Oak Ridge Site-wide IRB (FWA #00005031)

August 21, 2015

Title of Study:	SLE Focus Groups
Investigator:	Ben Wilburn
Type of Review:	Non-Committee Review
Expedited Category	(7)(a) Behavioral research, (6) Voice, video, digital, or image recordings
IRB Submission ID:	ORAU000139
Funding:	Other
Documents Reviewed:	• ATTACHMENT_A_Protocol_Summary.docx, Category: IRB Protocol; • Appendix I Potential Participating Clinics.docx, Category: Other; • ATTACHMENT_B_Full_Protocol.docx, Category: IRB Protocol; • ATTACHMENT_C_Discussion_Guides.docx, Category: Recruitment Materials; • Appendix M Office Recruiting Script.docx, Category: Other; • ATTACHMENT_D_Participant_Screeners.docx, Category: Recruitment Materials; • Appendix J K L Participant Information Sheets.docx, Category: Other; • ORSIRB__Initial_Study_application_ lupus 6-2-15.pdf, Category: Other; • Appendix F Mock Up of Schedule.docx, Category: Other; • Appendix H Recruiting Poster.docx, Category: Other; • Appendix G IRB Planning.docx, Category: Other;
Action:	Approved
Approval Date:	8/21/2015
Expiration Date:	8/20/2016
Consent Waiver:	Waiver of consent documentation

Before the expiration date or within 30 days of study closure, whichever is earlier, you must submit a continuing review application/ progress report. To submit a continuing review navigate to the active study and click “Create Modification / CR.”

This approval is based on an appropriate risk/benefit ratio and a study design wherein the risks have been minimized. All research must be conducted in accordance with this approved submission.

Any changes in the approved research activity or to previously approved materials must be approved by this office prior to initiation. Please use the appropriate revision forms for this procedure.

All unanticipated problems or adverse events must be reported to this office (see DOE Order 443.1B). Please use the appropriate form for this procedure. All FDA and sponsor reporting requirements should also be followed.

Report all NON-COMPLIANCE issues or COMPLAINTS regarding this study to this office (see DOE Order 443.1B).

Please note that all research records must be retained for a minimum of three years.

If continuing review approval is not granted before the expiration date of 8/20/2016, approval of this study expires on that date and all study activity that involves human subjects must cease.

Sincerely,
The Oak Ridge Site-wide IRB
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865-574-4359