LOCAL TITLE: CLINICAL RESEARCH/STUDY DRUG INFORMED CONSENT [T]
STANDARD TITLE: RESEARCH NOTE
DATE OF NOTE: JUL 01, 2008@10:18     ENTRY DATE: JUL 01, 2008@10:18:57
AUTHOR: ___________________        EXP COSIGNER: ___________________
URGENCY: ___________________        STATUS: COMPLETED

STUDY/VA PROTOCOL #: ____________
TITLE OF STUDY/PROTOCOL: ______________________
PRINCIPAL INVESTIGATOR: _______________________
Pager #: ___________
Phone #: ___________

Was a signed informed consent obtained? ______
Informed consent version date verified as current? ______

On what date was consent obtained? ______@_______ Loc: __________
The Subject (or legally authorized representative) was capable of understanding the consent process? ______
Did the author of this note explain the research study to the subject/legally authorized representative? _____
If someone else explained the study (name/credentials): ________________________
This subject is being screened for the protocol specific Inclusion and Exclusion criteria? ______
Was the consent obtained from the subject? _____
If the consent was obtained from someone other than the subject (name/relationship)_______________________
Describe the subject's mental status at the time consent was obtained:
______________________________________________________________________
Were all of the relevant aspects of the procedure/treatment including indications, risks, benefits, and alternative options discussed with the subject and/or legally authorized representative? ______
Was the subject and/or legally authorized representative given the opportunity to ask questions?_____
Were all of the subject's and/or legally authorized representative's questions answered? ______
Did the subject freely consent without fraud, duress, deceit, or coercion?_____
A copy of the signed Informed Consent along with the abstract will be sent to the File Room for scanning into the subject's CPRS record. The INVESTIGATOR will retain the original consent? ______
Subject and/or legally authorized representative has been given a copy of this signed Informed Consent? ______
Subject and/or legally authorized representative was offered additional research information such as a copy of the VA brochure, "Volunteering in Research: Here Are Some Things You Need to Know" and/or the pamphlet, "Information About Your Rights & Responsibilities as a Participant in Human Studies Research" and/or website info http://www.clinicaltrials.gov? ______
Consent was obtained prior to performing any study related procedures._____

/es/ Sally Ann Nurse
RESEARCH COORDINATOR
Signed: 07/01/2008 10:28