iRIS USER MANUAL: NONDISCLOSURE AGREEMENTS

Integrated Research Information System
Version 2018.12.5

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LOG IN TO iRIS

Go to https://iris.louisville.edu/.

Enter user ID and password.

Click Log In.
PROJECT APPLICATION SHELL

Create a Shell

- Go to My Grants and Contracts.
- Click Add a New Project.

1.0 Title

- Enter the full title of the project.
- Enter a short title for the project.
- Click Save and Continue to Next Section.
2.0 Project Access

2.1—2.2—2.3—2.4

- **Click + Add** in any category to enter personnel who require access to the iRIS project.

- **Search the directory by name and/or department to locate an individual.**
- **Click Select User.** Choose a role if a dropdown menu appears below the name.

  1. **Principal Investigator**: Ultimate responsibility for project design, execution and management. *(This role is authorized to submit iRIS forms.)*
  2. **Project Personnel**:
     A. **Additional Investigators**: Specify Multiple PI, Additional PI, Co-Investigator *(these may submit)*, or Co-PI *(may not submit)*.
     B. **Research Support Staff**: Specify Technician, Other, Other Professional, Postdoctoral Fellow, Graduate Student (GRA), Undergraduate Student or Key Personnel *(these may not submit)*.
     C. **Primary Research Administrator**: Defaults to creator; change as needed *(may not submit)*.
     D. **Other Administrative Personnel**: Specify Additional Research Service Coordinator, Postaward Coordinator, Clinical Trials Coordinator, Clinical Contact, Regulatory Contact, Budgetary Contact *(these may not submit)*.
  3. **Project Contact**: Add all who need to receive system notifications *(may not submit)*.
  4. **Administrative Assistants**: Add anyone who needs editing access *(may submit on behalf of PI).*

- **Click Save and Continue to Next Section.**
3.0 Departments

3.1—3.2

1. Click + Add to enter the department that will house the project’s financial account (chartfield/speedtype). Defaults to PI’s primary appointment. Change as needed. (Search the directory by name/number to locate a department. Check Select, then click Save.)

2. Click + Add to enter all departments involved with the project. Defaults to PI’s primary appointment. (Locate a department. Check Select, then click Save.)

   Mark the department providing the majority of resources as primary.
   - Click Save and Continue to Next Section.
4.0 Shell is Complete

- Screens may vary at this point. Click either Back, Exit Form or Project Management Workspace. (Do not sign or submit the shell.)
NONDISCLOSURE AGREEMENT

Request Creation

Older Projects (Existing PeopleSoft Projects Only)

- Search **My Projects** by proposal number (PeopleSoft number) or project short title to determine if an older project exists in iRIS. If not and if a new form is needed for the project, contact Sponsored Programs Administration about having the project converted.

Create a Nondisclosure Agreement Request

- After a project application shell has been created, navigate to its submissions screen.
- Click **Request Negotiation of Nondisclosure Agreement**.

- Click **Add a New Form**.
1.0 Nondisclosure Agreement Request

1.1 NDA Information

- Enter start and end dates for discussions to be covered by the nondisclosure agreement.
- Click Add a New Row to enter the sponsor and any other external party to the nondisclosure agreement. Include sponsor type, organization/individual names and contact information.

1.2 Purpose

- Choose all applicable purposes for establishing a nondisclosure agreement. Provide details.

1.3 Specifics of Nondisclosure

- Indicate the direction(s) of flow for confidential/proprietary information.
1.4 Upload Sponsor Template

- Click **Add a New Document** to upload sponsor’s template in Word format.

  ![Add a New Document](image)

- Browse to find the document. Enter **Document Title**.
- Enter **Version Number** (begin with 1 and increase incrementally if adding later versions).
- Enter **Version Date** (date of document creation, or if revised, date of latest modification).
- Select **Proposal** for **Category**. Click **Save Document** to return to NDA form.
- Click **Save and Continue to Next Section**.

### Nondisclosure Signoff and Submit

- Click **Signoff and Submit**.
Submission Routing Signoff

- Choose Approve. Enter user ID and password. Click Save Signoff.

Workflow–Submission Tracking

- The Workflow–Submission Tracking screen displays the status of the request. Click Back twice to return to home screen or click Logout.
Glossary

**Budget** Anticipated amount of funding needed for a project.

**Budgeted** Subamounts grouped into separate categories (salary, fringe, travel, etc.).

**Nonbudgeted** Direct and indirect costs combined into a single budget amount.

**Budget entry method** In iRIS, means of budget input into the system.

**Budget module** Fully detailed component that automatically pulls in salary data, performs many calculations and populates forms in the NIH sponsor packet. The module requires certain data entry and therefore may involve duplication of effort if a budget spreadsheet has already been prepared.

**Summary budget** Simple data entry of amounts into budget pools, with no automatic calculations and no population of sponsor packets. However, if the project involves personnel on other than 12-month appointments, the summary budget must be used. A detailed budget spreadsheet needs to be attached.

**Center grant (program project)** Large, multi-project effort that generally includes a diverse array of research activities. See also cooperative agreement.

**Contract** Written agreement whereby an individual, firm, partnership or corporation is to perform certain services requiring professional skill or professional judgment for an agreed-upon price for a specific period of time. The contractor has a specialized knowledge in a particular field and often requires originality, creativity and decision-making abilities. A contract is established for the purpose of obtaining goods and/or services and creates a procurement relationship with the contractor (compare with subaward/subrecipient).

**Contract research organization (CRO)** Entity which provides contracting or management services to the sponsor of a project.

**Cooperative agreement** Type of assistance award used when an activity is technically and/or managerially complex and requires extensive or close coordination between the agency and the awardee. Examples: Research centers, large curriculum projects, multi-user facilities, projects which involve complex subcontracting, construction or operations of major inhouse university facilities and major instrumentation development. See also center grant (program project).

**Cost share** Portion of project costs not borne by the funding agency. It may include effort, matching funds, unrecovered F&A, and in-kind contributions that a recipient makes to an award. In general, cost sharing must be necessary, reasonable and allowable under applicable cost principles; provided for in the approved budget and readily verifiable from the recipient’s records; not paid by the federal government and not included as cost sharing for any other sponsored award.

**Mandatory** Required by sponsor as a condition of obtaining an award. It must be included in the proposed budget; otherwise, the proposal will not be considered by the sponsor.

**Voluntary committed** Resources offered by the university (documented and quantified in the proposal) when not specifically required by the sponsor. If accepted by the sponsor, it becomes a binding commitment which the recipient must provide as part of the performance of the sponsored agreement.

**Date**

**Discussion end** Anticipated end point for discussions covered under a nondisclosure agreement.

**Discussion start** Anticipated beginning point for discussions covered under a nondisclosure agreement.

**Project end** Anticipated end point of a project.

**Project start** Anticipated beginning point of a project.

**Submission due** Point set by sponsor or prime sponsor as the deadline for a proposal application. Enter the deadline time in Eastern (Louisville) time.

**Department** Unit within a UofL college or school with which project personnel are associated.

**Document category** In iRIS, grouping of documents for purposes of organization and searching.

**Award** ACF/CAS, notice of award, amendment, supplement, UBM-13A award summary, contract fully executed

**Closeout**

**Compliance** ADF/COI, IRB, IACUC, human subjects training certification, representations and certifications

**JIT** Other support, F&A rate agreement, detailed
budget, fringe rates

Modication No-cost extension, change in principal/co-/multiple investigator, revised scope of work, budget modification approval, carryover approval, award transfer out, IBED revision request, amendment

Proposal Funding opportunity announcement, letter of intent, proposal clearance form, PCF clinical attachment, TRIA, MIRA, additional signature page, project application, budget, budget justification, scope of work/abstract, F&A waiver approval/sponsor restriction, contract template, protocol, informed consent form, NDA review form, NDA, startup service agreement

Related Memorandum of understanding, membership agreement, facility use agreement, data use agreement, not-funded notification, PI withdrawal request, program income, guarantee/preaward spending request, personal service contract, letter of indemnification, payment/check

Reporting Progress report, financial report, property report, invention report, RPPR–final, PRAM–final

Subrecipient Subaward/contractor determination, subrecipient commitment form, subrecipient risk assessment, executed subaward, amendment, purchased service agreement

Document date Date of document creation/revision, or date of upload.

Document version number Used to differentiate among multiple editions of a document.

Documents, project Forms and documentation needed to review a proposal for submission to sponsor or to begin the negotiation of an award. Examples: Sponsor forms, internal/detailed budget, budget justification, statement/scope of work, letter of intent, subrecipient documents. Draft documents specific to clinical projects: Sponsor’s agreement template or work order, protocol, informed consent form, letter of indemnification (LOI) or facilities use agreement (FUA).

Effort, percent Portion of an individual’s time committed to a specific sponsored project. It is expressed as a percentage of the individual’s total activity for the university during the appointment period (whether calendar, academic or summer).

eProposal In iRIS, dataset encompassing the basic information of a project which may be submitted to a sponsor for funding consideration or may be used to begin agreement negotiations.

FDA device determination letter Letter issued by the FDA indicating if an investigational device study is considered basic physiological research, exempt or not exempt from premarket approval, and the degree of risk posed to study subjects by the device.

Flowthrough Funding which originates with a first-tier sponsor as an award to a second-tier entity, who passes through a portion as a subaward to a third-tier entity.

Indirect (F&A) cost base Portion of direct costs subject to F&A charges.

Indirect (F&A) cost type Basis for calculating the amount of indirect costs (also known as facilities and administrative, F&A, or overhead costs) of a project.

Modified Total Direct Costs (MTDC) Includes: All direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award). Excludes: Equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000. Other items may only be excluded when necessary to avoid a serious inequity in the distribution of indirect costs, and with the approval of the cognizant agency for indirect costs.

Total Costs (TC) Includes: All direct and indirect costs, with no exclusions. F&A is calculated as a percentage of the total project amount.

Example: Determining the maximum amount of F&A to charge when sponsor limits to 10% TC

Step 1: Deduct the allowed F&A percentage from 100% (e.g., 100% - 10% = 90%).

Step 2: Divide the amount of total direct costs in the budget by this percentage to obtain total costs (e.g., $100,000 / .90 = $111,111).

Step 3: Multiply the total costs obtained by the percentage for F&A allowed by the sponsor. This will generate the maximum allowed F&A (e.g., $111,111 * .10 = $11,111).

Step 4: Check the calculation. The total costs minus the total direct costs should equal the amount of the F&A charged to the sponsor (e.g., $111,111 - $100,000 = $11,111).

Total Direct Costs (TDC) Includes: All direct costs of the project. F&A is calculated based upon the full direct cost amount with no exclusions, and is used for:
Industry-sponsored clinical trials with discounted F&A rate (Note: MTDC used when clinical trial sponsor is governmental or non-profit and full federally negotiated rate is charged)

Projects for which governmental or non-profit sponsor has an established, published policy limiting the amount of F&A costs (provide policy documentation/URL)

Exceptions as approved by the EVPRI (via the F&A Cost Burdening Waiver Request)

Off/on campus

Off Property not owned or leased by UofL, including affiliated hospitals and private medical practices.

On Property owned or leased by UofL, including Belknap Campus, university space within Health Sciences Center, and Shelby Campus.

Person month Unit of time for measuring the effort that university personnel (faculty and staff) devote to a specific project. Based on the individual’s institutional appointment type (which may be calendar year, academic year, and/or summer term) it is expressed as calendar months for individuals with 12-month appointments, and as a combination of academic and summer months for individuals with non-12-month appointments.

Personnel category Grouping used in online submission forms.

Senior/key personnel PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition. Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as senior/key personnel.

Non-key personnel Individuals who participate in a project but who do not contribute to its scientific development or execution in a substantive, measurable way, whether or not they receive salaries or compensation under the grant.

Other significant contributor Individual who has committed to contribute to the scientific development or execution of the project, but is not committing any specified measurable effort (person months) to the project. The individual’s contribution is typically presented as "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as other significant contributors. Consultants should be included if they meet this definition.

Project In iRIS, entire dataset representing a grant or contract (compare with study).

Project contribution, percent Represents the contribution that each investigator (PI, Co-I) makes to a project. Based upon an agreement between the project’s PI(s) and Co-I(s), it is used to assign institutional “credit” for a project to individuals, units, departments, schools and/or colleges. Project contribution (which does not necessarily align with percent effort) must total to 100 percent for a project and must be greater than or equal to 1 percent for each individual investigator. Only PIs and Co-Is are eligible for project contribution. In the absence of an entry for project contribution, RIF percentages will be used to distribute institutional “credit” for a project.

Purpose Primary intent or aim of a project.

Research and development

Research (basic and applied) Systematic study directed toward fuller scientific knowledge or understanding of subject studied.

Development Systematic use of knowledge gained from research directed toward production of useful materials, devices, systems or methods, including design and development of prototypes and processes.

Research training Training in research techniques where such activities utilize the same facilities as other research and development activities.

Instruction University teaching and training activities (excluding research training), offered for credits toward a degree/certificate or on a non-credit basis; through regular academic departments or separate divisions such as a summer school or extension division.

Public service Non-instructional/non-R&D services beneficial to individuals and groups external to the university; includes health service projects and community service programs but excludes fee-for-service arrangements (e.g., technical testing).
Other sponsored activity  Work other than research/development, instruction, and public service; includes contracted/fee-for-service arrangements, non-research standard technical testing/services.

Clinical trial  Research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Clinical research and development  Non-interventional or non-prospectively assigned project conducted with human subjects or on human-derived material such as tissues, specimens, and cognitive phenomena (e.g., observational or specimen study, chart review, survey research).

Research infrastructure funds (RIF), percent  Return of a percentage of F&A costs to principal investigators and co-investigators (individual RIF, IRIF) and departments (departmental RIF, DRIF) to support efforts to secure and maintain extramurally funded activities. The percent RIF breakdown is negotiated between a project’s PI(s) and Co-I(s) and determines the distribution of IRIF and DRIF for a project. RIF must total to 100 percent for a project and is limited to PIs and Co-Is.

Role

Additional principal investigator  See multiple principal investigator.

Administrative assistant  In iRIS, anyone not otherwise named as project personnel who needs access to edit a project in the system (e.g., one tasked with clerical entry into the system on behalf of the PI or with project review on behalf of the unit head).

Co-investigator (Co-I)  Key personnel with responsibilities similar to that of a PI on a sponsored project. While the PI has ultimate responsibility for the conduct of a project, the Co-I is also obligated to ensure the project is conducted in compliance with applicable laws, regulations and institutional policy.

Co-principal investigator (Co-PI)  See multiple principal investigator.

Department administrator  Person who provides varied services for a particular department in the administration of a project.

Department approver  Chair, dean or a designee responsible for approving a project on behalf of a department. Specify whether department chair, department chair-scientific reviewer, eProp authorized organizational representative, eProp contract specialist, eProp dean, eProp department chair, eProp division chief, eProp EVPRI, eProp grants management specialist, eProp research dean, scientific reviewer.

Multiple principal investigator  Term used under the NIH multiple PI model to accommodate team-based science and recognize the contributions of team members for projects that do not fit the traditional single PI model. (NSF uses the term Co-PI.) Under the model, one investigator specifically responsible for communication is named the contact principal investigator.

Other administrative personnel  Personnel who provide specialized services in the administration of a project. Specify whether additional research service coordinator, postaward coordinator, clinical trials coordinator, clinical contact, regulatory contact or budgetary contact.

Primary research administrator  Person responsible for overall administration and management of an iRIS project. Defaults to project creator.

Primary research service coordinator  Person responsible for overall coordination of the research activities of a sponsored project.

Principal investigator (PI, also project director, PD)  Individual who has ultimate responsibility for the design, execution and management of a sponsored project.

Project contact  In iRIS, any person who needs to receive system notifications regarding an iRIS project. Defaults to project creator, and others may be added (e.g., PI, research coordinator).

Research support staff  Personnel who carry out the research activities of a sponsored project. Specify whether technician, other, other professional, postdoctoral fellow, graduate student (GRA), undergraduate student or key personnel.

Study author  Individual, group, or organization primarily responsible for the content of a planned study.

Shell  In iRIS, fundamental dataset of a project encompassing the title, assignment of access for personnel, and department involvement.

Site  Location where the activities of a project take place.

Solicitation  Call or request from a funding entity for proposals for sponsored projects or research, typically
### Glossary

<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Sponsor</td>
<td>Patron or funder of a project or research.</td>
</tr>
<tr>
<td>PeopleSoft</td>
<td>Entity making payments directly to UofL.</td>
</tr>
<tr>
<td>Prime</td>
<td>In cases of flow-through funding, top-tier entity from which funding originates.</td>
</tr>
<tr>
<td>Study</td>
<td>In iRIS, entire dataset representing a compliance committee submission (compare with project).</td>
</tr>
<tr>
<td>Study type</td>
<td>Specific design or aim of a clinical project.</td>
</tr>
<tr>
<td>Chart review</td>
<td>Pre-recorded, patient data are used to answer research questions.</td>
</tr>
<tr>
<td>Device study</td>
<td>Medical device is being clinically evaluated, regardless of study design.</td>
</tr>
<tr>
<td>Drug study</td>
<td>Evaluation of the use and effects of drugs in regard to efficacy, toxicity, pharmacokinetics, dose-ranging, effectiveness, safety.</td>
</tr>
<tr>
<td>Observational study</td>
<td>Researcher systematically observes behavior without influencing or interfering with it.</td>
</tr>
<tr>
<td>Other</td>
<td>Project or study design—not otherwise listed here—involving human subjects or human-derived material such as tissues, specimens, or cognitive phenomena.</td>
</tr>
<tr>
<td>Registry</td>
<td>Collection/maintenance of information on individuals who consent to their data being used for future studies.</td>
</tr>
<tr>
<td>Repository</td>
<td>Collection/storage of identifiable specimens from subjects who consent to their data being used for future studies.</td>
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<tr>
<td>Specimen study</td>
<td>Tissue, blood, urine, or other biologically derived material is used for diagnosis and analysis.</td>
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<tr>
<td>Subaward (subrecipient)</td>
<td>Agreement written under the authority of and consistent with the terms of a prime award (grant, contract or cooperative agreement) that transfers a portion of the research or substantive effort to another organization when such expertise is not available with the primary awardee’s institution (compare with contract).</td>
</tr>
<tr>
<td>Submission method</td>
<td>Means by which a project proposal is submitted to sponsor.</td>
</tr>
<tr>
<td>Sponsor portal</td>
<td>Online proposal application. Specify whether FastLane (NSF); iRIS-generated system-to-system (Grants.gov); Proposal Central (government, nonprofit and private grant-making organizations); Grants@Heart (American Heart Association); NIH Assist; Workspace (Grants.gov); Other (describe the portal).</td>
</tr>
<tr>
<td>Email</td>
<td>Electronic mail delivery.</td>
</tr>
<tr>
<td>Paper</td>
<td>Postal or courier delivery.</td>
</tr>
<tr>
<td>Other</td>
<td>Provide details.</td>
</tr>
</tbody>
</table>

#### Submission package, Grants.gov
Mapping of data from iRIS into a Grants.gov online submission form.

#### Submission version
Edition of a project proposition.

#### Continuation
Request for continued funding of a project for which the funding or project period is about to terminate. Such proposals are similar to "new" proposals and must be routed and approved in the same manner.

#### Internal
Used for the purpose of tracking documents that will not result in a funded award. Examples include membership agreements, facility use agreements, data use agreements, memorandums of agreement/understanding.

#### New
Application not previously proposed, or an application that was previously proposed but not funded and either not eligible for resubmission or the PI elects to submit as a new application.

#### Pre-Proposal
Application required by a sponsoring agency in advance of an official proposal which will not result directly in an award. May be used for the purpose of determining eligibility, level of competition, volume of anticipated proposals. May be referred to as a "white paper.”

#### Resubmission
Application that was previously submitted but not funded, and is being updated and resubmitted for consideration.

#### Revision
Application that proposes a change in 1) the sponsoring agency’s financial obligations or contingent liability from an existing obligation, or 2) any other change in the terms and conditions of an existing award.

#### Supplement
Request for (or the awarding of) additional funding for an existing award. Examples include administrative supplements and minority supplements.

#### Transfer
Submission of a proposal requesting transfer of an award from another institution due to the transfer of the PI/PD to UofL.

#### Unrecovered indirect (F&A) costs
When the university’s F&A rate is higher than the rate allowed on an award, the difference between recovered F&A and what would have been recouped if allowed to use the standard F&A rate. Also, because the university does not charge itself F&A, the amount of F&A lost on university cost share.