Form CP-W: Worksheet for Designing Clinical Field Trials under Channel Catfish Pituitary (CP) INAD 11-468

INSTRUCTIONS

1. Investigator must fill out Form CP-W for each trial conducted under this INAD **before** actual use of channel catfish pituitary. The Investigator is responsible that Form CP-W is completed accurately.
2. Investigator should keep the original on file, and fax a copy to the Study Monitor for review.
3. After review, the Study Monitor will fax a copy to the Bozeman NIO for assignment of the Study Number.
4. 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.
5. **Note:** Both Investigator and Study Monitor should sign and date Form CP-W.

SITE INFORMATION

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

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated						
Average fish size (in)					Average fish weight (gm)	
Number of treated males					Number of treated females	
Number of control males					Number of control females	
Anticipated date of treatment					Estimated total amount of drug for proposed treatments (g)	
Intended CP dosage (mg/kg body weight)	Females		Males		Method of administration	**Injection**
Number of injections	Females		Males		Injection interval (hours)	
Drug manufacturer	**Hybrid Catfish Company**				Drug lot number	

Worksheet for Designing Clinical Field Trials - Version 1

STUDY DESIGN: Describe in detail the purpose of the clinical trial. For example you might compare dosage, or treated fish compared to untreated fish. 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):

☐ Fish treated with channel catfish pituitary (CP) must be maintained in culture facilities or captivity for at least 3 days following final CP treatment before they can be harvested for human consumption or released/stocked. Investigator should initial here to indicate awareness that fish disposition must be in compliance with FDA-mandated withdrawal times as described in Section XV of the Study Protocol.

WORKER SAFETY CONSIDERATIONS:

☐ Investigator should initial here to indicate that all personnel handling channel catfish pituitary have read the Material Safety Data Sheet for common carp pituitary (CCP) and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ **Investigator:** _____

Date Reviewed: _____ **Study Monitor:** _____