AHF Exemption Umbrella App 4.2014

Advanced Heart Failure Therapy Patient Clinical Outcomes – Exemption Umbrella IRB# 60928

Approved: 1/9/2014 (VA approval 2/25/14) Exemption Category 4 PI: Craig Selzman, MD / Jose Nativi-Nicolau, MD Coordinator: Ashley Elmer Contact: <u>ashley.elmer@hsc.utah.edu</u> Phone: 801-585-3188 Office: SOM AC144

Project Title: Click here to enter text.
Date Started: Click here to enter text.
Date Completed (or estimated date): Click here to enter text.
Names of Investigators: Click here to enter text.

<u>Short Description of Project Aims and Procedures</u>: (or attach a short-protocol description) Click here to enter text.

<u>Person submitting application (name & title)</u>: Click here to enter text. <u>Number of Participants (or estimated #)</u>: Click here to enter text.

## Requirement Checklist (ALL MUST BE CHECKED AND VERIFIED BY PERSON SUBMITTING APPLICATION)

□ This research study is an observational review of Advanced Heart Failure Patients (HF, VAD, Heart Tx) at the University of Utah Hospital and SLC VAMC patient clinical outcomes in relation to their heart failure therapy.

 $\Box$  This research presents no more than minimal risk to participants.

 $\Box$  This research does not require patient consent.

Coordinator

 $\Box$  This research involves NO direct contact with patients.

□ This research involves no study-only related testing or procedures.

 $\Box$  This research involves no changes in standard of care for patients.

□ This research involves the collection or study of <u>existing</u> data, documents, records, pathological specimens, or diagnostic specimens.

□ Subjects in this research cannot be identified directly or through identifiers linked to the subjects.

Read: <u>http://irb.utah.edu/\_pdf/IGS - Exempt Research 090113.pdf</u>

□ I have read the IRB Investigator Guidance Series: Exempt Research and agree to comply with all items including the protection of information gathered. SIGN\_\_\_\_\_\_DATE\_\_\_\_\_

FOR OFFICE USE ONLY:	
I have reviewed this research proposal and agree that it meets the requirements of the Advanced Heart Failure Therapy Patient Clinical Outcomes – Exemption Umbrella Protocol.	
Principal Investigator	Date
An IRB Amendment has been completed in order to add study staff for this research proposal.	

Date