


This completed form may be submitted in person to the Research and Clinical Trials Administration Office or via email to the Director of Human Subjects Protection, IRB Manager, Senior IRB Consultant, and/or IRB Chair (with the subject line "Determination of Human Subject Research"). A copy will be returned to you upon review by the above named individuals.

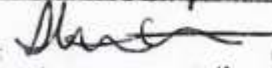
The submission must include the following items:

- ☒ completed form.
- ☒ a description of project goals and an abstract of the project including project methods.
- ☐ If the project will be conducted at an outside institution, a letter or other documentation of review must be included from the institution where the activities will occur that indicates the institution does not consider the activities to be human subjects' research and/or require IRB review.

Signature of Investigator:  Date: 11/20/14

Signature of Faculty Sponsor:  Date: 11/20/14
(if applicable)

For IRB Administrative Staff Use:

Date Request Received: <u>11/21/14</u>	Administrator Assigned: <u>SP</u>
Qualifies as Non Human Subject Research <u>Yes</u> / No <u>Case study</u>	
Date Investigator Notified: <u>11/21/14</u>	Signature of Administrator: <u> MS, CIP</u> <u>Stephanie Pittman, MS, CIP</u> <u>IRB Manager</u>

- 1) Attach copy of any correspondence with the investigator and file in appropriate Fiscal Year folder.
- 2) Forward a copy of all documentation to the investigator for their files.



RUSH UNIVERSITY MEDICAL CENTER

Determination of Whether an Activity Constitutes Human Subjects Research

Investigator Information		
First Name: Marie-France	Middle Initial:	Last Name: Poulin
Degree (s) : <input checked="" type="checkbox"/> MD <input type="checkbox"/> Ph.D. <input type="checkbox"/> RN <input type="checkbox"/> JD <input type="checkbox"/> Other, Specify:		
Job Title: Cardiology Fellow		Affiliation (circle one):
Department or School/College: Internal Medicine/Cardiology		Medical Staff Faculty <u>Fellow</u> Resident Student
Contact Address: 1750 West Harrison Street, Suite 1021 Jelke, Chicago, IL 60612		
Contact Phone Number: (312) 942-8771		E-Mail: Marie-France_Poulin@rush.edu

Rush Faculty Sponsor (required when the investigator is a student, fellow, or resident)		
First Name: Richard	Middle Initial: G.	Last Name: Trohman
Degree (s) : <input checked="" type="checkbox"/> MD <input type="checkbox"/> Ph.D. <input type="checkbox"/> RN <input type="checkbox"/> JD <input checked="" type="checkbox"/> Other, Specify: MBA		
Department and College: Internal Medicine/Cardiology		
Campus Address: 1750 West Harrison Street, Suite 983 Jelke, Chicago, IL 60612		
Phone: (312) 942-2887		E-Mail: Richard_Trohman@rush.edu

Per Policy RA-IRB-118, activities that the Rush IRB may determine do not represent human subjects' research and do not require submission in the Rush Research Portal (RRP) include the following categories. Please select the category that applies to your project. If it is determined that your project does not fit any of these categories, you will be required to submit the project through the [Rush Research Portal](#).

- ☐ Research involving only the use/analysis of deceased individuals' information or specimens (cadaveric studies).
- ☐ Course-related activities designated specifically for educational or teaching purposes, where data is collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom (not intended to develop or contribute to generalizable knowledge).
- ☒ Case report(s) involving the observation of a patient or patients whose novel condition or response to treatment was guided by the care provider's judgment regarding the best interest of the individual and no comparison of data is taking place. Please note that Rush HIPAA policies must be followed.
- ☐ Collection of data with the sole purpose to conduct a quality improvement/quality assurance project for internal use only. This also applies to students of Rush University who are employed at another medical center, when the work is part of their class requirements and the employer institution has certified the activities do not constitute human subjects research.
- ☐ Other research that is not human subjects or animal research, but does not fit the criteria above. Please explain: _____