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Activity Details (Letter Sent to Study Team)

Author:	Maria Melendez-Vargas (Human Subjects Research Office)
Logged For (Protocol):	Retrospective chart review of patients with biliary surgical problems: treatment and outcomes.
Activity Date:	6/5/2012 9:27 AM EDT

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Instructions:

- Use this activity to create the Letter that will be sent to the Protocol Team.
- A default letter is shown below with information merged in from the protocol application. You may choose a different template from the selection list.
- Pick applicable items - delete others; items italicized are to be deleted or "typed over"
- Edit the text of the letter as necessary and click the **OK** button to save it.
- Letter will not be visible to the study team while the protocol is in the "Expedited/Exempt Review Complete: Awaiting Correspondence" state.

UNIVERSITY
OF MIAMI



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Human Subjects Research Office (M809)
PO Box 016960, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, Florida 33136

Ph: 305-243-3195
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EXEMPT – CONFIRMATION

June 5, 2012

Danny Sleeman, M.D.
University of Miami
Department of Surgery, Division of General Surgery
Medical Campus, Locator Code: M-875
1475 NW 12 Ave , Room 3524
Miami, FL 33136

HSRO STUDY

20120314

NUMBER: -----
STUDY TITLE: **Retrospective chart review of patients with biliary surgical problems: treatment and outcomes.**
IRB ACTION DATE: **5/30/2012**
FWA #: **FWA00002247**

On May 30, 2012, an IRB Designee determined that the above referenced protocol qualifies for exemption from IRB review, with a full waiver of HIPAA and a waiver of Informed Consent.

APPROVAL INCLUDES:

New Research Protocol
Research Materials (English Version Only)
Data Collection Sheet

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

If chart review will occur at UM, you must submit your IRB approval letter and watermarked data collection sheet to the Office of HIPAA Privacy & Security, PAC 409, Locator M-879, telephone: 305-243-5000. If chart review will occur at Jackson Health Systems, please contact the Jackson Privacy Office at 305-585-6854 for further information.

You must prepare and submit to the Office of HIPAA Privacy & Security a record of disclosure for each disclosure of patient information under a waiver of authorization by using the HIPAA Accounting for Disclosures form (HIPAA Attachment 45) located on the HSRO HIPAA page.

Your study indicates JHS as a performance site. As the PI, you must ensure that you have been granted permission by the JHS Clinical Research Review Committee prior to commencing study activities at JHS. **If you have any questions regarding this process, please contact the JHS Clinical Trials Office at 305-585-7596.**

Your study indicates UMH is a performance site. As the PI, you must ensure that you have been granted permission by the UMH Quality Department prior to commencing study activities at UMH. **If you have any questions regarding this process, please contact the UMH Quality Department at 305-325-5410.**

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Please remember that the Human Subjects Research Office (HSRO) must be notified of any proposed changes in research activities. Changes must receive IRB review and approval prior to implementation. Upon completion of the study, submit a closure report via eProst.

Sincerely,

[This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature]

Amanda Coltes-Rojas, MPH, CIP
Director

Regulatory Affairs & Educational Initiatives

/mmv
cc: IRB File
James Davis

For JHS-related studies: (if JHS permission has not been granted or JHS has not yet reviewed, please make changes to the letter accordingly)

Pending ancillary approvals:

JHS permission granted:

ID

Jackson Health Systems (JHS)

Check here if this letter is complete and you are ready to send it. *Checking this box will Approve the project and send the letter to the protocol team.*

[Exit](#)