

Form LHRHa-W: Worksheet for Designing Individual Field Trials Under LHRHa INAD 8061

INSTRUCTIONS

- Investigator must fill out Form LHRHa-W for each trial conducted under this INAD **before** actual use of Luteinizing Hormone-Releasing Hormone analog. The Investigator is responsible that Form LHRHa-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 AADAP Office for assignment of the Study Number.
- The AADAP Office 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 LHRHa-W.

SITE INFORMATION

Facility	Fish Hatchery A		
Address	123 Hatchery Dr		
	Anywhere, USA 55555		
Investigator	John Doe		
Reporting Individual (if not Investigator)			
Phone	555-555-5555	Fax	555-555-5556

FISH CULTURE AND DRUG TREATMENT INFORMATION

Fish species to be treated					Paddlefish	
Average fish size (in)	48 - 60				Average fish weight (gm)	40 - 70 lbs
Number of treated males	4				Number of treated females	12
Number of control males	0				Number of control females	0
Anticipated date treatment will be initiated	March 08				Estimated total amount of drug for proposed treatments (mg)	30
Intended LHRHa dosage (ug/kg)	100	Female	20	Male	Method of administration	Injection
Number of injections	2	Female	1	Male	Injection interval (hrs or days)	12 hr
Drug manufacturer	Western Chemical, Inc.				Drug lot number	1111

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.

To induce ovulation and spermiation in treated fish.

Study designed by John Doe

DISPOSITION OF TREATED FISH (Human Food Safety Considerations):

No Estimated time (days, months) from last treatment day to first possible harvest for human
release consumption

jd Fish treated via injection will be maintained in culture facilities or captivity for at least 14 days following treatment before they are released or allowed to enter the food chain. 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:

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

Date Prepared: 2/12/08

Investigator: Sign here

Date Reviewed: 2/12/08

Study Monitor: Sign here