



UCSD Florence Operational SOPs:

[ACTRI BIDS Florence Website](#)

Description

**This document provides
UCSD's Florence
Operational Guidelines:**

UCSD Florence is a cloud based eRegulatory application that replaces paper forms and physical binders, giving research teams an efficient, compliant way to electronically sign, manage, store, and collaborate on study documents.

UCSD's Florence instance is managed by ACTRI's BIDS section. These are the high-level operational SOPs used to manage the system and to guide users on the minimum standard work to access and utilize UCSD's Florence.

How to:

**Request Florence
related services.**

All Florence Requests for Services are submitted using the link::
<https://ucsd-actri.jotform.com/232994806487978>. The following serves are available:

- Create a Study Structure
- Update and existing study structure
- Grant/Update UCSD Departmental User Access
- Grant/Update External Monitor User Access
- Grant/Update Study-Specific User Access
- Remove User Access

How to:

**How to get Help with
UCSD Florence**

To get general help with Florence issues or questions:

- For MCC User Questions: Submit to [MCC Florence Questions](#)
- Non-MCC General Questions: Email actri-florence@health.ucsd.edu

1. Departmental specific workflow related questions should be directed to the designated Departmental Support Florence user. BIDS will not be the point of contact for department specific workflow related issues and questions.
2. BIDS will be the interface with the Florence Support for Application and Systems related issues. Email actri-florence@health.ucsd.edu

How to:

**Reporting of
Florence Bugs and
Issues**

Email BIDS Florence support actri-florence@health.ucsd.edu for reporting of Florence Bugs and Issues.

- Description
- Impact on your workflow
- If you have a temporary workaround, please describe
- PI name and contact information
- Department requesting change

1. BIDS will verify the issue, submit a Florence ticket, and notify you of results.
2. Turnaround Time = 5 business days



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How to:

Adding a new User to Florence (Study Specific)

Submit a BIDS Florence Grant/Update Study-Specific User Access request (requested by study team).

1. BIDS Completes the request by adding the User to the study role(s) requested for the user
2. Study team is sent notification of completion of work
3. Turnaround Time = 2 business days

How to:

Adding a new User to Florence (Department)

Submit a BIDS Florence Grant/Update UCSD Departmental User Access (requested by study team)

1. BIDS Completes the request by Creating the User and Adding the User to study role requested window for the user
2. Study team is sent notification of completion of work
3. User is sent notification to initially login to Florence and create user profile.
4. Turnaround Time = 2 business days

How to:

Remove a User from Florence

Submit a BIDS Florence Remove User Access request (requested by study team).

1. BIDS Completes the request by:
 - If one or more User Roles are listed on the request, the User is removed from the role(s).
 - Else, the User is removed from the UCSD Florence Membership list.
2. Study team is sent notification of completion of work
3. Turnaround Time = 2 business days

How to:

Create/Modify User Role in Florence

Email BIDS Florence support actri-florence@health.ucsd.edu requesting the creation or modification of a user role. Include:

- Department name
 - Study IRB if study specific role
 - PI name and contact information
 - Role Permissions worksheet
1. Role creation or changes must follow BIDS CM processes.
 2. Requestor will be sent notification of completion of work
 3. Turnaround Time = 5 business days



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How to:

Requesting changes to Kuali/Florence Integration

Email BIDS Florence support actri-florence@health.ucsd.edu requesting an addition or change to the Kuali/Florence Integration. Include:

- Description of the addition or change
- Justification for change
- PI name and contact information
- Department requesting change

1. Integration modifications must follow BIDS CM processes.
2. Requests for integration changes will be initially evaluated by the BIDS team for risk vs reward as well as resourcing costs. Florence, Inc., entertains changes to integration on a quarterly basis.
3. Successfully vetted requests will trigger a conversation with Kuali and Florence integration teams to develop a SOW and project timeline.
4. Costs incurred for major department specific changes will be incurred by the department at the discretion of ACTRI.
5. Requestor will be sent notification at benchmarks and at completion of work.
6. Turnaround Time = 3 - 6 months minimum turnaround

How to:

Request External Monitor Access Request

1. Submit a BIDS Florence External Monitor request (requested by study team).
2. BIDS Completes the request by Creating the User and Adding the User to study External Monitor role using the requested window of time
3. Study team is sent notification of completion of work
4. User is sent notification to initially login to Florence and create user profile.
5. Turnaround Time = 2 business days

How to:

Request a New Study structure build in Florence

1. Submit a BIDS Florence Study Creation request (requested by study team)
 - Include Department, PI, IRB#, study type, requested structure
 - Optionally include study personnel list with appropriate roles
2. BIDS Completes the request by Creating the User and Adding the User to study External Monitor role using the requested window of time
3. Study team is sent notification of completion of work
4. Turnaround Time = 4 business days



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How to:

Adding a new Departmental Binder in Florence

Email BIDS Florence support actri-florence@health.ucsd.edu requesting the creation of a new department binder. Include:

- New Department name (note: must match Kuali's name)
 - Requesting PI name and contact information
1. Department Binder additions or changes in UCSD Florence must follow BIDS Change Management (CM) processes.
 2. Department Name **MUST** match the department's name in Kuali/IRB.
 3. Requestor will be sent notification of completion of work
 4. Turnaround Time = 5 business days

How to:

Choosing a study folder structure for Florence to use to set up a study

There are seven study folder structures that can be chosen when setting up your study. They are as follows:

1. Feasibility
2. NCI Trial - CIRB as IRB Record
3. Therapeutic Trial - External IRB as IRB of Record
4. Single Patient Investigator-held FDA Application Trial
5. Investigator-held FDA Application Trial
6. Therapeutic Trial - OIA as IRB of Record
7. NonTherapeutic Trial - OIA as IRB of Record

How to:

How to Access Florence Training

Trainings for Florence is provided by the Florence Academy and in the UC Learning Center. A list of trainings (specific to study team role) can be found on the [Training Module Grid/UCLC eCourse URLs](#) chart at the end of this document.

All users accessing the Florence system are required to take their appropriate eBinders training before their account can be created. Training must be completed before users can be added to the system and a completed certificate must be provided when requesting access to the system.

Training Module Grid/UCLC eCourse URLs:

Module Name	Description	Link to Florence Training
E-Regulatory System Certified Electronic Copies course in UCLC	This course is designed for all users that will be using Florence platform.	https://go.ucsd.edu/3Aa7XO4
eTMF Training for Monitors	This is recommended for eTMF Monitors. It includes day-to-day basics specific to monitors, and the Monitor Review Module.	https://academy.florencehc.com/path/etmf-training-for-monitors
eISF Training for Monitors	This is recommended for eISF Monitors. It includes day-to-day basics specific to monitors, and the monitor review module. Both eISF and eTMF versions are identical with the Monitor Review Module as optional in eISF.	https://academy.florencehc.com/path/eisf-training-for-monitors
eTMF Training for Implementation Team	This is recommended for users responsible for both admin tasks and day-to-day tasks and that may also be utilizing the Monitor Review Module feature. This is Florence's most comprehensive training.	https://academy.florencehc.com/path/etmf-training-for-implementation-team
eISF Training for Implementation Team	This is recommended for users responsible for admin tasks and day-to-day tasks. Both eISF and eTMF versions are identical with the Monitor Review Module as optional in eISF.	https://academy.florencehc.com/path/eisf-training-for-implementation-team
Florence Basics for Remote Site Access	This is recommended for site staff members who are being given access to a team. It was renamed from "eTMF Training for Site Users" to "Florence Basics for Remote Site Access" (Nov 8th).	https://academy.florencehc.com/path/etmf-training-for-site-users
eTMF Training for Internal Users	This is recommended for day-to-day Sponsor and CRO users.	https://academy.florencehc.com/path/etmf-training-for-internal-users
eISF Training for Study Staff	This is recommended for site staff members who are using Florence eBinders at their institution.	https://academy.florencehc.com/path/eisf-training-for-study-staff
PI Training for eTMF and eISF	This is recommended for Principal Investigators simply needing to know how to register, find and view documents, and sign them.	https://academy.florencehc.com/path/pi-training-for-etmf-and-eisf
Team Admin Training for eTMF and eISF	This is recommended for admin users responsible for user and role management.	https://academy.florencehc.com/path/team-admin-training-for-etmf-and-eisf
View Only Training for Ancillary Roles	This is recommended for users with ancillary roles or anyone needing to register and view documents and audit trails.	https://academy.florencehc.com/path/view-only-training-for-ancillary-roles