**Part B**

**UofL MIRA**

* For assistance: 502.852.3788, Sponsored Programs, 300 E Market Suite 300, Louisville KY 40202
* Submit signed Part B MIRA (with completed Part A TRIA if no previous submission) via [iRIS](https://iris.louisville.edu/)
* Instructions at [Part A TRIA & Part B MIRA Instructions](http://louisville.edu/research/common/tria-mira-instructions)

1. Previously Submitted Tracking Number TRIA PCF N/A

2. Negotiator (If Known)

3. Date This Form Submitted to OSPA

PROJECT TITLE

4. Title of Study

5. Protocol or Award Number

PRINCIPAL INVESTIGATOR

6. Principal Investigator (Contact PI if Multiple PIs)

CLINICAL TRIALS WEBSITE

7. ClinicalTrials.gov Registration Number (If Available)

N/A—Registration is not required

KEYWORDS

8. Keywords

PROJECT TYPES

9. Purpose Code

Choose one Purpose Code that best describes this project.

a. Clinical Research (CLR)

*Involves human subjects but not a “clinical trial” by definition (no medical intervention; e.g., observational/  
specimen study, chart review, survey research)*

b. Clinical Trial (CTA)

*Human subjects in a control group and/or group receiving clinical/medical intervention (meds, clinical/medical procedure, device) for clinical condition, who provide informed consent and interact with study personnel. Non-budgeted, industry-sponsored clinical trials*

c. Clinical Trial Research (CTR)

*Clinical trial but set up to report time and effort/budget categories (as for federal grants). If both fixed and per-patient costs, OGMB portion is CTR and OGMN is CTA*

d. Unfunded Collaborative Research (CRES)

*Collaborative research in which no funds are exchanged between University and sponsor (although equipment/material transfer or sponsor personnel may be involved)*

e. Research (RES)

*Default Purpose Code for sponsored activity involving research, development or research training (other than clinical, unfunded collaborative, service, training or other)*

f. Service (SERV)

*Sponsored activity involving UofL service mission (public service)*

g. Training/Education (TRNED)

*Sponsored activity providing education or training to sponsor (e.g., seminars) or meeting a need for training/educating individuals to fulfill community or national need*

h. Other Sponsored Activity:

*Used only if no other Purpose Code is applicable*

10. Award Type

a. Contract

b. Cooperative Agreement

c. Grant

d. Intergovernmental Personnel Agreement

e. Subaward

f. Task Order

g. Other:

FOREIGN COMPONENT

11. Project involves a foreign component (funding, site, etc.)

a. No

b. Yes

FOR OSPA USE

The assigned specialist will determine the following.

12. PCS Code

a. 01 Instruction

b. 01C Instruction\_contract

c. 02 Research

d. 02C Research\_contract

e. 03 Public Service

f. 03C Public Service\_contract

g. 06 Institutional Support

h. 08 Student Financial Aid

Negotiator Signature Date

FIELD OF SCIENCE

13. Indicate ONE NSF-defined Field of Science (FOS) that most closely represents the work in this project. [Additional info](http://louisville.edu/research/common/fos-uofl-forms-updated).

A1 **Computer & Information Sciences**

**Engineering:**

B1 Aerospace/Aeronautical/Astronautical

B2 Bioengineering/Biomedical

B3 Chemical

B4 Civil

B5 Electrical/Electronic/Communications

B6 Industrial/Manufacturing

B7 Mechanical

B8 Metallurgical/Materials

B9 Other:

**Geosciences, Atmospheric & Ocean Sciences:**

C1 Atmospheric

C2 Geological/Earth

C3 Ocean/Marine

C4 Other:

**Life Sciences:**

D1 Agricultural

D2 Biological/Biomedical

D3 Health Sciences

D4 Natural Resources/Conservation

D5 Other:

E1 **Mathematics & Statistics**

**Physical Sciences:**

F1 Astronomy/Astrophysics

F2 Chemistry

F3 Materials

F4 Physics

F5 Other:

G1 **Psychology**

**Social Sciences:**

H1 Anthropology

H2 Economics

H3 Political/Government

H4 Sociology/Demography/Population Studies

H5 Other:

I1 **Other Sciences**

**Non-Science Areas:**

J1 Business/Management

J2 Communication/Communications Technologies

J3 Education

J4 Humanities

J5 Law

J6 Social Work

J7 Visual/Performing Arts

J8 Other:

UNIVERSITY GRAND CHALLENGES

14. Does this project align with a University Grand Challenge area (check one, primary association)?

a. No

b. Empowering Our Communities

c. Advancing Our Health

d. Engineering Our Future Economy

UNIVERSITY RESOURCES

15. University Resources Needed for Project  
(If yes, initialed and dated by Chair and Dean/Designee)

a. Faculty Release from Work Plan Responsibilities

No Yes Chair Initials Date Dean Initials Date

b. Faculty Salary Recovery

No Yes Chair Initials Date Dean Initials Date

c. Supplemental Base or Approved Additional Non-Base Pay

No Yes Chair Initials Date Dean Initials Date

d. Sponsor-Required Cost Share (If yes, fill in details in budget section)

No Yes Chair Initials Date Dean Initials Date

e. University Commitments after Extramural Support is Terminated

No Yes Chair Initials Date Dean Initials Date

f. New Credit Courses, Degree Programs, Centers or Institutes

No Yes Chair Initials Date Dean Initials Date

g. Additional Space or Facilities

No Yes Chair Initials Date Dean Initials Date

h. Facility Modification

No Yes (Check all that apply)

Installation

Equipment Maintenance

Space Renovation

Building Modification

Chair Initials Date Dean Initials Date

i. Other Special Requirements of Department and Unit  
(If yes, attach requirements)

No Yes Chair Initials Date Dean Initials Date

j. Major Equipment (Single Piece at Over $200,000)

No Yes Chair Initials Date Dean Initials Date

Contact Person

Phone

BUDGET TO BE USED FOR PEOPLESOFT CHARTFIELD SETUP

16. Location of Majority of UofL Performance  
(A project is considered on-campus or off-campus dependent on where more than 50% of its salaries and wages are incurred; subcontracts are excluded—Mark one)

a. Belknap Campus *On-Campus F&A Rate*

b. Health Sciences Center (UofL-owned/leased space)  
 *On-Campus F&A Rate*

c. Shelby Campus *On-Campus F&A Rate*

d. Off Campus (Includes hospitals, practice groups, leased space charged directly to project)  
 *Off-Campus F&A Rate*

17. Department ID for Budgeting/Expending Purposes

18.a. Start Date for Entire Budget Period (MM/DD/YY)

MM/DD/YY

b End Date for Entire Budget Period (MM/DD/YY)

MM/DD/YY

19. Budget a. Costs from Sponsor b. Exclusions from F&A c. UofL Cost Share

| *Budget Pool* | *Direct Costs* | *Excluded Costs* | *Description* | | *Cost Share* | *Speed Type* |
| --- | --- | --- | --- | --- | --- | --- |
| Salary & Wages 511000 | 0 | 0 |  | | 0 |  |
| Fringe Benefits 512000 | 0 | 0 |  | | 0 |  |
| Equipment (≥$5K per item) 190000 | 0 | 0 |  | | 0 |  |
| Alt/Renovation (≥100K per) 190000 | 0 | 0 |  | | 0 |  |
| Subawards ≤ $25K 545295\* | 0 | 0 |  | | 0 |  |
| Subawards > $25K 545297\* | 0 | 0 | > $25K on each sub | | 0 |  |
| Supplies & Expense 519000 | 0 | 0  0 | Off-Site Rental  Patient Care‡ | | 0 |  |
| Travel 535000 | 0 | 0 |  | | 0 |  |
| Participant Support  Tuition  Other Scholar/Fellowship 520000 | 0  0  0 | 0  0  0 | Participant Support  Tuition | | 0 |  |
| Total Direct Costs (TDC)† | 0 | 0 |  | | 0 |  |
|  | d. F&A Calculations |  | |  |  |  |
| Direct Cost Base (amount subject to F&A) | 0 |  | | | 0 |  |
| F&A Rate % |  | % | | |  |  |
| F&A Costs 577000† | 0 |  | | | 0 |  |
|  | e. Total Amount |  | | |  |  |
| Total Cost of Project† | 0 |  | | | 0 |  |

**Select F&A Type:** Industry Clinical **Select F&A Base:** Industry Direct Clinical (IDC)

20. Budget Remarks  
Include explanation of cost share, third-party match, non-standard F&A items, direct cost items typically unallowable based on federally negotiated rate agreement (e.g., office supplies, telephones, computers, administrative support).

\* Contact Purchasing Department for consulting agreement requirements prior to starting the project.

† For projects in which the TDC F&A calculation is used, only amounts for TDC, F&A and total project costs are required unless sponsor limits spending to budget categories or requires approval for variances from proposed budget.

‡ Costs for routine and ancillary services. See [NIH patient care policy](http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch19.htm?print=yes&) for details.

See [Indirect Cost webpage](https://louisville.edu/research/common/f-a-indirect-cost) for additional information.

RESPONSIBLE SIGNATORY

21. By signing this MIRA, the undersigned certify that

1. the listed effort is consistent with University policies and procedures and any applicable sponsor/funding agency requirements, current workload assignments, and current (or active) grants and contracts (or that they will revise their respective effort on other projects such that this listed effort is consistent with the preceding);
2. they will abide by the terms and commitments of the award/contract/agreement resulting from this MIRA submission;
3. they have read, understand, and are bound by the University of Louisville’s Conflict of Interest Policies, located at [COI Policies](http://louisville.edu/conflictofinterest/policies) and that they have made all disclosures required by it, if any, and will comply with any conditions or restrictions imposed by the Institution to manage, reduce, or eliminate actual or potential conflicts of interest; further, they certify that they will comply with the University of Louisville’s Conflict of Interest Policies throughout the life of this project and will update the Attestation and Disclosure Form (ADF) whenever new reportable interests occur;
4. they are currently eligible to participate in governmental programs as outlined at [Purchasing Policies](http://louisville.edu/purchasing/policies) and the associated Sanctions Check Policy and should their eligibility change that they will notify Office of Sponsored Programs Administration of such;
5. all project participants represent and warrant that they have never been (a) debarred or threatened to be debarred or (b) convicted or indicted of a crime or otherwise engaged in conduct for which a person can be debarred under Section 306(a) or 306(b) of the Federal Food Drug and Cosmetic Act of 1992 and further agree to promptly notify Office of Sponsored Programs Administration upon becoming aware of any debarment, conviction, threat of such, or indictment against themselves or any affiliated individuals providing services for this project.

The appropriateness of this submission is the responsibility of the PIs, departmental units and academic units (college or school). If an electronic version of the signed MIRA is submitted, it is understood that the MIRA with original signatures (which was scanned and sent electronically) will be maintained by the respective department(s) of academic appointment, college(s) or institutional office(s) that obtained the signatures.

**PRINCIPAL INVESTIGATOR ATTESTATION**

1. I certify that, to the best of my knowledge, the project described in this submission is scientifically sound, ethical, and respects and protects the rights and welfare of human participants in research.
2. I certify the information contained in this application is true, complete and accurate, to the best of my knowledge, and acknowledge that any false, fictitious or fraudulent statements or claims may subject me to criminal, civil or administrative penalties.
3. I agree to adhere to the credential requirements of the respective site(s) at which the research will be conducted (as applicable).
4. I agree to adhere to the compliance policies and procedures and all billing practices of the respective site(s) where the project is being conducted, to comply with all regulations, not to bill any third-party payer for items specifically reimbursed by the sponsor, and to conduct study within guidelines of good clinical practice (as applicable).
5. I understand that I am responsible for the budget specified in this submission and any deficits or uncollectible costs per the Research Handbook.
6. I agree to accept responsibility for the scientific conduct of the project.
7. I agree to provide required progress reports and/or other deliverables as specified in any award/contract/agreement that results from this MIRA submission.
8. I agree to notify Office of Sponsored Programs Administration should any external governmental regulatory entity notify me of an investigation/audit or other inspection/review of the project described in this MIRA submission.

The term affiliated persons includes, but is not limited to, clinical investigators, nurses, technicians and other individuals or parties working on the project or involved with the development or submission of data related to the research study/project.

**UofL PI’S DEPARTMENT CHAIR APPROVAL**

1. I certify for those individuals in my department that the proposed listed effort is consistent with University policies and procedures and the individuals’ work plan assignments within my department.
2. I certify that resources (funding, space, faculty/staff members) are adequate to support or supplement this project.

|  |  |  |  |
| --- | --- | --- | --- |
|  | CONTACT/PRINCIPAL INVESTIGATOR | MULTIPLE PI  CO-INVESTIGATOR  (Key/Add’l Use Separate Page) | MULTIPLE PI  CO-INVESTIGATOR  (Key/Add’l Use Separate Page) |
| Department Number (Used for Dept RIF)1 |  |  |  |
| Department Name |  |  |  |
| Printed Name1,2 |  |  |  |
| Job Title (Include rank)1,2 |  |  |  |
| UofL Employee ID Number1,2 |  |  |  |
| Phone1,2 |  |  |  |
| Email1,2 |  |  |  |
| Street Address |  |  |  |
| City, State, Zip |  |  |  |
| Percent Effort on Project1,2 |  |  |  |
| [Percent RIF](https://louisville.edu/research/common/project-contribution) (*formerly Collaboration*—Cumulative 100%)1 |  |  |  |
| [Percent Project Contribution](https://louisville.edu/research/common/project-contribution) (Cumulative 100%)1 |  |  |  |
| FOR OSPA USE—Individual RIF Code |  |  |  |
| FOR OSPA USE—Departmental RIF Code |  |  |  |
| Percent if VA Appointment1 |  |  |  |
| I acknowledge that I am in compliance with the UofL Conflict of Interest Policy and have a current Attestation & Disclosure Form (ADF) on file with the COI Program 1,2 |  |  |  |
| **Signature of PI, MPI or Co-I**1,2 |  |  |  |
| Date1,2 |  |  |  |
| Signature of Division Chief (If applicable)1 |  |  |  |
| Printed Name1 |  |  |  |
| Date1 |  |  |  |
| **Signature of Department Chair or Unit Head**1 |  |  |  |
| Printed Name1 |  |  |  |
| Date1 |  |  |  |
| **Signature of Dean or Unit Head**1 |  |  |  |
| Printed Name1 |  |  |  |
| Date1 |  |  |  |

1Required for principal investigators/co-investigators 2Required for other individuals [Click here for additional signature page](http://louisville.edu/research/common/pcf-mira-addsig)