



# LIBERTY IRB

An Independent Central IRB



## CERTIFICATE OF IRB REVIEW

Date of Review: February 1, 2013

Study Sponsor: [Redacted] Cryogenic Center

Study Name: Hospital and Dental Plan

Protocol #: NECCIFDT-1

Principal Investigator: [Redacted] Ph.D.

Liberty IRB Tracking #: 10.01.0008

Last Approval Date: December 19, 2012      Expiration Date: December 18, 2013

Although Liberty provides the service of continuing review notification beginning at 2 months before study expiration, the site is responsible for monitoring their study expiration date to ensure no lapse in study coverage.

The following materials have been reviewed through expedited review pursuant to the regulation of 21 CFR, Parts 56.110, concerning Investigational Review Boards in regards to the above study:

<b>Items Submitted:</b>	<b>IRB Determination:</b>
<input checked="" type="checkbox"/> Informed Consent, Version 3/15/2011 Liberty IRB approved 2/1/13, Rev. 2	<b>Approved</b>

The IRB agrees to participate in an active exchange of information with the investigator throughout the course of the clinical study until the study is completed or terminated. This exchange of information will include all pertinent findings and developments related to the study including, though not necessarily limited to, adverse effects and deviation from the Plan, recommendations, advice and counsel.

In accordance with 21 CFR Part 56.108, there must be prompt reporting to the IRB of changes in research activities. Changes in approved research, during the period for which IRB approval has been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects.

*[Signature]*  
Chairman/Designee Institutional Review Board

2/1/13  
Date