

## Common Carp Pituitary Clinical Field Trials

### CCP-W: Worksheet for Designing Study Numbers - Version 4

### Common Carp Pituitary INAD 8391

#### **INSTRUCTIONS**

1. Investigator must fill out Form CCP-W for each trial conducted under this INAD **before** actual use of Common Carp Pituitary. The Investigator is responsible that Form CCP-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 CCP-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 treatment will be initiated			
Intended CCP dosage (mg/kg)	Female	Male	Estimated total amount of drug for proposed treatments (mg)
Number of injections	Female	Male	Injection interval (hrs or days)
Drug manufacturer			Drug lot number

## Worksheet for Designing Study Protocols - Version 4

**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):

\_\_\_\_\_ Estimated time (days, months) from last treatment day to first possible harvest for human consumption

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 drug have read Material Safety Data Sheet for Common Carp Pituitary and have been provided protective equipment, in good working condition, as described in the MSDS.

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

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