

Table of Contents

- MOA Scope of Work
- Policies and Procedures
- Guidelines for Students
- Research Plan Approval Form
- Research Proposal Approval Form

Scope of Work

This MOA forms the basis for development of scientific collaborations, outreach and educational initiatives and intellectual partnerships between FDA and DISL. The types of activities expected to develop from this MOA include:

- Exchanges between university faculty and staff and FDA scientists and staff;
- Educational opportunities for qualified students (graduate), staff members and faculty members in the Parties' laboratories, classroom and offices;
- Joint meetings for education and research;
- Research collaborations;
- Cooperative international activities including outreach; and
- Sharing of unique facilities and equipment for increased cost efficiencies for scientific endeavors.

Under this Agreement, joint efforts will also be undertaken to obtain grants and other extramural funds to support collaborative research and training as permitted under appropriate statutory authority. Before any specific collaboration is initiated or implemented, the parties shall identify priorities, topics of mutual interest, and develop separate, written agreement for collaboration and sharing of resources. Where applicable, these agreements shall incorporate by reference this memorandum of agreement. FDA may enter into a contract, grant or cooperative agreement with DISL to the extent authorized by law and available appropriations. The terms and conditions of any such awards will be in accordance with applicable federal law and regulations and shall be negotiated and executed by appropriate representatives of institutions within the DISL and the FDA.

For programs agreed to in writing, and in advance by both parties, FDA may, as permitted by applicable statutes and regulations and subject to the availability of funds, and as it deems appropriate, offer DISL the following:

- Laboratory and/or office space in support of activities under this agreement.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education and outreach efforts with faculty, students, and staff within DISL member institutions.
- Participation in courses and seminars within DISL, based on availability of resources.
- Continuing and frequent communication with faculty and staff.
- Openness and welcome to faculty, staff, and students wishing to visit FDA laboratories (currently, access to FDA facilities is limited to U.S. Citizens and those holding valid green cards).

- Promulgation and communication of identified collaborative efforts through appropriate means.

For programs agreed to in writing, and in advance by both parties, DISL may offer FDA the following:

- Recruitment and administration of four graduate degree students and associated faculty advisors to collaborate in seafood safety research in FDA laboratories under joint direction of FDA scientists and DISL faculty advisors.
- Laboratory and/or office space in support of activities under this agreement at identified institutions.
- Access to facilities and equipment, including necessary training and guidance, in so far as such use does not interfere with the primary mission of either party.
- Active participation in establishing collaborative research, education and outreach efforts with FDA scientists and staff.
- Continuing and frequent communication with FDA scientists and staff.
- Openness and welcome to FDA scientist and staff wishing to visit relevant DISL programs and laboratories.
- Promulgation and communication of identified collaborative efforts through appropriate means.
- Adjunct, affiliates and research facility appointments for appropriate FDA professional staff, provided that appointment of such candidates will advance specific programmatic objectives of the parties as appropriate, and provided that such appointments comply with university policies on appointment of faculty/affiliates.

In an effort to enhance collaborative interactions and communication between both institutions, FDA and DISL will collaborate in the development of regular workshops where faculty from all the institutions within the DISL and FDA scientists and staff share information about ongoing research, education and outreach efforts of mutual interest.

Additionally, it is agreed that:

- It is recognized that from time-to-time FDA and DISL will be sharing in expenses and may require compensation of either party by the other. As research projects are developed, details of how costs are to be shared will be agreed to in advance under other contractual mechanisms as appropriate in compliance with all applicable federal requirements.
- This agreement may be amended any time upon mutual agreement between the parties in writing.

The foregoing represents the broad outline of the parties' present intent to enter into specific agreements for collaborative efforts in intellectual areas of mutual interest to the FDA and the institutions within the DISL. It does not create binding, enforceable obligations against any Party. All activities undertaken pursuant to the MOA are subject to the availability of personnel, resources, and funds. This MOA does not affect or supersede any existing or future agreements or arrangement among the Parties and does not affect the ability of the Parties to enter into other agreements or arrangements related to this MOA.

Policies and procedures

Selection of Awardees: Selection of students will be based on acceptance by the DISL and FDA advisors and subject to regular admission to an eligible degree-granting institution within the Marine Environmental Sciences Consortium for which there is an available mentor in residence at DISL. Students must meet the minimum requirements for admission and must not be classified as provisional at the time of admission. Students who meet these criteria, may apply for a fellowship according to the criteria in the published request for fellowship applications, which will be posted in the fall of years preceding any period for which funding is available. Fellowships will be awarded as determined by a selection committee comprised of DISL and FDA staff. Upon acceptance of an individual to the fellowship program, the student will be provided an award letter detailing the benefits and requirements of the program.

Duration of Award: Initial awards of fellowships will be 2.5 years for Master's degree candidates, 4 years for Ph.D. candidates entering the program with a M.S. and 5 years for Ph.D. candidates entering the program with a B.S. degree. Funding award periods may be shorter, depending on availability of funds and the nature of the proposed work (e.g.; dissertation improvement research may be funded for one year). Funding beyond the specified period will be considered on a case-by-case basis and will be contingent on satisfactory progress and projected completion date. Maintenance of an individual as a fellowship recipient will be contingent upon successful and timely completion of milestones as detailed in the "Guidelines for Students".

Award Details: Each fellow will receive a stipend and up to \$7,000 per year for support, depending on availability of funds. A tuition waiver for students on research fellowships may be issued by degree-granting institutions, but it cannot be guaranteed by DISL or FDA. Support funds for each student will be separately accounted, managed jointly by the student and their DISL faculty advisors. Support funds can be used for equipment and lab supplies for the fellowship project, student meeting registrations, travel, and publications as well as to meet additional financial needs for progress of the student's research and scientific development. Upon the start of a new academic year or completion of degree requirements, remaining funds in the account will be returned to the general fund account. If funding allows, faculty advisors may request tuition and insurance coverage for students who are not eligible for tuition waivers at their home institution and where other grant support for tuition and insurance is not available. These costs also may be taken from the student's support funds. Students with a clear demonstrated need may apply for additional funds, which will be considered by the DISL-FDA joint program coordinators on a case-by-case basis contingent on availability of funds and satisfactory progress by the student.

General Funds: Funds not committed to graduate student stipends or support costs will be placed in a general funds account and can be used for additional fellowships, short-term internships, undergraduate research positions, or in support of other cooperative program activities. Use of these funds will be discussed and agreed upon by a majority of participating DISL and FDA advisors. Funds in the account at the end of each year will carry over to the next year unless otherwise restricted by the funding program.

Publications: Dissemination of research findings of fellowship awardees will be through standard scientific meetings and peer reviewed journals. All abstracts, posters, presentations, and publications shall have authorship representing DISL and FDA and will require clearance through FDA. FDA requires a minimum of 3 weeks for approval of abstracts and other written materials and a minimum of 7-9 weeks for approval of publications. No submissions can be made without FDA approval.

All publications resulting from work funded by the DISL-FDA graduate fellowship program must include an acknowledgement of the funds (i.e.; This work was funded in part by a DISL-FDAgraduate fellowship to Student Last Name). Students or advisors should request the most up-to-date award number to include in all products.

Guidelines for DISL-FDA Students

- Upon matriculation, all students will have selected a DISL and an FDA advisor.
- By the end of the **sixth month**, the student will submit a Research Plan to DISL and FDA advisors. This plan will be a 2 to 3 page document (completed according to the document *Research Plan Format_FDA*) that will demonstrate the student’s general conceptual knowledge of the proposed research, research objectives and/or hypotheses, and expected academic milestones. Students must submit signed copies of the Research Plan Approval Form (attached) to DISL and FDA advisors to complete this requirement. The Research Plan is not a prospectus and can be a refined version of the student’s program application.
- By the end of the **first year (six months for MS students)**, the student will select all committee members based on requirements of DISL and their home institution.
- Also by the end of the **first year**, the student will give a brief (15-20 min) presentation of the proposed research. The audience will consist of DISL-FDA students and their advisors and other members of the DISL and FDA communities. Student presentations will be required annually to share updates on research progress with the greater research community.
- By the end of **18 months (12 months for MS students)**, the student will submit a Research Prospectus to the DISL and FDA advisors. This document may be the same, or an excerpt of one used to satisfy the prospectus requirements of degree-granting institutions. This document will demonstrate the student’s background knowledge and significance of the proposed research as well as outline the specific research objectives and methodologies. Students must submit signed copies of the Research Proposal Approval Form (attached) to DISL and FDA representatives to complete this requirement.
- Thesis and dissertation submission format and timelines will be based on requirements of DISL and the home institution.
- Current program representatives are R Carmichael (rcarmichael@disl.org) and J Jones (Jessica.Jones@fda.hhs.gov)

Target milestones for DISL-FDA joint graduate program students

	Research Plan Submission	Committee Selection	Presentation of Research	Research Prospectus Submission	Thesis/ Dissertation Submission
Doctoral student w/ M.S.	6 months	12 months	Every 12 months	18 months*	4 years*
Doctoral student w/o M.S.	6 months	12 months	Every 12 months	18 months*	5 years*
Master’s student	6 months	6 months	Every 12 months	12 months*	2.5 years*

*Deadlines for these milestones may vary based on home institution, but do not extend funding timelines.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
Gulf Coast Seafood Laboratory
P.O. Box 158, 1 Iberville Drive
Dauphin Island, AL 36528-0158

RESEARCH PLAN APPROVAL FORM

Date Submitted: _____

Student: _____
Last First MI

FDA APPROVAL CHAIN

<u>Print Name</u>	<u>Signature (required)</u>	<u>Date</u>
1. _____ <i>DISL Advisor</i>	_____	_____
2. _____ <i>FDA Advisor</i>	_____	_____
3. _____ <i>Chief, MHSB or CHSB</i>	_____	_____

Student's Signature: _____ Date: _____



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
Gulf Coast Seafood Laboratory
P.O. Box 158, 1 Iberville Drive
Dauphin Island, AL 36528-0158

RESEARCH PROSPECTUS APPROVAL FORM

Date Submitted: _____

Student: _____
Last First MI

FDA APPROVAL CHAIN

Print Name	Signature (required)	Date
1. _____ <i>DISL Advisor</i>	_____	_____
2. _____ <i>FDA Advisor</i>	_____	_____
3. _____ <i>Chief, MHSB or CHSB</i>	_____	_____
4. _____ <i>Director, DSST</i>	_____	_____

Student's Signature: _____

Date: _____