

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	Fish Hatchery A		
Address	123 Hatchery Rd		
	Anywhere, USA 11122		
Investigator	John Doe		
Reporting Individual (if not Investigator)	Josey Jo		
Phone	555-555-5555	Fax	555-555-5556

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated	Steelhead	Disease to be treated	BGD	
Average fish weight (gm)	4.4	Average fish length (in)	3.0	
No. of fish per unit (e.g. 10,000 fish/raceway)			47,500	
Number of treated units	3	Number of treated fish	142,500	
Number of untreated control units	0	Number of control fish	0	
Anticipated date treatment will be initiated			8/23/08	
Check type of treatment method used		<input checked="" type="checkbox"/> Flow through <input type="checkbox"/> Standing bath		
Check treatment objective		<input type="checkbox"/> A	<input checked="" type="checkbox"/> B	<input type="checkbox"/> C <input type="checkbox"/> D
Intended drug target dosage (mg/L)	10 mg/L X 15 mg/L 20 mg/L	Estimated total amount of drug needed for proposed treatment (Kg)	6.12	
Drug manufacturer	B.L. Mitchell, Inc	Drug lot number	111222C	

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.

To determine the efficacy of a three day flow-through treatment of 15 ppm of CLT, for one hour, for BGD in steelhead trout.

Study designed by John Doe

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

JD 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:

JD 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: 8/22/08 **Investigator:** Sign here

Date Reviewed: 8/22/08 **Study Monitor:** Sign here