

# CLINICAL RESEARCH CHART AUDIT TOOL

Medical Record Number \_\_\_\_\_

Attending Physician Name \_\_\_\_\_

Protocol (Key Words) \_\_\_\_\_

Primary Investigator \_\_\_\_\_

Protocol IRB Number \_\_\_\_\_

GCRC Protocol Number (R-) \_\_\_\_\_

Admission Date \_\_\_\_\_

Reviewed By \_\_\_\_\_

Date of Review \_\_\_\_\_

RESEARCH, CLINICAL TRIALS, & EXPERIMENTATION	IS STANDARD APPLICABLE?		DOCUMENTATION PRESENT?	
	YES	NO	YES	NO
All patients asked to participate in a research project are given:				
φ Description of benefits to be expected: (RI. 1.2.1.1.)				
φ Description of potential discomforts and risks: (RI.1.2.1.1.)				
φ Description of alternative services: (RI.1.2.1.3.)				
φ Full explanation of procedures to be followed: (RI.1.2.1.4)				
φ Assurance of right to refuse to participate (RI.1.2.1.5.)				
All consent forms related to research, experimentation, and/or clinical trials indicate:				
φ Name of person who supplied prospective participant information (RI.3.1, scored at IM.7.2)				
φ Date form was signed; and (RI.3.1, scored at IM 7.2)				
φ Address the participant's right to privacy and confidentiality (RI.3.1, scored at IM. 7.2)				
φ The procedures documented in the chart match those described in the consent form				

If any item is checked "NO", please explain: \_\_\_\_\_