

Form sGnRH_a/Ovaplant-W: Worksheet for Designing Clinical Field Trials under sGnRH_a INAD 11-375

INSTRUCTIONS

- Investigator must fill out Form sGnRH_a/Ovaplant-W for each trial conducted under this INAD **before** actual use of salmon Gonadotropin Releasing Hormone analog. The Investigator is responsible that Form sGnRH_a/Ovaplant-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 sGnRH_a/Ovaplant-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 (mg)	
Intended sGnRH _a dosage (ug/kg)	Females		Males	Method of administration	Pellet Implant
Pellet size (i.e., ug sGnRH _a per pellet)	Females		Males	Number of pellets per fish	
Drug manufacturer	Syndel International, Inc.			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 sGnRH α (Ovaplant[®]) may not be stocked, released, or harvested for human consumption. All treated fish must ultimately be destroyed. 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 the Material Safety Data Sheet for salmon gonadotropin releasing hormone analog (Ovaplant[®]) and have been provided protective equipment, in good working condition, as described in the MSDS.

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____