Over Age Study Participants for Research Studies Form

Date: _______________________

Reason for including over age patients:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Check list concerning Over Age Participants:

☐ No subject over 45 years of age will participate in the study.

☐ Ensure study participants will be healthy or be at low risk for acute untoward event such as heart attack, stroke, seizure, a fall if handicapped, or other acute decompensation.

☐ For those participants with diseases that place them at low risk, will arrange for emergency coverage On-site by a Med-Peds resident or other qualified physician while patient is at Le Bonheur.

   Name of physician who will cover for emergencies: ____________________________________________

☐ Obtain approval and signature from Hospital Division Chief where services will be performed at Le Bonheur-- for study participants who are over age.

   Approval signature of Division Chief: ______________________________________________________

☐ Submit the request form to include over-age participants for your research study to the PCRU Advisory Committee. Please send the completed form to Terrie Swearingen, Research Center, Suite 471R.

☐ Agree to complete and submit the Le Bonheur over-age request form for individual participants who are over-age.

☐ Agree to stop the study immediately if an acute untoward subject event occurs and evaluate the situation before proceeding further.

________________________________________________________________________

Principle Investigator/Sub Investigator Signature                        Date

________________________________________________________________________

PCRU Advisory Committee Approval                              Date