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**List of Attachments**

- Attachment 1. Legislative Authority
- Attachment 2. Federal Register Notice
- Attachment 3. Project Information Sheet
- Attachment 4a. Screener for Women
- Attachment 4b. Screener for Men
- Attachment 5. Participant Information Sheet
- Attachment 6. Discussion Guide for Use in Focus Groups with Women or Interviews with Men
- Attachment 7. ORAU IRB Determination
- Attachment 8. Prototype CDC SLE Self-management Tool

## B. Supporting Statement B

The proposed information collection does not involve statistical methods.

### B.1. Respondent Universe and Sampling Methods

All focus group participants will be female, will have been diagnosed with SLE by a rheumatologist, will be conversant in English, and will be at least 18 years of age. All one-on-one interview participants will be male, and also will have been diagnosed with SLE by a rheumatologist, be conversant in English, and will be at least 18 years of age.

Participants will be volunteers and so will constitute a non-random sample. However, purposive sampling will be employed so as to gather a pool of participants that varies across race (white/all other races) and time since diagnosis of SLE (fewer than 3 years/at least 3 years).

SLE patient participants will be recruited with the assistance of rheumatologists' offices in four locations. Candidate cities include Detroit, Atlanta, San Francisco, and New York City (with Chicago, Oklahoma City, Los Angeles, Miami, and Washington D.C. as alternates). The project will conduct four focus groups in each of 4 locations for a total of 16 groups. For each group, 12 potential participants will be recruited, anticipating 8 to participate. The total number of potential participants to be recruited will therefore be up to 192 (i.e., 16 X 12). However, the number of participants who will participate in the focus groups will be up to 128 (i.e., 16 X 8). The numbers of participants with specific characteristics that will need to be recruited to fulfill the segmentation requirements described above are provided in Table B.1.1.

Table B.1.1. Female Focus group participant recruiting breakdown by segmentation factor

	Race		
Time since diagnosis	All Other Races	White	Total
Fewer than 3 years	48	48	96
At least 3 years	48	48	96
Total	96	96	<b>192</b>

Male SLE patients will be recruited using the procedure described above for focus groups with female SLE patients. Purposive sampling will be employed so as to gather a pool of up to 20 participants that varies on two factors (see Table B.1.2).



Table B.1.2. Male SLE interview participants

<b>Time since diagnosis</b>	<b>Race</b>		<i>Total</i>
	<i>All Other Races</i>	<i>White</i>	
<i>Fewer than 3 years</i>	5	5	10
<i>At least 3 years</i>	5	5	10
<i>Total</i>	10	10	<b>20</b>

Participants will be selected so as to meet these requirements to the greatest extent possible. In addition, to the extent possible, the sample of participants will also vary across age (categories) and education level (categories). However, recruiting constraints, individual show rate at groups, and/or resource limitations may prevent the formation of groups of all types as well as the desired representation of all types of individuals.

## **B.2. Procedures for the Collection of Information**

Participants will be recruited with the assistance of rheumatologists’ offices in four locations: likely Detroit, Atlanta, San Francisco, and New York City. Staff in participating clinics will distribute Project Information Sheets (Attachment 3) to their lupus patients via mail or electronic mail addresses on record at the clinic. Contact information for a marketing firm will be included in the information sheets. Patients interested in participating will contact the project marketing firm. Participants will be selected from among these volunteers by the marketing firm, under supervision of project staff and according to the selection criteria described above using the approved Participant Screener (see Attachments 4a and 4b). The marketing firm will identify qualified patients and provide information on date, time, location, tokens of appreciation and other related issues. This procedure will continue for approximately three weeks.

All individuals who are qualified and agree to participate will receive a Participant Information Sheet (Attachment 5). In addition, informed consent will be obtained from each patient prior to their participation. The names and contact information for these patients will be provided to the marketing firm, which will provide participants with information on date, time, location, tokens of appreciation and other related issues.

Once a participant is confirmed, the marketing firm will provide the participant with a link to an electronic version of the tool. This will be a beta version of the tool. Participants will be able to review the tool (either via downloading onto a mobile device or using a website version) prior to

taking part in the groups. Participants are requested to spend at least two hours using and reviewing the tool prior to the group to familiarize themselves with its features and functionality.

Using rheumatologists to solicit participation will ensure that all potential participants have a diagnosis of SLE from a rheumatologist (and cannot, for example, simply self-identify as a patient with SLE). Recruiting will continue in this manner until a sufficient number of groups have been conducted in each location.

Focus groups will be conducted by a professional moderator at commercial marketing firms. Groups will be facilitated by a professional moderator using a discussion guide (Attachment 6) and are expected to last approximately 120 minutes. Project staff will observe sessions via an observation room and will confer with the moderator to determine the need for any further discussions and/or clarification from participants (as time permits) before ending a session. Groups will be audio and videotaped, and a verbatim transcript of each session will be produced that identifies participants by a unique participant ID number.

Male SLE patients will be recruited for one-on-one telephone interviews using the procedure described above. Interviews will last up to 45 minutes and will be recorded and transcribed for analysis.

### **B.3. Methods to Maximize Response Rates and Deal with No Response**

Professional marketing firms are being contracted to maximize response rates. To minimize the possibility of having too few appropriate participants (thereby forcing group or interview cancellation), 4 additional participants will be recruited to each group than is needed. For interview participants that fail to show for their interview, the marketing firm will contact them to reschedule one (1) time. In the event that too many participants report, excess participants will receive the honorarium of \$75 and will be dismissed. The firms will place reminder phone calls in the weeks leading up to the groups to confirm participation. If a previously identified participant is not able to be reached, the marketing firms will identify alternate participants from the additional women who were previously screened. The same procedure will be followed with men with SLE who are chosen to participate in the one-on-one interviews. For interview participants that fail to show for their interview, the marketing firm will contact them to reschedule one (1) time. The response rate for this information collection is not anticipated to be less than 80%

#### **B.4. Tests of Procedures or Methods to be Undertaken**

Methods consist of focus groups and interviews. The discussion guides are organized by topic (Attachment 6) and will focus on participant's thoughts and opinions about CDC's SLE Self-Management Tool. All questions are semi-structured and open-ended.

#### **B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data**

The proposed protocol and discussion guide were developed and reviewed extensively by CDC staff, and Oak Ridge Associated Universities (ORAU) staff identified below. CDC and ORAU staff will participate in the analysis of the data, tool refinement, as well as development of scientific manuscripts.

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