Persons using assistive technology may not be able to fully access information in this file. For assistance, e-mail niddk-cr@imsweb.com. Include the Web site and filename in your message.

DOSE CHANGE (DC)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	To capture information related to a **prescribed** change of study medication dose.
PERSON(S) RESPONSIBLE	Study Coordinator/study physician
SOURCE(S) OF INFORMATION	Investigator or medical record
WHEN TO ADMINISTER FORM	At the times of the prescribed change in study medication dose
GENERAL INFORMATION	The Dose Change (DC) form is completed when the investigator prescribes a change in the dose of study mediation or instructs the patient to temporarily discontinue the study medication. Each page of the form captures up to 6 dose changes per patient. Each new change, whether a decrease or increase in the prescribed study medication dose, should be recorded on one line of the form. If a patient has more than 6 prescribed dose changes, move to the next page. Every prescribed dose change should be recorded, regardless of the duration of the prescribed change or interruption in dosing. NOTE: per protocol and investigator discretion, if the patient experiences a drug related adverse event and does not tolerate dose reduction to a dose that is 2 levels below the original dose, the patient should not be dose reduced again but study drug should be discontinued.
PATIENT ID	Record the Patient ID number in the top left hand corner of the page.
PAGE	Record the page number. Begin with page 1 for each patient and continue to add pages as needed. **SPECIFIC INSTRUCTIONS:** Date of change: Record the date (day/month/year) that the changed dose was taken for the first time (regardless of whether it was the first, second, or third dose taken that day) or the date that the study medication was temporarily discontinued. Type of change: Check only one response to indicate whether the patient was instructed to temporarily discontinue use of the study medication, or decrease or increase the prescribed dose of study medication. Check 'Decrease' if the patient was dose reduced by one dose level. Check 'Increase' if the patient was increased one or more dose levels on a given date. If the investigator prescribed an increase in dose, indicate whether the patient is to return to the original dose, or in the case of a patient who had been dose reduced more than once, the patient was increased 1, 2, etc. dose levels. Reason for decrease or temporary discontinuation: check only one response to indicate the reason for the prescribed decrease in dose or temporary discontinuation. If 'Other symptom/AE' record the symptom or AE that resulted in the dose reduction. 'Patient preference' is defined as an instruction from the investigator to decrease the dose of study medication, in response to a request from the patient. If 'Other' specify the reason for the dose reduction in the space provided.