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# MIRA
## TITLE OF STUDY

**PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR (PI/PD) INFORMATION**

**Institutional Address:**

Name

UOFL ONLY – UofL Employee Id

Title

Primary Department Name

E-mail Address

Telephone Number

Pager/Cell Phone Number

Fax Number

Expected Start-Up Date

**Check each site (below) where you will conduct research:**

**University of Louisville Hospital** (FWA 00002163)
- UofL Hospital (CCB) _
- James Graham Brown Cancer Center (BCC) _

**UofL Facilities**
- Ambulatory Care Building (ACB) _
- Other UofL Health Sciences bldgs _
- Belknap Campus buildings _

**VA Medical Center** – Requires separate submission to VA _

**Norton Healthcare Facilities** (FWA 00002217)
- Norton Hospital _
- Kosair Children's Hospital _
- Audubon Hospital _
- Southwest Hospital _
- Suburban Hospital _
- Norton Physicians Practice _
- Physician Leased Space in Norton Facilities _

**Jewish Hospital Healthcare Facilities** (FWA 00002167)
- Jewish Hospital _
- Frazier Rehab _
- Clark Memorial Hospital _
- Jewish Medical Center East _
- Jewish Hospital Shelbyville _
- Other JHHS site: _

**Other Site(s) where you will conduct research: (Attach Contact Information)**

_

_

**PRIMARY CONTACT FOR CORRESPONDENCE (Complete if different from PI/PD)**

**Institutional Address:**

****Budget/Business Contact****

Name

UOFL ONLY – UofL Employee Id

Title

Primary Department Name

E-mail Address

UOFL Only – PeopleSoft Dept Number of budget contact

Telephone Number

Pager/Cell Phone Number

Fax Number

****Regulatory or Clinical Contact****

**Institutional Address:**

Name

UOFL ONLY – UofL Employee Id

Title

Primary Department Name

E-mail Address

UOFL Only – PeopleSoft Dept Number of clinical contact

Telephone Number

Pager/Cell Phone Number

Fax Number

☐ **I have submitted a copy of this application and attached paper work to each of the sites listed above. OIC does not have to submit any paperwork on my behalf.**

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## TITLE OF STUDY

**STUDY INFORMATION:** Check all that apply in each column (below): **Multi-center study?** Yes ☐ No☐ **Compassionate use?** Yes ☐ No☐

| Initiator of study: | Author of protocol: | Type of study: | Funding source(s): | |
|---|---|---|---|---|
| ☐Investigator | ☐Investigator | ☐ Drug study | ☐Industry | ☐ Not funded |
| ☐Sponsor | ☐Sponsor | ☐ Device study | ☐Government | ☐ Internally supported by UofL, JHHS, NHC or UofL Hospital |
| ☐Cooperative group | ☐Cooperative group | ☐ Chart review | ☐Cooperative group | |
| | | ☐Observational | ☐Foundation | |
| | | ☐ Specimen study | | |
| ☐Other _____________ | ☐Other _____________ | ☐Other _____________ | ☐Other _____________ | |

**For submissions to Agencies/Sponsors:**

1. Sponsor's Deadline Date: Target ☐ Postmark ☐ or Receipt: ☐ / / ________________

   Enter Agency/Sponsor's program name/identifying number (typically used by federal agencies)

2. Name of Program __________________ Agency Program Num (RFA/RFQ/PA): _____________ If applicable: CFDA Num: ___________

**SPONSOR CONTACT INFORMATION** **(Complete if externally sponsored)** ☐ Not applicable

☐ Check if funding for study will come from this entity.

Address:

Name

Sponsor Name

Title

Address Line 1

E-mail Address

Address Line 2

Telephone Number

Fax Number

City State Zip

**Coordinating Research Organization (CRO) CONTACT INFORMATION** **(If applicable)** ☐ Not applicable

**(or enter AGENCY (e.g. NIH) if federal or state flow through)**

☐ Check if funding will come via this entity rather than above entity.

Address:

Name

CRO/Agency Name

Title

Address Line 1

E-mail Address

Address Line 2

Telephone Number

Fax Number

City State Zip

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**MIRA**
# SIGNATURE PAGE

**TITLE OF STUDY** ____________________________________________

____________________________________________

**Complete this boxed section if you are a UofL Principal Investigator/Project Director**

**Publication Rights Exception – Public reporting option**

**Yes** ☐

**No** ☐

This is a multi-center/multi-site clinical study which is sponsor-initiated and has a sponsor authored/developed protocol. The research will not involve a substantial effort by residents or students. I do not intend to publish and am requesting an exception to the University's policy requiring the sponsor to provide me the opportunity to publish results from this study. I understand that approval of this exception of publication rights is contingent upon the approval of my department chair and the sponsor's willingness to agree to make the clinical trial/study results public within two years of completion of the study. **See Publications Rights Exception for additional information.**

**Intellectual Property Rights Exception**

**Yes** ☐

**No** ☐

This is a multi-center/multi-site study with a sponsor authored/developed protocol. I am willing to waive my rights in any intellectual property I may have under University policy that I might develop while performing this study and agree to execute the appropriate documents to convey any rights I may have under University policy to the sponsor. Further as Principal Investigator/Project Director, I agree to obtain a similar waiver statement from any others performing activities for this clinical trial/study prior to execution of the resulting agreement. **See MultiCenter Sponsor Developed Clinical Trial IP Waiver for additional information.**

**PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR – REQUIRED FOR SUBMISSION:**

- I certify that, to the best of my knowledge, this proposal is scientifically sound, ethical, and respects and protects the rights and welfare of human participants in research.
- I certify the information contained in this application is complete and true, to the best of my knowledge.
- I agree to adhere to the credential requirements of the respective site(s) at which the research will be conducted.
- I agree to adhere to the Compliance Policies & Procedures and all billing practices of the respective site(s) where the research 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.

NAME (PRINTED): ____________________________________________

SIGNATURE: ______________________ DATE: ______________________

TITLE: ____________________________________________

**DEPARTMENT CHAIR APPROVAL FOR UOFL FACULTY ONLY - *REQUIRED IF EITHER BOX IS CHECKED YES ABOVE***

☐ I approve the exceptions from normal policy checked above by the PI/PD regarding intellectual property and/or publication rights.

☐ I certify that resources (funding, space, faculty/staff members) are adequate to support or supplement this research project.

NAME (PRINTED): ____________________________________________

SIGNATURE: ______________________ DATE: ______________________

TITLE: ____________________________________________

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|---|
| Tracking Control Number________________ |

**MIRA**

# BILLING COMPLIANCE/RESOURCE TABLE

**TITLE OF STUDY** ______________________________________________

**Instructions:** Protocol "procedures" are defined as all items, procedures, products, services, professional fees etc. required by the research protocol. List each protocol-required "procedure" that will be performed at the facility in Column 1. Mark the responsible party in "Bill To" Column 2. *****Important *** If you are billing insurance for a specific study related "procedure," the procedure must qualify as Standard of Care (SOC) in order to be considered for reimbursement by insurance. Standard of care (routine costs) are items or services that are typically provided in the treatment of the patient absent the research study. Please note that if the "procedure" is considered SOC and is being paid for, provided by or covered by the sponsor or another non-insurance source, then the procedure is not eligible to be billed to Insurance.** List in Column 4 the appropriate time point (e.g. initial enrollment, day 5 of hospitalization, visit 2, final visit) during the study for which the procedure takes place. Please make additional copies of this form if additional space is required.

**IND #** [ ] **IDE #** [ ] **IDE CATEGORY** [ ] **Not Applicable** [ ]

List each protocol-required procedure under the "procedure" box, mark the responsible party in the "bill to" box and mark the appropriate site the procedure will take place in the "site" box. Please refer to the following examples:

| (Column 1) | (Column 2) | (Column 3) | (Column 4) | (Column 5) |
|---|---|---|---|---|
| **Procedure** | **Bill To:** | **Site of Procedure** | **Time Point** | **Admin Use Only** |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |
| | Insurance<br>Research Program<br>Sponsor<br>Other __________ | Hospital<br>Private Practice<br>UPA<br>Other _____________ | | CDM:<br><br>Research Charge |

**Please attach study calendar.**
**Adjust the size of this table as needed to reflect all of the procedures that will be done as part of the study protocol. Use additional sheets, if needed.**

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# MIRA
## CONFLICT OF INTEREST DECLARATION (FOR JHHS, NHC & U of L Hospital)

- **This page must be copied & completed by all personnel who are directly involved in the treatment or evaluation of research subjects.**
- **You must answer all questions & explain any questions answered yes.**
- **In accordance with the federal regulations, "You" is defined to include a spouse, each dependent child and partnership interests.**
-

YES ☐ NO ☐ Is your compensation affected by the outcome of the clinical study? Check any of the following that do or could apply to your compensation and fully explain any "yes" response.

☐ Compensation tied to sales of product, such as royalty interest
☐ Compensation could be higher for favorable outcome or result
☐ Compensation in the form of equity interest in the sponsor of the study
☐ Other ________________________________________

Explain:________________________________________

YES ☐ NO ☐ Are there incentive programs being offered based on patient accrual (escalating payments, equipment gifts, other)? Please Explain:________________________________________

YES ☐ NO ☐ Do you have an equity interest in the sponsor of the study? (excluding mutual funds)

☐ Ownership interest Amount ________________ Dollar Value ______________
☐ Stock options Amount ________________ Dollar Value ______________
☐ Other______________________ Amount ________________ Dollar Value ______________

YES ☐ NO ☐ Do you have a proprietary or financial interest in the test product?

☐ Patent Amount ________________
☐ Trademark Amount ________________
☐ Copyright Amount ________________
☐ Licensing agreement Amount ________________
☐ Other Proprietary Interest Amount ________________ Type __________________

YES ☐ NO ☐ Will/have you receive(d) payment of another sort from the sponsor? (This does not include the cost of conducting clinical studies.)

☐ Grant for ongoing research Amount ________________
☐ Equipment Amount ________________
☐ Retainer for ongoing consultation Amount ________________
☐ Honoraria Amount ________________
☐ Other payment/compensation Amount ________________ Type ___________________

**Study Title** ________________________________________

**Study Sponsor** ________________________________________

**Research Personnel's Title** ______________________________**Printed Name**________________________________

By signing below, you certify that the above information is complete and accurate. If any change occurs regarding the information required in the above declaration during the course of the study and/or for one year following completion of the study, you further certify and agree to promptly update the above information.

**Research Personnel's Signature** ________________________________________**Date:** ____________________

CC: Compliance

# MIRA
## UOFL SPECIFIC PAGES

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1. This is for a: ☐ CLINICAL TRIAL ☐ CONTRACT (SRA/SERVICE) ☐ CO-OP AGREEMENT ☐ GRANT ☐ LICENSE ☐ SUBCONTRACT ☐ OTHER ______________

2. This is for a: ☐ AMENDMENT ☐ NEW ☐ COMPETING CONTINUATION ☐ SUPPLEMENTAL ☐ TRANSFER ☐ SBIR _______ ☐ STTR _______ ☐ OTHER ___________________

   If an amendment, continuation, renewal, or supplement of an existing grant/contract/project/study; please indicate previous GRNT# ________________

3. Project Purpose is: ☐ CLINICAL TRIAL ☐ RESEARCH ☐ UNFUNDED COLLABORATIVE RESEARCH ☐ TRAIN/EDUCATION ☐ OTHER SPONSORED ACTIVITY ☐ STUDENT AID ☐ SERVICE

4. Was the UofL Development Office involved in obtaining funding/donations for this project? ☐ Yes ☐ No
   If yes, please identify who assisted: ________________________________

5. If this research is being conducted through a Board of Trustees approved center/institute, please name it:

6. BUDGET PERIOD (Month/Day/Year) From: _____ / _____ / ______ To: _____ / _____ / ______

   PeopleSoft Department ID for Expending Funds if Awarded: ____________________

| SPONSOR Requested Amount | | Budget Category | U of L Cost Share Amount | | Speed Type | |
|---|---|---|---|---|---|---|
| ________ | | Salaries/Wages | ________ | / | ________ | |
| ________ | | Fringe Benefits | ________ | / | ________ | |
| ________ | | Tuition/Scholarship | ________ | / | ________ | |
| ________ | | Equipment >=$5K | ________ | / | ________ | |
| ________ | | Supplies & Expenses | ________ | / | ________ | |
| ________ | | Travel | ________ | / | ________ | |
| ________ | | Patient Care Costs | ________ | / | ________ | |
| ________ | | Subcontracts/ Consultants | ________ | / | ________ | List in 7 below |
| ________ | | Other | ________ | / | ________ | Specify |
| ________ | + | **SUBTOTAL (5000 pool)** | ________ | | | |
| ________ | + | F&A Costs % | ________ | | | |
| ________ | + | **TOTAL Costs** | ________ | | | |

+ For industry sponsored funding (with the exception of federal flow through which requires budget categories), only these lines are required unless sponsor limits spending to budget categories or requires approval for variances from proposed budget.

BUDGET REMARKS: (Including third party cost sharing) (Identify detail about per patient costs for clinical trials below.)

7. List consultants or specify subcontracts to be issued (Costs included in Supplies & Expenses above):

| Consultant or Organization Name | If Subcontract, provide PI/Contact Name | Requested Cost for Current Year | Anticipated Cost for Remaining Years |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

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8. Will project use: (Click here for corresponding web address: research.louisville.edu/compliance-contacts.htm)

| | | | | | |
|---|---|---|---|---|---|
| a. Humans as subjects | ☐ No | ☐ Yes | Approval Date ________ | UHSC# | ________ |
| b. Experimental Animals? | ☐ No | ☐ Yes | Approval Date ________ | IACUC# | ________ |
| c. Ionizing radiation devices/isotopes? | ☐ No | ☐ Yes | Approval Date ________ | | ________ |
| d. Recombinant DNA? | ☐ No | ☐ Yes | Approval Date ________ | | ________ |
| e. Toxic, carcinogenic, mutagenic agents? | ☐ No | ☐ Yes | Approval Date ________ | | ________ |
| f. Pathogenic organisms? | ☐ No | ☐ Yes | Approval Date ________ | | ________ |
| g. CDC/USDA Select Agent? | ☐ No | ☐ Yes | Approval Date ________ | | ________ |

**NOTE: YOU ARE RESPONSIBLE FOR COMPLYING WITH UNIVERSITY SAFETY RULES, POLICIES AND PROCEDURES.**

9. The University needs to report expenditures using the federal government categories listed below, please **indicate ONE area** that most closely represents the work in this project. Only those most applicable are included below. Supply your category in the Other space if it is not listed.

**Engineering**: ☐ Bioengineering/Biomedical (FOS-A2) ☐ Chemical (FOS-A3) ☐ Other, specify

**Life Sciences:** ☐ Biological (FOS-F2) ☐ Medical (FOS-F3) ☐ Other, specify ________
☐ **Psychology** (FOS-G1) ________

**Social Sciences:** ☐ Sociology (FOS-H3) ☐ Other, specify
☐ **Other sciences:** ________ ________

**Non-Sciences Areas:** ☐ Social work (FOS-J7) ☐ Other fields, specify ________
☐ **Computer Sciences** (FOS-E1)

10. List Keywords ____________________________________________

11. Review the following and indicate any that involve UofL resources: (**If Yes**, please initial and date.)

A. Any faculty release, salary recovery?
☐ Yes ☐ No Authorized by Chair ________________ / ________

B. Extra compensation? (Overload, consulting, etc.)
☐ Yes ☐ No Authorized by Chair ________________ / ________ **AND** Dean ________________ / ________

C. Required cost share. If yes, fill in details in budget section.
☐ Yes ☐ No Authorized by Dean ________________ / ________

D. Does project require University commitments after extramural support is terminated?
☐ Yes ☐ No Approved by Dean ________________ / ________

E. New credit courses, degree programs, centers or institute?
☐ Yes ☐ No Approved by Dean ________________ / ________

F. Is additional space of facilities needed? ☐ Yes ☐ No

**Project will be performed:** If yes, attach plan. Approved by Dean ________ / ________

**MARK ONE:** ☐ **Belknap** ☐ **HSC** ☐ **Shelby** ☐ **Off Campus** **BLDG/RM#** ________________

G. Will ☐ installation, ☐ equipment maintenance, ☐ space renovation, or ☐ building modification be required?

Check type and attach plan. ☐ Yes ☐ No Approved by Dean ________________ / ________

H. Are there other special requirements of department and unit?

☐ Yes ☐ No Approved by Dean ________________ / ________

I. Major equipment: single piece at over $100,000?
☐ Yes ☐ No Contact person ________________ Phone # ________

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12. **Responsible Signatory:** By signing below, you confirm (1) that the proposed effort is consistent with University regulations, current workload agreements, and current (or active) grants and contracts; (2) that you will abide by and honor the terms and commitments of this project; (3) that you understand that you are responsible for the budget specified above and any deficits or uncollectible costs per sections 6.4 and 6.9 of the Research Handbook.

    _ PI/PDs, Co-Investigators/Project Directors further certify that you have read, understand, and are bound by the University of Louisville's Conflict of Interest Policy, (which is located at http://www.ori.louisville.edu/SFI/SFI-index.htm ) and that you have made all financial 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, you certify that you will comply with the University of Louisville's Conflict of Interest Policy throughout the life of this project and will update the Disclosure of Significant Financial Interests whenever new reportable Significant Financial Interests occur.

    _ The appropriateness of this project is the responsibility of the principal investigator/project director, departmental unit, and unit (e.g., College or School). Signatures indicate that all information on this form is accurate.

| | **PI/PD** (from page 1) | CO-INVESTIGATOR/DIRECTOR | CO-INVESTIGATOR/DIRECTOR |
|---|---|---|---|
| PeopleSoft Dept Num for Dept (Used for Dept RIF) | | | |
| Typed/Printed Name | | | |
| Job Title (include Rank) | Supplied on pg 1 | | |
| UofL Employee ID Number | Supplied on pg 1 | | |
| Phone | Supplied on pg 1 | | |
| E-mail | Supplied on pg 1 | | |
| Percent Effort on Project: | | | |
| Percentage Collaboration (equals 100%) (For calculating RIF's only) | | | |
| If appointment with US Dept Veterans Affairs/VA Hospital, specify percent | | | |
| **Signature of PI/PD or CO-PI/PD** | | | |
| Date | | | |
| **Signature Division Chief (if applicable)** | | | |
| Typed/Printed Name | | | |
| Date | | | |
| **Signature Department Chair or Appropriate Unit Head** | | | |
| Typed/Printed Name | | | |
| Date | | | |
| **Signature Dean or Appropriate Unit Head** | | | |
| Typed/Printed Name | | | |
| Date | | | |

**13. Total # of Other Personnel:** _______ Click here, to list additional individuals engaged in the sponsored activity/research

| For Internal Use | **Grants Management/Industry Contracts** |
|---|---|
| **Signature** | |
| Typed Name | |
| Date | |

| Confidentiality Restrictions | Tuition | Flow through: Fed State CRO Other |
|---|---|---|
| | | |