

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

### INSTRUCTIONS

1. Investigator must fill out Form sGnRHa/Ovaplant-W for each trial conducted under this INAD **before** actual use of salmon Gonadotropin Releasing Hormone analog. The Investigator is responsible that Form sGnRHa/Ovaplant-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 sGnRHa/Ovaplant-W.

### SITE INFORMATION

Facility	Fish Hatchery A		
Address	123 Hatchery Rd		
	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				steelhead		
Average fish size (in)	30.0			Average fish weight (gm)	3,200	
Number of treated males	31			Number of treated females	41	
Number of control males	20			Number of control females	35	
Anticipated date of treatment	March 2008			Estimated total amount of drug for proposed treatments (mg)	28.8	
Intended sGnRHa dosage (ug/kg)	Females	40	Males	40	Method of administration	<b>Pellet Implant</b>
Pellet size (i.e., ug sGnRHa per pellet)	Females	150	Males	75	Number of pellets per fish	1
Drug manufacturer	<b>Syndel International, Inc.</b>			Drug lot number	111000	

**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 synchronize male and female spawning.

Study designed by	<a href="#">John Doe</a>
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**DISPOSITION OF TREATED FISH (Human Food Safety Considerations):**

		Fish treated with sGnRH $\alpha$ (Ovaplant <sup>®</sup> ) 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.
<a href="#">J</a>	<a href="#">D</a>	

**WORKER SAFETY CONSIDERATIONS:**

<a href="#">J</a>	<a href="#">D</a>	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 <sup>®</sup> ) and have been provided protective equipment, in good working condition, as described in the MSDS.

<b>Date Prepared:</b>	<a href="#">2/15/08</a>	<b>Investigator:</b>	<a href="#">Sign here</a>
<b>Date Reviewed:</b>	<a href="#">2/15/08</a>	<b>Study Monitor:</b>	<a href="#">Sign here</a>