



Human Research Protection Program Committee on Human Research

Notification of Expedited Review Approval

Principal Investigator
Vanessa L Jacoby

Type of Submission: Initial Review Submission Packet
Study Title: Uterine Leiomyoma Treatment with Radiofrequency Ablation Registry
IRB #: 14-13325
Reference #: 084414
Committee of Record: Laurel Heights Panel
Study Risk Assignment: Minimal
Approval Date: 04/25/2014 **Expiration Date:** 04/24/2015

Regulatory Determinations Pertaining to this Approval:

Individual Research HIPAA Authorization is required for one or more subject groups (patients). Use the Permission to Use Personal Health Information for Research form.

HIPAA rules do not apply to one or more subject groups (physicians).

A waiver of the requirement to obtain a signed consent form is acceptable for this study because, as detailed in the application, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. The waiver applies to some subjects (physicians), as detailed in the application.

IRB Comments:

All changes to a study must receive CHR approval before they are implemented. Follow the [modification request](#) instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these [instructions](#).

Expiration Notice: The iRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for [continuing review](#) approval has been submitted by the required time. In addition, you are required to submit a [study closeout report](#) at the completion of the project.

Approved Documents: To obtain a list of documents that were [approved with this submission](#), follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR [website](#) has more information.