

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: _____

FORM CCP-1. Report on Receipt of Drug - Guide for Reporting Investigational New Animal Drug Shipments for Poikilothermic Food Animals

INSTRUCTIONS

1. Investigator must fill out Form CCP-1 **immediately** upon receipt of CCP.
2. Investigator should keep the original on file, and send one copy to the Study Monitor for review.
3. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO.
4. Note: Both Investigator and Study Monitor should sign and date Form CCP-1.

The sponsor, U.S. Fish and Wildlife Service, submits a notice of claimed investigational exemption for the shipment or delivery of a new animal drug under the provisions of Section 512 of the Federal Food, Drug, and Cosmetics Act. The following information is submitted in triplicate:

| | | | |
|--|---|---------------------------------------|-------------|
| Name of Drug | CCP | INAD Number | 8391 |
| Proposed Use of Drug | To induce gamete maturation in a variety of fish species. | | |
| Date of CVM Authorization Letter | July 7, 2006 | | |
| Date of Drug Receipt | | Amount of Drug | |
| Drug Lot Number | | Study Worksheet Number | |
| Name of Investigator | | | |
| Address of Investigator | | | |
| Location of Trial | | | |
| Pivotal Study (yes/no) | | Non-pivotal Study (yes/no) | |
| Approximate Number of Treated Animals | | Approximate Number of Control Animals | |
| Number of Animals Used Previously ¹ | | | |
| Study Protocol Number | 8391 | | |
| Approximate dates of trial (start/end) | | | |
| Species, Size, and Type of Animals | | | |
| Maximum total dose | 25 mg/Kg body weight | | |
| Methods(s) of Administration | Injection | | |
| Withdrawal Period | 72 hrs for wild stock; 30 days for domestic (non-wild) broodstock. | | |

¹ To be filled out by the NIO

Date Prepared: _____

Investigator: _____

Date Reviewed: _____

Study Monitor: _____

Date Reviewed: _____

Sponsor: _____

Common Carp Pituitary Clinical Field Trials

CCP-3: Results Report Form - Version 4

Common Carp Pituitary INAD 8391

INSTRUCTIONS

1. Investigator must fill out Form CCP-3 no later than 10 days after completion of the study period. Study Number must be recorded on all pages of Form CCP-3. Attach lab reports and other information.
2. If Common Carp Pituitary was not used under the assigned Study Number, fill out only the Site Information portion on this page, and skip to the end of page 3 and fill out only the "Negative Report" section.
3. Investigator should keep the original on file, and send a copy to the Study Monitor. Within 10 days of receipt, the Study Monitor should send a copy to the Bozeman NIO for inclusion in the permanent file.
4. **Note:** Both Investigator and Study Monitor should sign and date Form CCP-3.

SITE INFORMATION

| | |
|----------------------|--|
| Facility | |
| Reporting Individual | |

FISH CULTURE AND DRUG TREATMENT INFORMATION

| | | | |
|---|--|--|--|
| Drug lot number | | Total amount drug used (mg) | |
| Fish species treated | | Water temperature (°F) | |
| Drug dosage male (mg/kg body wt) | | Drug dosage female (mg/kg body wt) | |
| Average fish weight (gm) | | Average fish length (in) | |
| Number of treated males | | Number of treated females | |
| Number of control males | | Number of control females | |
| Treatment dates | | | |
| Number of injections/males | | Number of injections/females | |
| Injection interval (hrs or days) | | Treatment method (IP or IM injection) | |
| Spawning/evaluation interval (time from treatment until spawning) | | Spawning/evaluation date | |

Hormone Results Record - Version 3

INSTRUCTIONS

1. Green females are those fish that have not ovulated or released their eggs, green males are those fish that are not actively spermiating.
2. Motility Score based on a scale of 0 - 4 (see Study Protocol Section VI).
3. Use additional copies of this form for additional treatment days.
4. Please attach additional documentation to further describe treatment procedures/evaluation.

Be sure the facility name is written here: _____

| | | TREATED FISH - Females | | | | | | CONTROL FISH - Females | | | | | |
|--------------|----------------|------------------------|-------------|--------------|--------|----------|---------|------------------------|-------------|--------------|--------|----------|---------|
| Date Treated | Date Evaluated | # of Fish | Number Ripe | Number Green | % Ripe | % Eye-Up | % Hatch | Number of Fish | Number Ripe | Number Green | % Ripe | % Eye-up | % Hatch |
| | | | | | | | | | | | | | |
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| | | | | | | | | | | | | | |

| | | TREATED FISH - Males | | | | | | CONTROL FISH - Males | | | | | |
|--------------|----------------|----------------------|-------------|--------------|--------|-----------------|----------------|----------------------|-------------|--------------|--------|-----------------|----------------|
| Date Treated | Date Evaluated | # of Fish | Number Ripe | Number Green | % Ripe | Milt/ fish (mL) | Motility Score | # of Fish | Number Ripe | Number Green | % Ripe | Milt/ fish (mL) | Motility Score |
| | | | | | | | | | | | | | |
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RESULTS: Describe in detail treatment results. Was treatment successful? If treatment did not appear to be successful, explain why not? Were there any mitigating environmental conditions that may have impacted treatment results? Were there any deviations from the Study Protocol? Attach pathology reports; Both Pre-and Post-Treatment.

Toxicity observations: Report any apparent drug toxicity including a description of unusual fish behavior.

OBSERVED WITHDRAWAL PERIOD OF TREATED FISH:

Observed withdrawal period: _____ no withdrawal period _____ 72 hours _____ 30 days

Estimated number of days between last treatment and first availability of fish for _____ human consumption (ensure this time period meets the withdrawal period).

NEGATIVE REPORT Common Carp Pituitary was not used at this facility under this Study Number during the reporting period. (Investigator should initial for negative reports as soon as the Study Number is known to be no longer needed or valid.)

Date Prepared: _____ Investigator: _____

Date Reviewed: _____ Study Monitor: _____