

PI/Mentor's Name: _____
 Fellow's Name: _____
 Rascal #: _____
 Project Officer: _____
 PT Record #: _____

Target Deadline Date: _____
 Sponsor Deadline Date: _____
 Deadline Type: ___Receipt ___Postmark
 Date Rec'd in SPA: _____
 Date Submitted: _____

The Proposal Review Checklist is designed to assist Project Officers complete the proposal review process prior to submitting a proposal to a sponsor. By completing the Proposal Checklist, the project officers ensures, to the best of their ability, internal, sponsors, budget, compliance and other requirements have been reviewed.

SUMMARY INFORMATION

Proposal Type: New Competitive Renewal Supplement Transfer In Non-Competing Renewal

If competitive renewal or supplement, sponsor award number: _____

General Location: On-Campus Off-Campus

Cost Share Type: None Voluntary Committed Mandatory Mandatory and Voluntary Committed

Cost Sharing Type: Equipment Personnel Other

Cost Sharing Approval: On File Non-Sponsored Account Number: _____ Amount: \$ _____

Resubmission: No Yes If Yes, Grant Number: _____

Type of Submission: InfoEd PD (provide PT# above) Adobe FastLane Paper/Email Other Electronic

Maj. Of Work Location: CUMC MS Lamont Nevis NY-P (Approval Attached) NYPI Other N-Columbia

Is the majority of work outside of the US?: No Yes If Yes, List Countries: _____

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Multi-PI Research Plan (PO: Flag key personnel list in proposal. DC: Additional PIs need to be added to Personnel Screen, Columbia PIs only) |
| <input type="checkbox"/> | <input type="checkbox"/> | Stem Cells? If yes, <input type="checkbox"/> Human Embryonic Stem Cells? <input type="checkbox"/> Human Stem Cells? <input type="checkbox"/> Animal Stem Cells? |
| <input type="checkbox"/> | <input type="checkbox"/> | Limited submission approval from Office of Research Initiatives (ORI) |
| <input type="checkbox"/> | <input type="checkbox"/> | CTV Application (CTV executed) |
| <input type="checkbox"/> | <input type="checkbox"/> | Small Business Subcontracting Plan |
| <input type="checkbox"/> | <input type="checkbox"/> | Human Subjects – (IRB) If yes, then complete Clinical Trial Supplemental Review Checklist and attach. |
| <input type="checkbox"/> | <input type="checkbox"/> | Clinical Trial (drug, device or intervention) |
| <input type="checkbox"/> | <input type="checkbox"/> | Animal Subjects – (IACUC) |
| <input type="checkbox"/> | <input type="checkbox"/> | EHS (laboratory pathogens, hazardous materials select agents)*** (DC, see also page 2) |
| <input type="checkbox"/> | <input type="checkbox"/> | Code of Conduct Requirements |
| <input type="checkbox"/> | <input type="checkbox"/> | Display of Fraud Poster Requirement |
| <input type="checkbox"/> | <input type="checkbox"/> | Consortium/Subcontracts? If Yes, Number of Consortium/Subcontracts: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | International Subcontracts? If Yes, List Countries: _____ |

SPONSOR INFORMATION

Sponsor Name: _____

ID Number (Sponsoring Agent RFA/RFP/FOA of Appropriate Sponsor Guidelines): _____

CFDA#: _____

Sponsor Program Type: Research Training Fellowship Career Dev. Other Sponsored Training
 Conference Equipment Construction – Capital & Renovation
 Service Other

Instrument Type: Grant Contract Cooperative Agreement

Funding Source: Federal Non-Federal New York State NYC Funded

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Foreign Sponsor? If yes, Country of Foreign Sponsor: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | Pass through funding? If yes, name of originating sponsor: _____ |

BUDGET INFORMATION (flag budget pages, or provide direct & indirect costs for all budget years)

Budget Type: Detailed Budget PHS 398 SF 424 Sponsor's Form Excel Spreadsheet

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Current salary confirmation from all department involved* |
| <input type="checkbox"/> | <input type="checkbox"/> | Modular budget checked |
| <input type="checkbox"/> | <input type="checkbox"/> | Budget Justification |
| <input type="checkbox"/> | <input type="checkbox"/> | F&A Waiver (below sponsor maximum Allowable rate) – Department approval waiver attached** |
| <input type="checkbox"/> | <input type="checkbox"/> | Subcontract Proposal Face sheet or Letter of Intent |
| <input type="checkbox"/> | <input type="checkbox"/> | Subcontract Budget and Budget Justification |
| <input type="checkbox"/> | <input type="checkbox"/> | Subcontract Scope of Work |
| <input type="checkbox"/> | <input type="checkbox"/> | Biographical Sketch for subcontractor Key Personnel |

RESEARCH SECTION

- | Yes | No | |
|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | Human Subjects Protection Training – All Research Staff (TC0087) |
| <input type="checkbox"/> | <input type="checkbox"/> | HIPAA Research Training Course – All Research Staff (TC0019) |
| <input type="checkbox"/> | <input type="checkbox"/> | Research with rDNA infection tissues or gene transfer – (IBC)*** |
| <input type="checkbox"/> | <input type="checkbox"/> | Radiation Safety (IBC)*** |
| <input type="checkbox"/> | <input type="checkbox"/> | Export Controls |
| <input type="checkbox"/> | <input type="checkbox"/> | Responsible Conduct of Research (RCR) (TC0094) |

OTHER DOCUMENTATION & ATTACHMENTS

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Confidentiality Agreements |
| <input type="checkbox"/> | <input type="checkbox"/> | Consultant Collaboration Letter |
| <input type="checkbox"/> | <input type="checkbox"/> | IC Analysis Tool (School of Public Health Only) |
| <input type="checkbox"/> | <input type="checkbox"/> | International Research Risk Questionnaire /Matrix, if appropriate |
| <input type="checkbox"/> | <input type="checkbox"/> | Letters of Reference |
| <input type="checkbox"/> | <input type="checkbox"/> | PI Eligibility Waiver |
| <input type="checkbox"/> | <input type="checkbox"/> | New Hire Letters |
| <input type="checkbox"/> | <input type="checkbox"/> | Sponsor Certifications and Representations (Section K. Industry) |
| <input type="checkbox"/> | <input type="checkbox"/> | Third Party In-Kind Letters |

CERTIFICATIONS

- Full review completed. Proposal completed according to submission type and sponsor guidelines with a finalized & fully-approved RASCAL.
- Expedited review completed. Email sent to PI stating SPA had insufficient time to conduct a full review and reserves the right to withdraw the proposal or renegotiate an award, and if necessary return the funding to the sponsor.
- Email Date: _____ Review Date: _____
- Partial review completed for NOAs received without PT Record, TechVentures awards and transfer in Proposals.
- No review prior to submission. Email sent to PI stating SPA had insufficient time to conduct a review and reserves the right to withdraw the proposal or renegotiate an award, and if necessary return the funding to the sponsor.
- Email Date: _____ Review Date: _____

Reviewed By: _____

Date: _____

PT Record Entered By: _____

Date: _____

*Currently attained by Department Administrators / Chair / Dean's approval of Rascal proposal

**Medical Center Dean Office approval not required for the MSPH. MSPH has its own F&A waiver process

***If any of these are involved in the research, data coordinator should mark "YES" to EHS question in InfoEd UDFs

SPA Proposal/Award Checklist Clinical Trial Assessment Addendum

This form is to be completed whenever a proposal or award is reviewed that indicates any human subjects involvement. Any 'yes' answers to these questions require additional review to ensure that this proposal/award is handled and tracked appropriately.

The following criteria cannot be used to determine whether a proposal/award is a clinical trial (or not): 1) Rascal submitting to Health Sciences vs. Clinical Trials; 2) Rascal Expense Function: Research 2400 vs. Clinical Trial 2600; 3) Cost Reimbursable Budget (modular or detailed); 4) Budget without Patient Care Costs.

Please follow the guidelines in "Understanding the Definition of a Clinical Trial."

PI: _____ **Rascal #:** _____
Dept: _____ **Dept. #:** _____ **PT #:** _____
Title: _____
Sponsor: _____ **Flow-Thru Agency:** _____
Review Point:
 _____ **Proposal** **Reviewer:** _____ **Date:** _____
 _____ **Award** **Reviewer:** _____ **Date:** _____

	Proposal		Award	
	Yes	No	Yes	No
<i>Administrative Triggers that could indicate CT activity</i>				
Does Rascal indicate this is a clinical trial?				
Does Rascal indicate that this project is to be managed by the CTO?				
Does proposal or award indicate that this is a clinical trial?				
Does RFA/RFP/PA/FOA indicate that this will or may be a clinical trial?				
<i>Grant documentation (SOW, Abstract, Budget, Research Plan)</i>				
Patient Care Costs: are they standard of care (SOC)?				
Patient Care Costs: are they on the budget?				
Patient Related Costs (i.e. professional fees, lab tests (outside hospital)?				
Does the proposal include any key words? (see glossary attached)				
Is this a multi-site collaboration?				
Will subcontracts be issued?				
<i>Scope of Work</i>				
Will research study involve an intervention using:				
A drug?				
A device?				
A treatment?				
Will research study involve the testing of new ways of using an existing:				
drug				
device				
treatment				
DETERMINATION: Is this a clinical trial?				

For any projects that fall into a questionable area as to whether or not the project should be considered a clinical trial, please obtain a SPA or CTO manager signature to confirm.

SPA/CTO Manager's Name

Date

