**Part A**

**UofL TRIA**

* For negotiator assignment/review (prior to IRB submission/signed Part B MIRA/agreement execution)
* For assistance: Sponsored Programs, 300 E. Market, Suite 300, 502.852.3788 or [email](mailto:ospa@louisville.edu)
* Submit via [iRIS](https://iris.louisville.edu)
* Instructions at [Part A TRIA & Part B MIRA Instructions](http://louisville.edu/research/common/tria-mira-instructions/#_Toc338767888)

1. Tracking Number (Assigned by OSPA)

2. Negotiator (Assigned by OSPA)

3. Date This Form Submitted to OSPA

**PROJECT TITLE**

4. Title of Study (Include protocol number if sponsored)

**PRINCIPAL INVESTIGATOR**

5. Principal Investigator (Contact PI if Multiple PIs)

a. Name

b. UofL Employee ID

c. Email Address

d. Telephone Number Fax Number

e. Street Address

f. City State Zip

g. Primary ACAP Department Name

h. Primary ACAP Department Number

**CHECKLIST**

6. Attachments to this TRIA Submission

REQUIRED

a. Proposed Clinical Trial Agreement (CTA), Material Transfer Agreement, Equipment Loan Agreement, etc.

or use UofL Template for CTA, MTA, etc.

b. Copy of Protocol (Enter Protocol Number):

c. Non-Disclosure Agreement (if signed ONLY by PI but not by OSPA)

N/A—No NDA requested by sponsor

N/A—Signed by OSPA (Enter tracking number at right)

RECOMMENDED

d. Draft Research Budget (if available)

e. Draft Informed Consent & Research Authorization (HIPAA) Form (if available) *Inconsistencies between versions may delay contract signature. THIS DRAFT IS TO PRECEDE FINAL VERSION FOR IRB REVIEW.*

**PERIOD OF PERFORMANCE**

7.a. Expected Start Date of Project (REQUIRED—MM/DD/YY)

MM/DD/YY

b. Expected End Date of Project (REQUIRED—MM/DD/YY)

MM/DD/YY

**PRELIMINARY BUDGET INFORMATION**

8.a. External Funds Expected

No  IOGM Yes (Choose one)

OGMB—Budgeted into separate categories

OGMN—Non-categorized budget

b. Anticipated F&A Rate

c. Anticipated Total Budget

d. Financial Department Name

e. Financial Department Number

Payment Address If Different From PI’s  
f. Street Address

g. City State Zip

9. Support for a sponsored project may be in a form other than monetary. Check any that apply to this project:

a. ▪ Loan of equipment or in-kind materials, OR

▪ Sponsor supplying device, drug, equipment, compounds, proprietary software, personnel or other resources

No  Yes

b. Progress, technical, final reports or other deliverables are required, excluding stewardship reports on gifts

No  Yes

**PREVIOUS RELATED PROJECTS OR AGREEMENTS**

10. IOGM, OGMN, or OGMB Number(s) of Related Projects

**SPONSOR**

11. Sponsor

a. Payments to ULRF directly from this entity

No  Yes

b. Organization Name

c. URL

d. Address

e. City State Zip

Identify contract negotiator for non-governmental entities.

f. Contact’s Name

g. Contact’s Title

h. Contact’s Email Address

i. Contact’s Telephone Number Fax Number

12. CRO or Intermediary

a. Payments to ULRF directly from this entity

No  Yes  N/A (No CRO/Intermediary)

b. Organization Name

c. URL

d. Address

e. City State Zip

Identify contract negotiator for non-governmental entities.

f. Contact’s Name

g. Contact’s Title

h. Contact’s Email Address

i. Contact’s Telephone Number Fax Number

**PRIMARY CONTACTS FOR PROJECT**

13. Clinical Contact

a. Name

b. UofL Employee ID

c. Title

d. Email Address

e Telephone Number Fax Number

14. Regulatory Contact

Check if same as Clinical Contact

a. Name

b. UofL Employee ID

c. Email Address

d. Telephone Number Fax Number

15. Pre-Award Budget Contact

a. Name

b. UofL Employee ID

c. Email Address

d. Telephone Number Fax Number

16. Post-Award Budget Contact

Check if same as Pre-Award Budget Contact

a. Name

b. UofL Employee ID

c. Email Address

d. Telephone Number Fax Number

17. Other (Please list any other individual who should be copied on correspondence)

a. Name

b. UofL Employee ID (if applicable)

c. Title

d. Department (or Organization if not UofL)

e. Email Address

f. Telephone Number Fax Number

**PROJECT CHARACTERISTICS**

18. “Compassionate Use” FDA Treatment IND

No  Yes (Attach FDA determination letter)

19.a. FDA-Approved Drug/Device for Indication

No  Yes  N/A

b. Drug/Device Name

20. Initiator of Study (Check all that apply)

a. Investigator

b. Sponsor

c. Cooperative group

d. Other:

21. Multicenter Study

No  Yes

22. Phase of Study (FDA/NIH phase may differ—mark both)

a. FDA I  NIH I

b. FDA II  NIH II

c. FDA III  NIH III

d. FDA IV (post marketing)

e. N/A

23. Protocol Author (Check all that apply)

a. Investigator

b. Sponsor

c. Cooperative group

d. Other:

24. Study Type (Check all that apply)

a. Drug study

b. Device study (Attach FDA determination letter)

i. Premarket Application (PMA)

ii. Premarket Notification 510(k)

c. Chart review

d. Observational study

e. Specimen study

f. Registry of data or information

g. Repository of tissue or biological samples

h. Other:

25. Transfer of Biological/Chemical Materials (Human and/or non-human)

No  Not received or sent Yes (Check all that apply)

Being received from others

Being sent to others

**COMPLIANCE COMMITTEES**

26. UofL Participant(s) Will Be Directly Involved With

Committee No. Approval Date (or Pending)

a. Humans as Subjects

No  Yes IRB:

IRB of Record:  UofL  WIRB  Other:

b. Experimental Animals

No  Yes IACUC:

c. Radioisotopes

No  Yes RSO:

d. Recombinant DNA

No  Yes IBC:

e. Pathogenic Organisms

No  Yes IBC:

f. CDC/USDA Select Agents

No  Yes IBC:

g. Human Blood, Tissues, Cell Lines, OPIM

No  Yes IBC:

h. Highly Toxic, Carcinogenic, Mutagenic Agents

No  Yes DEHS:

Note: PI is responsible for complying with university safety rules, policies and procedures. Documentation of institutional approval for actions pending at time of proposal must be provided prior to activation of award.

**ANCILLARY CONTRACTS**

27. Ancillary Contracts To Be Issued

List any ancillary contracts needed, such as procurement contracts to organizations that will provide services or receive payments from ULRF for this project. See also the Purchasing Department’s [Personal Service Contracts](https://louisville.edu/purchasing/pscs) for more information.

(New recipients must complete New Vendor Survey Form <http://louisville.edu/finance/controller/acctops/forms/vendorsurveyinstr>   
and W-9 <http://www.irs.gov/pub/irs-pdf/fw9.pdf>)

a.i. Consultant/Organization Name

ii. Contact Information

b.i. Consultant/Organization Name

ii. Contact Information

c.i. Consultant/Organization Name

ii. Contact Information

**SITE FACILITIES AND RESOURCES ● PLACES ● INFORMATION ● PEOPLE ● ITEMS**

| 28. Study Sites | i. Facility/ Department Use | ii. Confidential Information | iii. Perform Research Services | iv. Equipment/ Drug/Device |
| --- | --- | --- | --- | --- |
| * *Check all applicable involvement.* * *Only check entities likely to be used.* * *Except for UofL (first site), a services agreement may be required by facility.* * *Approval by study site is required.* | *Project (or portion of it) will be performed in facility, within specific department(s)—If space only is provided, select “Other” and so state* | *Facility personnel will have access to sponsor’s confidential information* | *Facility personnel will perform project research services— Contact facility for research pricing* | *Sponsor-provided/ loaned drug, device, equipment, compounds, software or other resources will be used or housed in facility* |
| a. UofL Facilities (FWA 00002211) *Building Room*  UofL-owned/leased HSC  Belknap Campus  Shelby Campus  UofL Clinics (e.g., CTU) | Blood Bank  Cath Lab  Laboratory  Nutrition  Pathology  Pharmacy  Phys Ther  Radiology  Resp Ther  Other |  |  |  |
| b. UofL Health (FWA 00002163)  Frazier Rehab Institute  James Graham Brown Cancer Center (BCC)  Jewish Hospital  Mary & Elizabeth Hospital  Medical Centers  Peace Hospital  Rudd Heart & Lung Center  Shelbyville Hospital  UofL Hospital (CCB)  UofL Physicians (ULP)  Other, address: | Blood Bank  Cath Lab  Laboratory  Nutrition  Pathology  Pharmacy  Phys Ther  Radiology  Resp Ther  Other |  |  |  |
| c. Norton Healthcare Facilities (FWA 00002217)  Norton Brownsboro  Norton Children’s Hospital  Norton Children’s Med Ctr Brownsboro  Norton Hospital  Norton Physician Practices  Norton Women's & Children’s St. Matthews  Novak Center  Other, address: | Blood Bank  Cath Lab  Laboratory  Nutrition  Pathology  Pharmacy  Phys Ther  Radiology  Resp Ther  Other |  |  |  |
| d. VA Medical Center–address:  (Requires separate submission to VA) | Blood Bank  Cath Lab  Laboratory  Nutrition  Pathology  Pharmacy  Phys Ther  Radiology  Resp Ther  Other |  |  |  |
| e. Other sites—with contact information, address: | Blood Bank  Cath Lab  Laboratory  Nutrition  Pathology  Pharmacy  Phys Ther  Radiology  Resp Ther  Other |  |  |  |