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| **UofL PROPOSAL CLEARANCE FORM** | [INSTRUCTIONS](http://louisville.edu/research/common/pcf-instructions) for filling out this form are available on our web page.If problems filling out this form, call Sponsored Programs (852-3788), Industry Engagement (852-7253) or Clinical Contracts (852-8359) for assistance. | Revised 07/01/2017 |

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| PCF# | Office Use Only:  | Please indicate the person who can respond to questionsabout this proposal: | NAME |       |
| EMPLID |       |
| Date |  | PHONE |       |
| E-MAIL |       |

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| Sponsor’s Deadline Date: | [ ]  Target  | [ ]  Receipt  | NOTE: SIGNED PCF REQUIRED PRIOR TO ELECTRONIC SUBMISSION |
|     /    / 2018 | [ ]  Postmark  | [x]  Electronic  |

**ALLOW 5 FULL BUSINESS DAYS FOR PROCESSING OF ALL PROPOSALS**

**All grant/contract proposals must be approved** by Sponsored Programs Administration, Industry Engagement or Clinical Contracts **before submission** to outside entities and are to be received by SPA/OIE/CCD **5 full business days prior to the sponsor’s submission deadline date**. **Complete all sections** except areas marked “Office Use Only.” **Include completed additional forms as required. Obtain signatures** of appropriate department chair(s), dean(s), or unit head(s). For proposals not required to be submitted by the institutional signing official, **the PRINCIPAL INVESTIGATOR is responsible for sending the proposal** to the sponsor by the deadline unless prior arrangements have been made.

|  |  |
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| 1. PROJECT TITLE: |       |

|  |  |  |  |  |
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| 2. UofL PERSONNEL ONLY: | PRINCIPAL INVESTIGATOR (OR CONTACT PI IF MULTIPLE PIs) |  | [ ]  MULTIPLE PI[ ]  CO-INVESTIGATOR |  |
| Name: |       |  |       |  |
| Employee ID Number: |       |  |       |  |
| ACAP Department Name: |       |  |       |  |
| ACAP Department Number: |       |  |       |  |
| Division: |       |  |       |  |
| E-Mail: |       |  |       |  |
| Phone: |       |  |       |  |
| % Effort on Project: |       |  |       |  |
| % Collaboration (for RIF/unit reporting): |       |  |       |  |
| US Dept Veterans Affairs/VA Hosp appt amt / % |       |  |       |  |

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| [Click here to list all other UofL participants on the grant.](http://louisville.edu/research/common/pcf-mira-addsig) |

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| 3.a. PEOPLESOFT SPONSOR (Payments directly from this entity): Federal **[x]** State **[ ]**  |
|  | Peer Reviewed: Yes **[x]** No **[ ]**  |  | **Complete sponsor contact’s information for non-governmental entities.** |
|  | National Institutes of Health |  |       |
|  | Organization Name |  | Contact’s Name |
|  | https://grants.nih.gov/grants/guide/pa-files/PA-18-344.html |  |       |
|  | URL  |  | Contact’s Title |
|  |       |  |       |
|  | Address  |  | Contact’s E-mail Address |
|  |                   |  |             |
|  | City State Zip |  | Contact’s Telephone Number Fax Number |
|  b. PRIMARY SPONSOR IF FLOW-THROUGH (No direct payments from this entity): |  |
|  | Check if not applicable [x]  |  |  |
|  |       |  |       |
|  | Organization Name |  | Contact’s Name |
|  |       |  |       |
|  | URL |  | Contact’s Title |
|  |       |  |       |
|  | Address |  | Contact’s E-mail Address |
|  |                   |  |             |
|  | City State Zip |  | Contact’s Telephone Number Fax Number |

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| 4. NAME OF PROGRAM TO WHICH YOU ARE APPLYING: | NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required) |
|  Agency Program No.: | PA-18-344 | CFDA No., if applicable: | [Click here to review](#CFDA) |

\*Click here for UofL definition of [**CLINICAL TRIAL**](http://louisville.edu/research/ccd/faq). Click here for NIH definition of [**NIH CLINICAL TRIAL**](https://grants.nih.gov/policy/clinical-trials/definition.htm)

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|  5. a. Is this proposal for a [CLINICAL TRIAL/DEVICE/DRUG STUDY](http://research.louisville.edu/industrycontracts/common/clinical/clinical-trial-definition.html)\*? [ ]  No [x]  Yes(attach Clinical Attachment) b. Will this proposal involve any affiliated hospital site (ULH, NHC, JHSMH, OMHS, VAMC)? [ ]  No [ ]  Yes(attach Clinical Attachment) c. Will this proposal involve specimens, tissues or personally identifiable (not de-identified as defined by HIPAA) data/information (human materials) [ ]  No [ ]  Yes(attach Clinical Attachment) d. Will this proposal involve human materials or other biological/chemical materials?  [ ]  Yes—being received from others [ ]  Yes—being sent to others [ ]  No—not being sent or received |
|  6. Award type is: [ ]  Grant [ ]  Subgrant/subcontract [ ]  Co-op agreement [ ]  Contract |
|  7. Submission version is: [ ]  New [ ]  Competitive renewal\*\*\* [ ]  Continuation\*\*\* [ ]  Supplemental\*\*\* [ ]  SBIR Phase      [ ]  STTR Phase      [ ]  Transfer [ ]  Other:       \*\*\*Please indicate previous chartfield tracking number in 18a. |
|  8. Project purpose is: [ ]  Research [ ]  Training/education [ ]  Public service [ ]  Other sponsored activity [ ]  [Clinical trial](http://research.louisville.edu/industrycontracts/common/clinical/clinical-trial-definition.html)\* [ ]  Clinical research [ ]  Other       |
|  9. Was the Development Office involved in the preparation of the proposal? [ ]  No [ ]  Yes My contact was:       |
| 10. Is this research being conducted through a Board of Trustees approved center/institute?  [ ]  No [ ]  Yes If yes, please identify: |       |
| 11. Will this project utilize a UofL Service Center? [ ]  No [ ]  Yes If yes, specify the center, amount and time period: |       |
| 12. Will equipment be provided by the sponsor? [ ]  No [ ]  Yes If yes, please notify Risk Management. |
| 13. Will project use software provided by the sponsor or obtained from a third party? [ ]  No [ ]  Yes |

14. FOS—Indicate **ONE** NSF-defined Field of Science (FOS) that most closely represents the work in this project. [Additional information](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:

**Geoscience, 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:

|  |  |
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| 15. LIST KEYWORDS:  |       |

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| 16. WILL ANY UofL PARTICIPANT HANDLE: [(Click here for corresponding web address)](https://louisville.edu/research/compliance/complianceoffices)  | Yes | No |  | Committee Approval No. |  | Approval Date or Status (Submitted, Pending) |  | UofL Training Course Required |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| a. Humans as subjects? | [ ]  | [ ]  |  | IRB       |  |       |  | HIPAA/Human Subjects |
| b. Experimental animals? | [ ]  | [ ]  |  | IACUC       |  |       |  | RRF Level II Training |
| c. Radioisotopes? | [ ]  | [ ]  |  | RSO       |  |       |  | Radiation Orientation |
| d. Recombinant DNA? | [ ]  | [ ]  |  | IBC       |  |       |  |  |
| e. Pathogenic organisms? | [ ]  | [ ]  |  | IBC       |  |       |  |  |
| f. CDC/USDA select agents? | [ ]  | [ ]  |  | IBC       |  |       |  |  |
| g. Human blood, tissues, cell lines, OPIM? | [ ]  | [ ]  |  | IBC       |  |       |  | Bloodborne Pathogens |
| h. Highly toxic, carcinogenic, mutagenic agents? | [ ]  | [ ]  |  | DEHS       |  |       |  | Lab Safety/Haz Waste |
|  |  |  |  |  |  |  |  |  |
| **NOTE:** **YOU ARE 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.** |

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| 17. ITEMS TO BE CONSIDERED FOR PROPOSAL REVIEW THAT INVOLVE UNIVERSITY RESOURCES: (**If yes**, please initial and date.) |
|  | Yes | No | CHAIR |  | DEAN |
| a. Any faculty release from work plan responsibilities? | [ ]  | [x]  |  |  |  |
| b. Any faculty salary recovery? | [x]  | [ ]  |  |  |  |
| c. Supplemental base or approved additional non-base pay? | [ ]  | [x]  |  |  |  |
| d. Sponsor-required cost share? If yes, fill in details in budget section. | [ ]  | [x]  |  |  |  |
| e. Does project require University commitments after extramural support is terminated? | [ ]  | [x]  |  |  |  |
| f. New credit courses, degree programs, centers or institutes? | [ ]  | [x]  |  |  |  |
| g. Additional space or facilities needed? | [ ]  | [x]  |  |  |  |
| h. Will installation[ ] , equipment maintenance[ ] , space renovation[ ]  or building modification[ ]  be required? | [ ]  | [x]  |  |  |  |
| i. Are there other special requirements of department and unit? If yes, attach requirements. | [ ]  | [x]  |  |  |  |
| j. Major equipment/technology system/single equipment item over $200,000 (see instructions)? | [ ]  | [x]  |  |  |  |
| Contact person |       | Phone |       |
| k. Majority of project (more than 50%) will be performed (excludes subawards): |  |  |  |  |  |
|  Mark one: [ ]  Belknap [x]  HSC (UofL bldgs) [ ]  Shelby [ ]  Off Campus (includes affiliated hosp) |  |  |  |  |  |
|  Bldg-Rm No. |       |  |  |  |  |  |

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| 18. BUDGET  | a. If a renewal, continuation or supplement of an existing grant or contract, please indicate previous chartfield number: |       |
|  | b. Department ID for budgeting/expending if awarded: |       |
|  | c. Entire Proposed Budget Period (Month/Day/Year): | From: |       /    /      | To: |       /    /      |
|  | d. Requested from Sponsor (list ALL direct costs) | Budget Pool | f. UofL Cost Share |  | Speed Type |
|  |  |       | Salary & Wages 511000 |       |  |       |
|  |  |       | Fringe Benefits 512000 |       |  |       |
|  |  |       | Equip ≥$5K per item 190000 |       |  |       |
|  |  |       | Alteration/Renovation ≥$100K 190000 |       |  |       |
|  |  |       | Subawards 519000 |       |  |       |
|  |  |       | Supplies & Expense 519000 |       |  |       |
|  |  |       | Travel 535000 |       |  |       |
|  |  |       | Tuition 520000 |       |  |       |
|  |  |       | Participant Support 520000 |       |  |       |
|  | e. |       | Total Direct Costs |       |  |       |
|  | g. EXCLUSIONS to TDC Base (direct costs included in 18d above that are not subject to F&A) |
|  |  |       | Equipment ≥$5K per item (190000) |
|  |  |       | Alteration/Renovation ≥$100K (190000) |
|  |  |       | Off-Site Rental (519000) |
|  |  |       | Patient Care (519000) |
|  |  |       | Subaward amounts in excess of first $25K on each (519000) |
|  |  |       | Tuition (520000) |
|  |  |       | Participant Support Costs (520000) |
|  |  |       | Other       |
|  | h. |       | Total Exclusions |
|  | i. |       | Modified TDC Base (18e TDC minus 18h exclusions) |
|  | j. F&A (Indirect Costs) |
|  |  |       | F&A Rate 54% 577000 |       |  |       |
|  | k. Total Cost of Project (sum of direct costs on 18e plus F&A costs on 18j) |
|  |  |       | TOTAL Costs |       |  |       |
| [ ]  Check here if line item budget not required by sponsor (see instructions). |
| l. Budget Remarks (include explanation of cost share/third-party match/non-standard F&A items if applicable):      |
| 19. SUBCONTRACTS TO BE ISSUED: List below any organizations—including Professional Services Corporations (PSC) or Private Practice Plans—that will provide services or receive payments from ULRF for this project. Include cumulative costs in budget. With proposal submission, include a statement of work for each subcontractor. |
| Organization Name |  | SubcontractorPI/Contact Name |  | Requested Cost for Current Year |  | Anticipated Cost for Remaining Years |  | Services to be Provided |
|       |  |       |  |       |  |       |  | (attach scope of work) |
|       |  |       |  |       |  |       |  | (attach scope of work) |
|       |  |       |  |       |  |       |  | (attach scope of work) |
|       |  |       |  |       |  |       |  | (attach scope of work) |

20. RESPONSIBLE SIGNATORY:

By signing this PCF, 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 PCF 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 Clinical Contracts/Industry Engagement/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 Clinical Contracts/Industry Engagement/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 PCF is submitted, it is understood that the PCF 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 PCF submission.
8. I agree to notify Clinical Contracts/Industry Engagement/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 PCF 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** | **Department Chair orAppropriate Unit Head** | **Dean orAppropriate Unit Head** | **SPA/OIE/CCD** |
| [ ]  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. |  |  |  |
| **Signature** |  |  |  |  |
|  Typed Name |       |       |       |       |
|  Date |  |  |  |  |
| **Additional approvers signatures/dates:** |
|  | **Multiple PI orCo-Investigator** |
| [ ]  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. |
| **Signature** |  |  |  |
|  Typed Name |       |       |       |
|  Date |  |  |  |

|  |
| --- |
| Additional comments/clarification:     CFDA numbers: 93.307; 93.113; 93.846; 93.172; 93.173; 93.855; 93.279; 93.866; 93.361; 93.273 93.242 |

| **PCF/MIRA Additional Signature Page** | Tracking Number (If Known) | Title of Project/Study |
| --- | --- | --- |

**RESPONSIBLE SIGNATORY**

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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 PCF/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 Clinical Contracts/Industry Engagement/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 Clinical Contracts/Industry Engagement/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 PCF/MIRA is submitted, it is understood that the PCF/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.

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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 PCF/MIRA submission.
8. I agree to notify Clinical Contracts/Industry Engagement/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 PCF/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.

|  |  |  |  |
| --- | --- | --- | --- |
| **Check boxes for appropriate role:** | [ ] MPI [ ] Co-I [ ] Key [ ] Add’l | [ ] MPI [ ] Co-I [ ] Key [ ] Add’l | [ ] MPI [ ] Co-I [ ] Key [ ] Add’l |
| Description of Role for Key/Additional Personnel |       |       |       |
| 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 |       |       |       |
| Percent Effort on Project1,2 |       |       |       |
| Percentage Collaboration (RIF; Cumulative 100%)1 |       |       |       |
| FOR CCD/OIE/SPA USE—Individual RIF Code |       |       |       |
| FOR CCD/OIE/SPA—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 Individual Engaged in Research** |  |  |  |
| Date |       |       |       |
| **Signature of Division Chief (If applicable)** |  |  |  |
| Printed Name |       |       |       |
| Date |       |       |       |
| **Signature of Department Chair or Unit Head** |  |  |  |
| Printed Name |       |       |       |
| Date |       |       |       |
| **Signature of Dean or Unit Head** |  |  |  |
| Printed Name |       |       |       |
| Date |       |       |       |

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

**PCF
Clinical Attachment for Proposals**

* Clinical Attachment needed when PCF question 5a, b, or c is answered yes
* Attach to PCF and accompanying documents
* Instructions at [PCF Clinical Attachment Instructions](http://louisville.edu/research/common/pcf-clinical-attach-instructions)

If you have any problems filling out this form, call Clinical Contracts Division at 852-8359 for assistance.

1. Tracking Number (If Known)

2. Date This Form Submitted to CCD/SPA

**PRIMARY CONTACTS FOR PROJECT**

3. Clinical Contact

a. Name

b. UofL Employee ID

c. Title

d. Email Address

e. Telephone Number Fax Number

4. Regulatory Contact

[ ]  Check if same as Clinical Contact

a. Name

b. UofL Employee ID

c. Email Address

d. Telephone Number Fax Number

**Note for Public Health Service (PHS) Funding:** New federal Conflict of Interest regulations include a requirement that disclosures be made at the time of proposal for PHS. Each named member of a project team must have an updated Attestation and Disclosure Form (ADF) on file at time of proposal in order to be included on the submission. If there are positions (technicians, post docs, etc.) who will be hired if the award is received, those can be noted TBD. However, if an individual is named, he/she must have a current ADF. See [Attestation and Disclosure Form (ADF)](http://iris.louisville.edu) for additional information.

**PROJECT CHARACTERISTICS**

5. Under FDA “Compassionate Use” Treatment IND

[ ]  No [ ]  Yes (Attach FDA determination letter)

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

[ ]  No [ ]  Yes [ ]  N/A

b. Drug/Device Name

7. FDA Phase (Note: 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. FDA N/A

8. Funding Source (Check all that apply)

[ ]  a. Industry

[ ]  b. Government

[ ]  c. Cooperative group

[ ]  d. Foundation

[ ]  e. Not funded

[ ]  f. UofL

[ ]  g. ULH/NHC/JHSMH/OMHS

[ ]  h. Other:

9. Multicenter Study

[ ]  No [ ]  Yes

10. Author of Protocol (Check all that apply)

[ ]  a. Investigator

[ ]  b. Sponsor

[ ]  c. Cooperative group

[ ]  d. Other:

11. Initiator of Study (Check all that apply)

[ ]  a. Investigator

[ ]  b. Sponsor

[ ]  c. Cooperative group

[ ]  d. Other:

12. Type of Study (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:

13. 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

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

| 14. 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)            [ ]  Cardinal Rsrch Cluster (CRC)             | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| b. ULH (FWA 00002163) – KentuckyOne Health-CIRI[ ]  UofL Hospital (CCB)[ ]  James Graham Brown Cancer Center (BCC)[ ]  ULH svcs in UofL Health Care Outpatient Ctr (HCOC)[ ]  Other, address:       | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| c. Jewish Hos & St. Mary’s Hlthcare (FWA 00015939) – KentuckyOne Health-CIRI[ ]  Frazier Rehab Institute[ ]  Jewish Hospital[ ]  Jewish Hos Med Ctr East [ ] NE [ ] South [ ] SW[ ]  Jewish Hos Meade [ ] Shelbyville [ ] Outpat Ctr[ ]  Jewish Hos Rudd Heart Lung [ ] Hand Care[ ]  Our Lady of Peace[ ]  Sts Mary & Elizabeth[ ]  St Mary Surgery Ctr[ ]  Health Resource Ctr[ ]  Southern Ind Rehab[ ]  Taylor Regional Hos[ ]  VNA Nazareth Home[ ]  Other, address:       | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| d. Norton Healthcare Facilities (FWA 00002217)[ ]  Norton Hospital[ ]  Kosair Brownsboro[ ]  Kosair Children’s Hos[ ]  Norton Brownsboro[ ]  Norton Audubon Hos[ ]  Space leased by UofL [ ]  Norton Brownsboro Hos in NHC facility[ ]  Norton Women's & KCH St. Matthews[ ]  Norton Physician Practices[ ]  Other, address:       | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| [ ]  e. Owensboro Medical Health System—address:      | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| [ ]  f. VA Medical Center–address:(Requires separate submission to VA)      | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| [ ]  g. Private Practice/PSC (including in HCOC); e.g., UofL Physicians Inc., University Kidney Center LLC—name, address:      | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |
| [ ]  h. Other sites—with contact information, address:      | [ ]  Blood Bank [ ]  Cath Lab [ ]  Laboratory [ ]  Nutrition [ ]  Pathology [ ]  Pharmacy [ ]  Phys Ther [ ]  Radiology[ ]  Resp Ther [ ]  Other       | [ ]  | [ ]  | [ ]  |