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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/PAR-18-020.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: | NCI Clinical and Translational Exploratory/Developmental Studies (R21 Clinical Trial Optional) |
|  Agency Program No.: | PA-18-020 | 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)\*? [x]  No [ ]  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: 93.393, 93.394, 93.395, 93.396, 93.399 |

| **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;
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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.

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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.

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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)