Invasive Carp eDNA Program
Process for Making Program Changes and QAPP Modifications

IC eDNA Monitoring Program

U.S. Fish and Wildlife Service, Midwest and Northeast Regions
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IC eDNA Program Changes and QAPP Modifications
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Application/Purpose

The Invasive Carp (IC) eDNA Monitoring Program Quality Assurance Project Plan (QAPP) is a controlled document that is reviewed annually by IC eDNA Monitoring Program staff. Program staff consists of Midwest and Northeast Regions Fish and Wildlife Conservation Offices (FWCO), Project Leaders (PL), Whitney Genetics Lab (WGL), and Regional Offices (RO). This document outlines the process for addressing IC eDNA Monitoring Program QAPP changes.

Each year when revisions to the QAPP are proposed through the eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions), there are situations when proposed changes are more than grammatical in nature. These changes should be addressed with an appropriate level of review and subsequent decision-making processes. This document outlines the processes that should be followed if IC eDNA Monitoring Program staff are suggesting a higher-level change (further described below). These higher-level changes will need an experimental research project proposal (described below). An experimental research project would be any major change to a Program process or scientific method (sample collection, processing or analysis) that would potentially affect results.

eDNA Program Change Process Description

IC eDNA Monitoring Program QAPP changes have been categorized into three levels, with each level corresponding to significance within the IC eDNA Monitoring Program. All level changes are submitted through the eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions) that documents annual changes to the QAPP. In addition to the Microsoft Form, level 3 changes will require additional steps including submission through the IC eDNA Program Coordinator and approval by a review panel. The process is visually represented in Figures 1 through 3.

Level 1

Simple grammatic changes, or revisions to structure and flow of the document:

- Grammatical example: incorrectly spelled words, missing punctuation, adding a bulleted list, and/or adding a visual diagram to clarify a process.
- Structure and flow example: changes to staff identified in the document, moving a sentence in the document, and deleting information that is redundant.

Submission: through Microsoft Form.

Accepting level 1 changes: no additional review necessary.

Decision process: made by Program QA/QC specialist designee.

Documenting level 1 changes: Change Documentation Spreadsheet stored on the eDNA Program SharePoint site.

Level 2
Adjustments to minor Program processes or changes in technological platforms for data collection, analysis, and storage that may impact results, but in a quantifiable and predictable matter that does not decrease the chance of detection such as:

- Adjustment to the Program example: changing extraction elution volume and changing the preservation time requirement of samples.
- Changes to technological platforms example: change to ArcGIS online, Survey123, BioRad software, and R code analysis.

Submission: through eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions).

Accepting level 2 changes: requires information/literature/scientific documents.

Decision process: made by the IC eDNA Program Coordinator.

Documenting level 2 changes: Change Documentation spreadsheet stored on eDNA Program SharePoint site. Supporting information/literature/scientific document package will be kept with Program documents on eDNA SharePoint site and linked in the Change Documentation spreadsheet.

Level 3
A change to major Program processes or scientific methods (sample collection, processing or analysis) that would potentially affect results in a less direct or predictable matter, such as:

- A scientific method example: changing from centrifugation to filtration or the use of Smith-Root eDNA Sampler filtration units.
- A processing example: changing from conventional to quantitative PCR or changing IC marker sets.

Submission: through eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions) by the principal investigator after also submitting Study Report (Template C) and Change Request Summary (Template D) to the eDNA Program Coordinator.

Accepting level 3 changes: requires review and approval of a documented study plan and findings report (See Invasive Carp eDNA Program Experimental Research Protocol for complete process), Data Management Plan (DMP) (if scientific), replication, statistical significance (if scientific).

- Review panel: IC eDNA Program Coordinator, staff member representing the data aspect, WGL Project Leader (PL), one Region 3 FWCO Project Leader, one Region 5 FWCO, FWCO Project Leader, Northeast Fisheries Center Director, and Midwest Fisheries Center Director. A designated representative may be substituted for any of the above if they are unable to participate or have a conflict of interest (i.e. submitted the change request).

- Decision making will be done by consensus. Consensus is about assent and the absence of objection rather than unanimous agreement. It is a dynamic process of collective decision-making where the goal is to reach a broadly accepted resolution, even if not every individual fully agrees with every detail. If consensus is not reached, the proposed change is not approved.
- The panel's responsibility is to make decisions based on programmatic considerations.

Decision Process Disagreement: submitter could appeal and provide additional information/justification.

- Appeal is submitted to IC eDNA Program Coordinator.
- IC eDNA Program Coordinator provides the appeal to review panel.
- Panel has 30 days for a decision.

Documenting a level 3 change: Tracked with the documented study report that will be stored with Program documents on eDNA Program SharePoint site. Also recorded on Change Documentation spreadsheet stored on the eDNA Program SharePoint site.

Level Change Summary

Table 1. A summary of all three level changes with the requirements needed to propose a change, the decision process for the proposed change, the documentation used to record the proposed change and outcome, and the product from an approved change.

QAPP Revision Process	Level	Requirements	Decision	Documentation	Product
Microsoft Form	1 (Grammatical)	No additional review needed	None	Change Documentation Spreadsheet	Change to the QAPP
Microsoft Form	2 (Adjustments to the Program processes)	Supporting information/literature/scientific documents	eDNA Program Coordinator	Change Documentation Spreadsheet	Change to the QAPP
Package to IC eDNA Program Coordinator	3 (Change to the Scientific Method which would affect results)	Study Plan, DMP, replication, statistical significance	Internal/External Review	Study Report and Change Documentation Spreadsheet	If approved, change to the QAPP

Timeline

Level 1 and Level 2 Program Changes

QAPP revision period is open throughout the sampling year; however, the revision period closes at end of December for requested changes to be made for the following field season. For example, change requests made prior to December 30 in 2025 would be eligible for implementation in 2026, and change requested after December 30 in 2025 would be eligible for implementation in 2027, unless otherwise approved by the IC eDNA Program Coordinator and Program QA/QC Specialist for earlier inclusion. Level 1 and level 2 changes are submitted through the eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions) At the end of December, all changes will be addressed through the Change Documentation spreadsheet. Any level 2 changes will require scientific literature or additional information to support the change which is indicated on the eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions).

Level 3 Program Changes

A level 3 change can be submitted at any time during the sampling year with submissions closing by end of November. Final decision on change acceptance or denial will not be made during the sampling season. Only if a change is significant to protecting the health/safety of Program staff will changes be made during the sampling season.

Submitted level 3 changes will be addressed during the months of December through February. The panel will do their best to finalize a decision by February 14th and provide a timeline for level 3 change implementation dependent on internal and external communications which can take up to a year. Most panel recommended level 3 changes will be implemented in the following year's QAPP, unless factors such as partner and internal approvals affect final implementation.

Roles/Responsibilities

Submitter:

- Level 1 and level 2 changes are submitted through the eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions).
- Level 3 changes, submit research study ideas that may lead to a Level 3 change to the IC eDNA Program Coordinator for initial review through Template A. Invasive Carp eDNA Research Project Pre-Proposal Microsoft Form by September 1st at the latest (Template A. Invasive Carp eDNA Research Project Pre-Proposal).
- Level 3 changes, pending approval of the Pre-Proposal, submit a detailed Research Project Proposal (Template B. Invasive Carp eDNA Experimental Research Project Proposal) to the IC eDNA Program Coordinator for panel review by December 1st at the latest.

- Level 3 changes, if the research study is approved, carried out, and the findings support the submission of a Level 3 change, submit the change through eDNA QAPP Revisions Microsoft Form (eDNA QAPP Revisions) AND provide a detailed study report (Template C) and a Change Request Summary (Template D) to the IC eDNA Program Coordinator with explicit recommendations for the change.
- Level 3 changes, clearly identify which section of the QAPP will require a change.
- Level 3 changes, responsible for re-writing sections in coordination with Program QA/QC Specialist.

IC eDNA Program Coordinator:

- Determine the level of the proposed change (example of a level 1 is submitted but revised to be a level 2).
- Approve level 2 changes.
- Convene panel for review of proposed experimental research and level 3 change requests.

Program QA/QC Specialist role description:

- Addressing level 1 changes with the IC eDNA Program Coordinator.
- Assisting submitter with re-writing section for a level 3 change.
- Coordination, deadlines, 508 Compliance, structure and flow of documents. Tracking level submissions and facilitating review panel meetings.

Level 3 Change Review Panel:

- Provide input to level 3 change submitter(s) on the necessary information and studies needed to aid in the decision-making process. While the panel interacts with submitter(s) to offer insights and suggestions, this interaction does not imply automatic acceptance of a proposed change, even if the data appears supportive.
- Meet with the submitters to clarify any questions or concerns before the study to address the proposed change begins
- Individually and as a group, weigh the proposed change against the data submitted. Factors to consider when evaluating include but are not limited to:
    - Is the change sufficiently supported by scientifically rigorous data?
    - Is results interpretation impacted?
        - Can that impact be measured?
        - Will the overall detection be increased, decreased, or be roughly the same?
        - Does it impact interpretation of results including comparison to past years?
    - How are jurisdictions and/or partners affected?

        - What is the impact on jurisdictional entities?
        - Are we meeting partner expectations? If so, how?
    - How does it impact the eDNA process?
        - Will the quality of deliverables be improved? If so, how?
        - Does it affect other aspects of the process?
        - Will the change increase efficiency of processes in the program? If so, how? If detection is the same, do other improvements/efficiencies gained warrant approval?
        - Will the change impact overall sample size? Specifically require sample sizes large than the lab can handle or larger than the program can afford to collect?
- Provide a decision on the level 3 change proposal.
- Communicate decisions to lab, FWCOs, and partners
    - Develop summary of the decision with documented answers to the evaluation criteria
    - Meet with submitters to go over the decision regarding the proposed change, address any questions that the submitters may have and work with the submitters to develop next steps if required.

Invasive Carp eDNA Program Experimental Research Protocol

1. A pre-proposal (Template A. Invasive Carp eDNA Research Project Pre-Proposal Microsoft Form (Template A. Invasive Carp eDNA Research Project Pre-Proposal)) is submitted to the eDNA Program Coordinator who will then convene the review panel. Review panel has up to two weeks to review the pre-proposal and give approval for a full Experimental Research Project Proposal.

   Note: Prior to submission of a pre-proposal, Project lead should:

   - Conduct an evaluation of what data and information already exists or is currently being collected to reduce duplication of work.
   - Check the FWS Data Management Plan Power App for existing plans aligning with project's goals or purpose.
   - Reach out to eDNA Working Group to check in on what projects they are working on to avoid overlap and increase awareness of project proposal.
   - Review the scientific literature to see if similar studies have already been conducted.
   - Check federal data catalogs for information on existing information: ServCat, and Data.gov
   - Be aware of when pre-proposal is submitted to consider the potential impact to field work. Ideally, a pre-proposal should be submitted at least 6 months (September 1st) prior to the next sampling season, earlier is encouraged.
2. If the pre-proposal is approved by the panel, indicating that the research question is of interest to the program, a detailed Experimental Research Project Proposal (See Template B) is then submitted by December 1st at the latest, (earlier is encouraged) to the review panel for review. The review panel will have up to 2 months from December 1st to provide full support.
   a. During this period, discussions are encouraged between the review panel and principal investigator(s) on the full proposal details.
   b. If the review panel cannot come to consensus, an external review subject matter expert can be used to provide input and evaluate the proposal. This situation may not be required for most proposal submissions.
3. Once approved, project lead will work with the Midwest Fisheries Center Data Branch to determine appropriate data management workflow and data collection and mapping prior to the start of work.
   a. Data Coordinator: Jeena Koenig
   b. Database support: Jason Ross

This section describes recommendations for planning a study that may lead to a major change to a Program process or scientific method. Please use the Planning Requirements checklist during the project planning phase and the Submission Requirements when submitting a level 3 change.

Planning Requirements:

- ☐ Study plan
- ☐ DMP
- ☐ Sample replication and/or statistical significance (if scientific)
- ☐ Consult with field/lab staff
- ☐ Consult with eDNA Program Coordinator
- ☐ Identify data collection, schema, and data storage
- ☐ Identify data analysis methods
- ☐ Consult with MFC data branch

Additional considerations when developing a new study as applicable:

- Efforts should be made to develop and construct data sheets prior to project initiation.
- Data review, evaluation and validation procedures should be planned ahead of study initiation including when and how often data will be reviewed for the duration of the study
- All staff that will be participating in the study should be trained on proper data collection and study methods. If necessary, document staff training with the file folder structure.
- Outline how study documentation will be addressed and any relevant records or retention policies that would be applicable to the study should be stated.

Level 3 Submission Requirements:

- ☐ Study Report (Template C)
- ☐ Change Request Summary (Template D)
- ☐ Internal review panel
- ☐ External review panel (if necessary)

Template A

Invasive Carp eDNA Research Project Pre-Proposal

The content described below reflects the information included on the Pre-Proposal submission form located at this link (https://forms.office.com/g/21d3KpVxCh), which is required to be completed before a research project is initiated. Content is described here as a reference for planning. Please fill out the actual Microsoft Form following the link for official submission.

Application/Purpose

What is the purpose or need for the proposed experimental research project?

Program Resource Needs

Delineate if and what Program resources are needed (check all that apply).

- ☐ Is a new Survey 123 or Field Maps form needed for data collection?
- ☐ Will you be using an existing data collection form? If so, please name.
- ☐ Do you need results maps created by the Program GIS specialist?
- ☐ Will you be working with lab staff for this study? Will this study require lab processing of eDNA samples?
- ☐ Other
- ☐ What types of samples will be analyzed? (Check all that apply):
    - Filter
    - Centrifuge
    - Other:

Research Project Information

Basin/study location? Where will the study take place?

Roles/Responsibilities

- ☐ Who is the project POC?
- ☐ Who will manage field data?
- ☐ Who will manage lab results?
- ☐ Who will create the data management plan?
- ☐ Who will create the ServCat record?

Period of Performance

What sampling year(s) and time periods do you wish to conduct this research? Provide a timeline for the periods in which the research will be conducted.

Sample collection start date:

Sample collection end date:

Template B

Invasive Carp eDNA Experimental Research Project Proposal

Project Title

Include office name, and subject of project. For example:

Program Name: FWS Invasive Carp eDNA Monitoring Program

Office Name: La Crosse FWCO

Subject of Project: Backpack Filtration Study on Mississippi River

Contact Information

Name (first and last) and contact information (email and work number) for Principal investigator(s) /POCs and others associated with the project.

Introduction/Background

At a minimum, this section should answer the following questions:

- Why are we working on this project; what is the need?
- How will this project benefit the IC eDNA Monitoring Program?
- **Clearly stated objectives for the study**

Methods

What methods will be used to address the objective? Are there existing methods previously described in the literature? Will we develop new methods? Briefly describe how and where samples will be collected in the field (if applicable). It will be important to outline who will complete which aspects of the study (e.g., field collections, lab processing, data analysis). Will the project be completed in multiple phases?

Data Analysis

In this section, describe how the data will be analyzed. These steps should be taken prior to data collection.

- Consult with a statistician to help determine sample numbers and study design needed for statistical significance.
- Describe the statistical methodology and/or analysis process of the data.

Timeline and Deliverables

When will this work begin and how long will it continue? What will be produced at the end of this project (raw data, simple data summary, technical report, peer-reviewed manuscript, etc.)? Who will be responsible for these deliverables? At a minimum, each deliverable product (report, data summary, etc.) should include a brief (may be as simple as a paragraph in some instances) summary of the data collection methods and results.

Data Management & Data Management Plan

Data collected and managed for an experimental research project will be maintained and documented separately from the Invasive Carp eDNA Program sampling data since purpose, objectives, methods, and data collected are different. The study plan should cite an official USFWS data management plan for the project according to USFWS policy. The study plan should include information about how data will be shared with the public (e.g., upon request, online open-access format) and should include a statement along the lines of "All data and reports generated as a part of this study will be made available to the public."

- Separate datasets should exist for research projects and are likely managed by the principal investigator(s). These studies are independent of the Invasive Carp eDNA Program data.
- A new ServCat catalog record must be generated for the project, after completion, and reference the Invasive Carp eDNA Program's ServCat project record (see ServCat Record Creation Section)
- A metadata record must be created for the project (see Metadata Creation Section)

ServCat Record Creation

1. Follow the ServCat Help Documentation on Create a Reference for the project
2. Set Reference Type to Geospatial Data
3. Ensure Reference Access Level and File Access Level is set to Public
4. Set Quality of the Information Source Being Described by this Reference to High
5. Cross Reference the Invasive Carp eDNA Monitoring Program Project Record
    a. Go to the Cross-References Tab
    b. Select add and select code search
    c. Copy in this reference code into the text box: 129158
    d. Select the box next to the project code for the invasive carp eDNA Monitoring project record
    e. Select Add
6. Upload a .csv file of the data to the Add Files and Links tab (follow step 6 in ServCat Help documentation on Create a Reference)
7. Principle Investigator will contact a MFC data branch member for a final review of the ServCat record
8. Activate the reference when complete

Metadata Creation

1. Fill out the Data Dictionary provided during the MFC data branch consultation for planning requirements
2. Send filled out Data Dictionary Template to the eDNA data stewards
3. A metadata file will be sent to the project lead to file with the ServCat Record (Follow Step 6 from ServCat help documentation on Create a Reference)

Template C

Invasive Carp eDNA Experimental Research Project Summary Report

Introduction

Provides background information on the research topic, literature review, and the research question.

Methods

Describes the participants, materials, procedures, and data collection methods used in the study.

Results

Presents the findings of the study, including statistical analyses and key data points.

Discussion

Interprets the results, discusses their implications, limitations, and future research directions.

Recommendations (if applicable)

Recommendations for changes to the Invasive carp eDNA Program based on research results and conclusions.

References

A list of all cited sources.

Template D

Invasive Carp eDNA Program Change Request Summary

NOTE: fillable form is the IC eDNA QAPP Revisions Microsoft Form. Do not use this sample form.

Based on the results presented in the [title of study] report, we request that the following changes be made to the Invasive Carp eDNA Program.

Change 1 summary statement

State the first, or highest priority change request.

Justification

Paragraph or bulleted list summarizing the research results that support this specific request

Documents Impacted

Bulleted list of documents (QAPP, SOPs, Program Documents, etc.) and specific sections that will be impacted to reflect the requested change

Change 2 summary statement (if applicable)

State the second change request.

Justification

Paragraph or bulleted list summarizing the research results that support this specific request

Documents Impacted

Bulleted list of documents (QAPP, SOPs, Program Documents, etc.) and specific sections that will be impacted to reflect the requested change

Change 3 summary statement (if applicable)

State the third change

Justification

Paragraph or bulleted list summarizing the research results that support this specific request

Documents Impacted

Bulleted list of documents (QAPP, SOPs, Program Documents, etc.) and specific sections that will be impacted to reflect the requested change