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

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Supporting Statement Part A

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A. Supporting Statement A

List of Attachments

- The goal of this study is to collect feedback from SLE patients on their thoughts, opinions, and experiences on using the CDC SLE Self-Management Tool which is intended to increase the ability of SLE patients to manage their condition more effectively.
- The information collected will be used to make improvements to the tool in order to increase user satisfaction, utilization rates of the tool, and inform future promotional efforts.
- 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). We plan to recruit participants for 16 focus groups and 20 one-on-one interviews.
- The sub populations to be studied are males with SLE and fewer than 3 years since diagnosis, males with SLE and at least 3 years since diagnosis, females with SLE and fewer than 3 years since diagnosis, and females with SLE and at least 3 years since diagnosis. All subpopulations will be from the aforementioned locations.
- Interview and focus group data (transcripts/recordings) will be examined using content analysis. Themes within and between groups will be examined along with points of consensus and disagreement/variation between participants and groups. Focus group data will also be examined with respect to interaction patterns.

A. Supporting Statement A

A.1. Circumstances Making the Collection of Information Necessary

This is a request for a new information collection. Approval is requested for a data collection period of one year.

The Centers for Disease Control and Prevention (CDC) is authorized to collect this data under the Public Health Service Act (42 USC 241), Section 301 (Attachment 1). The information collection for which approval is sought is in accordance with CDC's commitment to saving lives and protecting people, and their National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP)'s mission to help people and communities prevent chronic disease and promote health and wellness for all.

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body leading to widespread inflammation and tissue damage. SLE may be characterized by periods of illness and "remission." SLE has a variety of clinical manifestations and can affect joints, skin, the brain, lungs, kidneys, and blood vessels. People with SLE may experience fatigue, pain or swelling in joints, skin rashes, and fevers. SLE can occur at any age, but primarily affects young women with peak occurrence between the ages of 15 and 40. It has strong disparities in incidence, prevalence, and survival by both sex and race/ethnicity, with women affected eight times more than men and minorities affected at higher rates than whites. Prevalence estimates of SLE vary widely, and misdiagnosis is common. A recent study conservatively estimated a 2005 prevalence of 161,000 with definite SLE and 322,000 with definite or probable SLE.

SLE self-management consists of things done on a day-to-day basis by SLE patients to manage their condition and pursue activities important to them. SLE self-management (self-management) requires gaining essential knowledge, skills, and confidence to manage the condition. CDC previously launched a two-year project called "*Filling a Gap: Creating Educational Program, Tools, or Materials to Enhance Self-Management in Systemic Lupus Erythematosus*" to identify and address the needs of lupus patients in practicing effective self-management. The purpose of this project is to develop a CDC SLE Self-Management Tool to improve the ability of people living with lupus to effectively manage their condition. The tool will be comprised of multiple SLE Self-Management resources that may include, but are not limited to: education resources about fatigue management, pain management, healthy diet, and exercise; symptom trackers; medication trackers; appointment calendars; resources about communication with family, friends, and co-workers about SLE; and strategies for coping with depression and anxiety. The tool will be available in an electronic format (web-based or a native mobile application), but may also be made available as a printed resource. A prototype CDC SLE self-management tool

(Attachment 8) was developed after a literature review, an environmental scan of self-management resources available to SLE patients, and a limited number (<9) of key informant interviews. Before finalizing the tool and releasing it to the public, CDC needs to conduct a qualitative assessment involving the target audience of SLE patients.

A.2. Purpose and Use of the Information Collection

The proposed information collection will assess a self-management tool that is in development to ensure that the tool is usable and useful to members of the target audience. The information collection will gauge the needs of the target audience(s), tool format and delivery method(s), and the tool's clarity, relevance, salience and appeal.

During this information collection, all respondents will be reacting to the same version of the tool. However, the information provided by focus group participants will be used to inform changes and further enhancements to CDC's Self-Management Tool for people with SLE. Without this data there will be no way to ensure the tool fills the identified gaps in existing self-management resources and will prevent CDC from fulfilling programs goals set for the current funding period. Findings will also be used by CDC to inform development of future tools and educational resources for people with SLE.

A.3. Use of Improved Information Technology and Burden Reduction

Previous consultations with rheumatologists' offices about their SLE patient population indicate that the use of information technology to collect data from respondents is not appropriate and would not reduce the burden to respondents in this information collection. All responses will be collected in person through focus group discussions led by a trained moderator, or in telephone interviews led by a trained interviewer. Administering the data collection instruments in person will reduce the likelihood of confusion and misunderstanding on the part of the respondents and the moderator. The discussion guide was designed to collect the minimum information necessary for the purposes of this project. This information request is in compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

A.4. Efforts to Identify Duplication and Use of Similar Information

The proposed information collection will collect information about the target audience's perceptions of a unique and newly-developed CDC tool. The tool will fill a gap in existing SLE tools as identified by an environmental scan conducted in spring 2015. There are thus no similar resources/tools available.

A.5. Impact on Small Business or Other Small Entities

This information collection will not involve small businesses.

A.6. Consequences of Collecting the Information Less Frequently

This request is for a one time information collection. There are no legal obstacles to reduce the burden. If the information collection being requested is not conducted, there will continue to be a gap in resources that effectively encourage and facilitate self-management among people with SLE. If the CDC SLE Self-Management Tool is not tested with members of the target audiences, it could limit potential effectiveness. Information is being collected from the minimum number of respondents to ensure a varied sample of people with SLE.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A.8.A. A 60-day Federal Register Notice was published in the Federal Register on November 10, 2015, vol. 80, No. 217, pp. 69679-80 (see Attachment 2). CDC did not receive public comments related to this notice.

A.8.B. Consultation with representatives of those from whom information is to be obtained has not occurred.

A.9. Explanation of Any Payment or Gift to Respondents

Incorporating modest incentives to aid in recruitment acknowledges participants' time and effort, boosts response rates, and may improve the quality of information collected. This incentive is based on market rates commensurate with the cities in which the data collection is to take place.

The most important aspect of an incentive plan may be its potential for reducing response bias, underreporting bias, and similar sources of error. Findings from the National Survey of Family Growth (a study in which childbearing and family planning patterns are collected from young women) demonstrated that incentives not only had positive effects on response rates, but they also increased the accuracy of reporting. Incentives are necessary for qualitative information collections such as the proposed materials testing in order to ensure that those who are willing to participate are as representative as possible of the target audience, which in this case includes participants of hard-to-reach racial and ethnic subpopulations, and young women who may have

responsibilities for child care, etc. Failure to provide a basic incentive is likely to bias samples in the direction of well-educated individuals who are generally predisposed to be helpful (http://www.cdc.gov/nchs/nsfg.htm).

Marketing firms will offer gift cards to the participants as a token of appreciation for participants' willingness to engage in the project. The token of appreciation offered ($75 per focus group participant and $40 for interview participants) is impacted by a number of variables for this project, including the following:

- Total participation time of 45-120 minutes: length of the interview (45 minutes) and focus group (120 minutes)
- Specifications that each participant has to meet to participate in the study
- Recommendations from the marketing facilities

To mitigate the cost of the recruitment, the token of appreciation offered should be attractive to the participant. Gift cards are useful in this respect in that they are not limited to a specific company, service or product and so have universal appeal. The gift card amount needs to be high enough so that participants feel it is worth their time to participate, but not so high that participants become skeptical as to the intention of the focus group or interview. In addition, the amount cannot be so low that participants perceive their time and candid responses are under-valued.

Recruiters from marketing firms have learned what various market segments expect to receive. Practical experience has shown that offering the recruiter-recommended amount is the most cost-effective approach, since it results in better show rates (than other amounts) and thus lower recruiting fees.

A.10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This information collection request has been reviewed by the NCCDPHP PRA Contact, and it has been determined that the Privacy Act does not apply. No new system of records will be created by CDC or CDC's contractor, ORAU (Oak Ridge Associated Universities). Recruitment will be facilitated by rheumatology offices/clinics in 4 cities, and conducted by a professional marketing firm in each city. The PII needed to recruit and schedule respondents will be retained in the marketing firm's existing records system. Neither CDC nor ORAU will have access to PII, and PII will not be linkable to or used to retrieve records containing response information. The PII needed to recruit and schedule participants will not be maintained, collected, or disseminated using information technology.

The marketing firm's representative may provide a potential study participant with the information needed to re-contact the representative, if the potential participant has additional

questions, or wishes to cancel their participation. The marketing firm's representative would provide only professional contact information to the potential participant, not their personal contact information. The marketing firm representative's professional contact information will not be provided to ORAU or CDC.

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 approved selection criteria. The marketing firm will identify qualified patients and provide information on date, time, location, tokens of appreciation and other related issues.

Marketing firms will use the approved Participant Screener (Attachment 4) to screen prospective participants and will provide only the first name and qualifications for screening criteria to project staff from CDC and ORAU. No personal identifiers (e.g., last name, address, social security numbers, completed screening instruments, etc.) are to be provided to ORAU or CDC.

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.

Paper documents will be kept in a locked filing cabinet when not in use and only research personnel will have access to them. Electronic documents will be kept on password-protected computers. ORAU will maintain no identifiers connecting any data collected to any particular respondent. ORAU will not provide any personal identifiers to CDC or others.

Prior to participating in the study, each prospective respondent will receive the Participant Information Sheet providing such information as sponsorship of the study, their rights as participants, risks and benefits in participating, and contacts for more information. Respondents' information and responses shall be held in a secure manner to the extent allowed by law. The information sheet will contain the elements of informed consent. Because this study presents no more than minimal risk, signatures for informed consent will not be required.

ORAU personnel will address any questions the participants have regarding the study before the session begins.

ORAU will hire a professional company to video tape the focus groups. Participants will be reminded to use only their first names in the focus groups and interviews. Video recordings will be used by professional transcriptionists to type verbatim transcripts that are identifiable by first name. This will allow ORAU to match the screening criteria to the participants' comments to see if there any differences based on age, race/ethnicity, etc. These procedures help project staff analyze qualitative data more efficiently and accurately by allowing for findings to be grouped by more detailed audience segment data.

ORAU will only receive audio recordings and transcripts from the audio. ORAU will retain audio recordings and transcripts for up to three years, then burn, shred, or otherwise destroy them. Firms which conduct recruiting and host sessions will NOT provide personal identifiers to ORAU. All information related to recruiting will be shredded after the last day of data collection in each city.

Additionally, ORAU will:

- Retain one set of de-identified audio recordings, transcripts, and at least one copy of any report it produces
- Develop a draft report for CDC review in an agreed-upon format summarizing the analysis of the focus group sessions and interviews. This report will not include personal identifiers -- that is, information sufficient to determine the identity of any participant (e.g. first and last name, address).
- Deliver to CDC a final report, which is to include the CDC comments received on the draft of the report.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This information collection was given a determination of "research involving human subjects, no CDC investigators" by CDC based on the decision that ORAU, as a contractor, would obtain local IRB approval. ORAU IRB approved this information collection and gave a waiver of consent documentation (Attachment 7).

When prospective participants contact the professional marketing firms, the approved screening instrument (Attachment 4) will be used to determine the participant has a diagnosis of SLE. This question will be asked as it is important to ensure participants represent the target audience for CDC's SLE Self-Management tool. Marketing firms will also ask about race, gender, and ethnicity. Because the disease disproportionately affects women and minorities, it is important to ensure that we have representation of minorities within the groups. Screening for these characteristics will allow us to have a mixed sample of gender, age, race, and ethnicity in order to ensure the tool is acceptable to many different segments of the SLE population. Participants

who do not wish to answer questions about race and ethnicity will still be able to participate in the groups.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A. The information collection requires the use of a screening document to determine eligibility to participate in subsequent focus groups and one-on-one interviews. Separate versions of the screening instrument will be used for women (see Attachment 4a) and men (see Attachment 4b). The same Discussion Guide (Attachment 6) will be used for focus groups with women and individual interviews with men, however, the estimated burden per response varies according to whether participation occurs through a focus group or an individual telephone interview.

All respondents will have been diagnosed with SLE by a rheumatologist, will be conversant in English, will be at least 18 years of age, and will have spent time becoming familiar with the CDC SLE Self-Management Tool prior to the group discussion.

For women with SLE, 192 respondents will be screened to obtain 128 focus group participants. It is estimated that each respondent will take 10 minutes to complete the one-time screening process, which results in 32 total burden hours. Each of the 128 focus group participants will spend up to two hours in the weeks before the focus groups reviewing the CDC SLE Self-Management Tool for a total of 256 burden hours. All 128 will also participate in one two-hour focus group using the discussion guide (Attachment 6), for a total of 256 burden hours.

For men with SLE, 40 respondents will be screened to obtain 20 one-on-one interview participants. It is estimated that each respondent will take 10 minutes to complete the one-time screening process, which results in 7 burden hours. Each of the 20 interview participants will spend up to two hours in the weeks before the interviews reviewing the CDC SLE Self-Management Tool for a total of 40 burden hours. All 20 interview participants will also participate in one 45 minute interview using the discussion guide (Attachment 6), for a total of 15 burden hours.

A total of 606 burden hours is estimated for this information collection.

The estimated burden hours to respondents is summarized in the table below. The average burden per response is based on previous and similar evaluations and includes the time for reviewing instructions, gathering needed information, and completing the information collection.

Table A.12.A.1 Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Women with SLE diagnosis	Screener for Women	192	1	10/60	32
	Review of Prototype CDC SLE Self-management Tool	128	1	2	256
	Discussion Guide for Use in Focus Groups with Women or Interviews with Men	128	1	2	256
Men with SLE diagnosis	Screener for Men	40	1	10/60	7
	Review of Prototype CDC SLE Self-management Tool	20	1	2	40
	Discussion Guide for Use in Focus Groups with Women or Interviews with Men	20	1	45/60	15
	Total				606

A.12.B. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for the general public's mean hourly wages [http://www.bls.gov/oes/current/oes_nat.htm#00-0000]. Based on DOL data, an average hourly wage of $22.71 is estimated for all respondents. The table below shows estimated burden and cost information. The total estimated annualized cost to respondents is $13,763.

Table A.12.B.1 Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden (in hrs.)	Average Hourly Wage Rate	Total Respondent Costs
Women with SLE diagnosis	Screener for Women	32	$22.71	$727
	Review of Prototype CDC SLE Self-management Tool	256	$22.71	$5,814
	Discussion Guide for Use in Focus Groups with Women or	256	$22.71	$5,814

	Interviews with Men			
Men with SLE diagnosis	Screener for Men	7	$22.71	$159
	Review of Prototype CDC SLE Self-management Tool	40	$22.71	$908
	Discussion Guide for Use in Focus Groups with Women or Interviews with Men	15	$22.71	$341
Total				$13,763

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no additional costs to respondents other than their time.

A.14. Annualized Cost to the Government

Estimates of annualized cost to the government are included in the table below. These include contract costs plus the personnel costs of federal employees involved in project oversight. Annualized salaries and wages are based on the Office of Personnel Management's 2015 Salary table for the locality pay area of Atlanta-Sandy Springs-Gainesville, GA-AL [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/ATL.aspx]

Table A.14.1 Estimated Annualized Cost to the Federal Government

Annualized Cost to the Government	Average Annualized Cost
[Grade 15 Step 5], [$137,401] at 7% time to provide project oversight.	$9,618.07
[Grade 14 and Step 5], [$116,808] at 12% time to provide project oversight.	$14,016.96
Contractor support for project leads	$8,532.55
Contractual costs which includes cost for personnel, planning, data collection, data analysis and report writing.	$1,174,000
Total	$1,206,167.58

A.15. Explanation for Program Changes or Adjustments

This is a new information collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Statistical methods will not be employed to analyze focus group or interview data, as it is not appropriate to report the percentage of focus group participants who expressed a particular view. Typically, not every participant in a group comments on every issue discussed, and the course of discussion will vary across groups, with some topics emerging in one group and not in another. Qualifiers such as "many," "several," and "few" will be used to describe the number of participants who expressed a particular view.

Table A.16.1 below presents the estimated timeline for conducting the information collection activities following receipt of OMB approval.

Table A.16.1. Project Time Schedule

Activity	Time Schedule
Recruit participants	3-4 weeks following approval
Participants familiarization period with tool	4-6 weeks following approval
Conduct focus groups and interviews	6-8 weeks following approval
Analysis of focus group and interview results	8-10 weeks following approval
Report Writing/Recommendations to CDC based on findings	10-12 weeks following approval

The overarching goal of the information collection is to obtain participant thoughts and opinions in order to refine and improve CDC's SLE Self-Management tool. The results of the evaluation will be provided in a report to CDC summarizing the findings and providing recommendations for improving and finalizing the tool. This will ultimately result in people with SLE having access to a tool to help them more effectively self-manage their condition and get back to enjoying life. Filling the current gap in SLE self-management tools will also help CDC fulfill their mission. Additionally, findings will be disseminated through presentations and/or posters at meetings and publications in peer-reviewed journals. All abstracts, poster presentations, and manuscripts will undergo CDC clearance review prior to submission to conferences or journals.

A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The display of the OMB expiration date is not inappropriate.

A.18. Exemptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.