

## Form CLT-W: Worksheet for Designing Individual Field Trials under Chloramine-T INAD 9321

### INSTRUCTIONS

- Investigator must fill out Form CLT-W for each trial conducted under this INAD **before** actual use of Chloramine-T. The Investigator is responsible that Form CLT-W is completed accurately.
- Investigator should keep the original on file, and Fax a copy to the Study Monitor for review.
- After review, the Study Monitor will fax a copy to the Bozeman NIO for assignment of the Study Number.
- The Bozeman NIO will review the worksheet, and then fax the assigned trial Study Number to both the Investigator and Study Monitor, at which time the trial may be initiated.
- Note:** Both Investigator and Study Monitor should sign and date Form CLT-W.

### **SITE INFORMATION**

Facility			
Address			
Investigator			
Reporting Individual (if not Investigator)			
Phone		Fax	

### **FISH CULTURE AND DRUG TREATMENT INFORMATION**

Fish species to be treated		Disease to be treated	
Average fish weight (gm)		Average fish length (in)	
No. of fish per unit (e.g. 10,000 fish/raceway)			
Number of treated units		Number of treated fish	
Number of untreated control units		Number of control fish	
Anticipated date treatment will be initiated			
Check type of treatment method used		___ Flow through    ___ Standing bath	
Check treatment objective		___ A	___ B
		___ C	___ D
Intended drug target dosage (mg/L)	_____ 10 mg/L	Estimated total amount of drug needed for proposed treatment (Kg)	
	_____ 15 mg/L		
	_____ 20 mg/L		
Drug manufacturer		Drug lot number	

**STUDY DESIGN:** Describe in detail the purpose of the clinical trial. For example you might compare dosage, treatment frequency, or treatment method (Flow-Through vs. Standing Bath). Study design must be carefully focused and lend itself to rigorous evaluation. If more space is required to describe study details, title additional page(s) "Study Design" and attach them to this Worksheet.

Study designed by \_\_\_\_\_

**DISPOSITION OF TREATED FISH (Human Food Safety Considerations):**

Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section VI, B, page 3 of the Study Protocol.

**WORKER SAFETY CONSIDERATIONS:**

Investigator should initial here to indicate that all personnel handling drug have read Material Safety Data Sheet for Chloramine-T and have been provided protective equipment, in good working condition, as described in the MSDS.

**Date Prepared:** \_\_\_\_\_ **Investigator:** \_\_\_\_\_

**Date Reviewed:** \_\_\_\_\_ **Study Monitor:** \_\_\_\_\_