

Forms will not be accepted after October 4th Beginning October 5th, all submissions must be completed in the iMedRIS electronic submission system.

REC'D HIC

OCT 01 2013

Beaumont Hospitals*

Human Investigation Committee
RBS

Human Subject Research Determination

Phone: (248) 551-0662 Fax: (248) 551-2884 Mail Code 104

Determining if a Research Proposal Constitutes "Human Subjects Research" Requiring HIC Review and Approval

Federal regulations and Beaumont Hospitals (BH) policies require IRB/HIC review of research involving human subjects. Activities that meet the regulatory definitions of "research" and "human subjects" constitute human subject research and require HIC approval and oversight.

Please answer the questions in Sections A and B below, to determine if your project is human subjects research. After doing so, if you remain unsure of whether your proposal constitutes "human subjects research", or if you would like confirmation and documentation from the HIC Office that your proposed activities do not constitute human subjects research, please complete Sections C, D and E below, and submit entire form to the HIC Office.

Section A: Determination of "Research"

45 CFR 46.102(d):

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1. Do the proposed activities involve a **systematic approach**? A "systematic" approach involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens; and analysis.

☒ YES☐ NO

If NO, please explain why the proposed activities do not involve a systematic approach: ☐☐☐☐

2. Is the intent of the proposed activities to **develop or contribute to generalizable (scholarly) knowledge**? Activities 'designed to develop or contribute to generalizable knowledge' are those activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

☒ YES☐ NO

If NO, please explain the intent of proposed activities and explain how the proposed activities are not intended to contribute to generalizable knowledge: ☐☐☐☐

If YES to both of the above questions, these activities constitute research.

Section B: Determination of "Human Subject"

45 CFR 46.102(f):

Human subject - a *living individual* about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) data through *intervention or interaction* with the individual or (2) *identifiable private information*.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between researcher and subject.

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record information). Private information must be individually identifiable. *Individually identifiable* includes where the identity of the subject is or may be ascertained by the researcher or associated with the information.

Use the definitions above to answer the following questions:

1. Do the activities involve obtaining information about *living individuals*?

☐ YES ☒ NO

- 1a. If "Yes" do the activities involve intervention or interaction with the individuals (i.e., prospective collection of data/specimens)?

☐ YES** ☐ NO

If YES**, the activities involve human subjects.

2. Do the activities involve obtaining *individually identifiable* and *private* information about living individuals?

☐ YES** ☒ NO

If YES**, the activities involve human subjects.

Is your Project Human Subjects Research?

If you answered YES to both questions in Section A and YES to either question in Section B, the activities constitute human subjects research.

Please complete and submit an HIC Application for project review and approval. All forms are available on the HIC website under HIC forms. If you have questions, please contact the HIC Office.

If you answered NO to either of the questions in Section A and to both questions in Section B, the activities do not appear to meet the definition of human subjects research, and you are not required to submit an HIC application.

If you would like confirmation and documentation from the HIC Office that your proposed activities do not constitute human subjects research, please complete the remainder of this form and submit to the HIC Office for review.

Section C: Contact Information

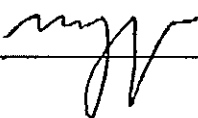
Principal Investigator (PI):	Maryconi Jaurigue	Title: M.D.
Department:	Internal Medicine	
Phone/ Pager:	248-992-0383	Fax: 248-551-9425
Email address:	maryconi.jaurigue@gmail.edu	
Mail Code or off-site Address:	None	
Project Title:	Therapy for Alcoholic Liver Disease	
Funding Source:	None	

NOTE: If BH is the prime recipient of a Federal award (e.g., NIH, NSF, DoE, DoD) through a grant, contract, or cooperative agreement, however a non-BH entity will carry out the non-exempt human subject research activities, OHRP considers BH engaged in human subjects research and BH HIC approval is required. For more information see OHRP's Guidance on Engagement in Human Subjects Research and Research Institute Policy #120 *Institutional Engagement in Research*.


Section D: Study Information

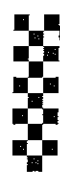
1. Describe the purpose of the proposed activities. State the overall objectives and specific aims. Provide a brief description of the procedures. Review article regarding therapy for alcoholic liver disease. A PubMed search will be performed to collect already published data about alcoholic liver disease treatment, and will be integrated and summarized in this article.
2. Describe the subject population, or the type of data and/or specimens to be studied. Published articles regarding management of patients with alcoholic liver disease, both prospective and retrospective.
3. Describe how the data and/or specimens will be obtained. PubMed search.
4. REQUIRED: Submit a list of the variables and/or information to be analyzed. Published articles (including retrospective and prospective studies) regarding management of patients with alcoholic liver disease.

Section E: Signature of Principal Investigator

Signature	Printed Name	Date
	Maryconi Jaurigue, MD	10/1/2013

Beaumont HIC Determination of Human Subjects Research

For HIC Use Only		
<input checked="" type="checkbox"/> The activities as described DO NOT constitute Human Subjects Research. Submission of an HIC Application is not required.		
<input type="checkbox"/> The activities as described DO constitute Human Subjects Research. Submission of an HIC Application IS REQUIRED . HIC Approval must be obtained before the research can begin.		
Signature of the HIC Chairman, Manager or Designee	Printed Name	Date
	Lynne Paul RN, MSN, CIP	10/1/13



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FAX COVER LETTER

To: **Bobbie Lewis, RN, CRRC or Lynne Paul, RN, MSN, CIP**

Company/Department: **WBH Human Investigation Committee**

Phone: **248-551-0662**

Fax Number: **248-551-2884**

Number of Pages (including cover letter): **5**

Date: **October 1, 2013**

Time: **10:20a**

From: **Maryconi Jaurigue, MD**

Department: **Internal Medicine**

Phone: **248-992-0383 (Pager)**

Fax Number: **248-551-9425**

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HIC Exemption Request