

## Instructions for ORS Proposal Transmittal and Approval Form

The ORS Proposal and Transmittal and Approval form is required to be submitted to ORS with all proposals at the time of review and approval. The principal investigator is responsible for completing and signing the transmittal form. By signing the form, the investigator certifies that the information contained in the proposal and on the transmittal form is accurate and complete. For schools, other than the School of Medicine, once the proposal has been approved and the transmittal form signed by the Dean(s) of the appropriate School(s), the original proposal and transmittal form and one copy of the proposal for ORS files should be delivered to the Office of Research Services (3451 Walnut St. P221 Franklin Building) for University approval and signature. In the School of Medicine, proposals may be signed by the ORS representative at the School, provided all human and animal protocols are on file in Regulatory Affairs and the proposal is not in response to a solicitation or does not require the execution of a contract.

1. **PROPOSAL DUE DATE:** Indicate the Sponsor's deadline for receiving proposal.
2. **TYPE OF PROPOSAL:** Check the appropriate box using the following definitions.
  - a. CHANGE IN GRANTEE INSTITUTE: Transfer of an existing grant or contract to Penn by a new faculty member.
  - b. COMPETING CONTINUATION: Applications to competitively renew or extend a funded grant beyond its current total project period.
  - c. NEW PROJECT: Applications being submitted for the first time to a sponsor. If a clinical trial, check if agreement was sent to ORS for early review.
  - d. NON-COMPETING CONTINUATION: Applications for continuation of a grant within its current project period.
  - e. PRE-PROPOSAL: Information requested by sponsor prior to submission of complete proposal. A transmittal form is only required if the Sponsor requires the signature of an authorized institutional official.
  - f. REVISED BUDGET: Budget - only revisions.
  - g. REVISION: Applications replacing a prior unfunded version of a new, competing continuation, or supplemental application.
  - h. SUPPLEMENTAL Applications for additional funds to supplement a currently funded project.
3. **NAME OF PI:** Names of PI's and Co-PI's and Fellows should be identical to those used in payroll.
4. **PENN ID:** Required for links from the ORS database to other campus data.
5. **EMAIL ADDRESS AND PHONE #:** Local email address and local camp extension.

6. **HAS PI CHANGED?** If this grant is active under a different principal investigator, or if a proposal has been submitted previously to the same Sponsor by a different principal investigator (someone other than the person listed under PI/FACULTY SPONSOR NAME), check “yes”. Indicate the previous PI if applicable. If this is a new proposal or the principal investigator has not changed check “no”.
7. **SCHOOL/DEPARTMENT:** Indicate the department in which the PI has his/her primary appointment.
8. **POSITION TITLE:** Indicate the investigator’s academic rank. ORS will reference this title if a transmittal letter is require by the sponsor.
9. **CO-PI/FACULTY SPONSOR NAME:** Names of CO-PI’s and Fellows should identical to those used in payroll.
10. **SPONSOR GRANT #:** If the grant is active and the sponsor has assigned a fund number, indicate the number here.
11. **UNIVERSITY FUND #:** If the grant is active and the University has assigned a grant number, indicate the number here.
12. **ORG NO.:** Provide the 4-digit Organization code associated with the proposed project. The School’s senior business administrator will have a complete list of the school’s ORG values.
13. **PROGRAM NO.:** Provide the 4-digit program code associated with the proposed project. The School’s senior business administrator will have a complete list of University Program values. If this field is left blank, the default value of 2000 – Research, will be used.
14. **CENTER REF:** Provide the 4 digit center reference associated with the proposed project. The School’s senior business administrator will have a complete list of their school’s CREF values.
15. **SUB-ACCOUNTS:** If sub-accounts are needed, complete and attach a sub-account worksheet.
16. **CONTACT PERSON, PHONES & EMAIL:** The name, phone # and email address of the person to be contacted if there are questions about the proposal.
17. **DEPARTMENT ADMINISTERING PROJECT:** If the proposal is funded, this block indicates the department that will administrator the grant. The department identified in this block will receive the AIS’s issued by ORS, have access to the account in Ben Financials, and will receive credit for the proposal within the University. Fellowships are administered by the Faculty sponsor’s home department. School requirements vary regarding proposals being administered by other PI’s primary department.

18. **TITLE OF PROJECT:** The title in this block must match the title on the proposal and IRB/IACUC protocol. While specifications vary by sponsor, PHS requires that the title not exceed 56 typewriter spaces, including spaces between words and punctuation. For sponsors which have no requirements, please limit the title to no than 2 lines of 50 characters each. ORS will reference the title listed in this block, if the sponsor requires a transmittal letter.
19. **PROPOSED PROJECT START DATE:** Self explanatory.
20. **PROPOSED PROJECT END DATE:** Self explanatory.
21. **SPONSORING AGENCY/GRANTING ORG.:** This block should indicate the agency or institution to which the proposal is being submitted along with a contact's name, address and telephone number. The sponsor and address will be used if ORS generates a transmittal letter, or needs to negotiate terms and conditions. If, when the proposal is funded the University of Pennsylvania will be a subaccount to another entity, list the entity from which Penn will receive a subaward, not the primary sponsor, e.g. NIH, NSF, etc.
22. **PROGRAM TYPE:** Check the appropriate box(es) using the following definitions.
  - a. COMMUNITY SERVICE: Programs which are entirely for the support of community services.
  - b. CONFERENCE: Programs which are entirely for support of conference.
  - c. CTA Single Site: Clinical Trial Agreement under which Penn is the sole study site, usually investigator sponsored.
  - d. CTA Multiple Sites: Pharma sponsored clinical trial in which Penn is one of many sites.
  - e. FACILITIES AND EQUIPMENT: Programs which are entirely for procurement of new buildings and structures, renovations of existing buildings, or equipment.
  - f. FELLOWSHIPS: Projects where principal funding is for stipends, tuition and fees and travel to aid the recipient in developing expertise in a specific area of study, work on a thesis or present a scholarly paper. The terms of the award may include specific deliverables or require participation in Research activity. Include all fellowships and scholarships.
  - g. OTHER: Projects such as health service projects, exhibitions and lecture programs that do not fit into any other category.
  - h. RESEARCH: Includes research projects under the direction of a PI with academic rank of Assistant Professor or higher (or equivalent). Do not include fellowships or scholarships.

- i. **RFP/RFA/PA:** Include proposals submitted in response to a specific Request for Proposals or Request for Applications. The RFP/RFA Program number should be provided.
  - j. **TRAINING:** Include projects for new or expanded University curricula, training courses, teaching programs, general education support programs.
23. **INDIRECT COST RATE(s):** The appropriate federally approved Facilities Administration cost rate should be used unless the sponsor has a stated policy requiring a different rate. Industry sponsored clinical testing of drugs and devices may use an F&A rate of 23.6% of total direct costs. The off campus rate (26%) may be used for projects or portions of projects performed in other than University owned facilities for a period of four (4) or more months. The University has approved rates for “Research”, “Instruction”, and other Sponsored Programs.
  24. **FUNDS REQUESTED:** Enter direct cost, F&A costs, total costs and cost sharing amounts for each requested budget period and also the totals for each category. If more than 5 budget periods are requested, use an additional sheet.
  25. **SUBCONTRACTORS:** If other entities will perform a portion of the proposed project and are included in the proposal budget to receive funds, please list the names of those organizations here. In addition, ORS requires that documentation what documentation (SPP Ref) from the subcontracting entity (including institutional signature) be included in the proposal.
  26. **SPECIAL INSTRUCTIONS:** ORS will generate a transmittal letter if one is required by the sponsor. Also, please attach any sponsor additional instructions.
  27. **COMMENTS:** Leave blank. These are for comments from ORS to the department.
  28. **FACILITIES:** Type of space. The individual schools are responsible for monitoring space usage. Please contact the school business office if you have questions concerning completion of this section.
  29. **EXPORT CONTROL:** This is a declaration as to whether or not this project is subject to export control laws. For further information:  
<http://www.upenn.edu/researchservices/exportcontrols.html>
  30. **REGULATORY AND OTHER APPROVALS:** The following review and approval procedures are mandated by federal statute and/or regulations. Failure to comply with these requirements may delay submission of your proposal. University policy requires these reviews for all projects, sponsored or un-sponsored.
    - a. **HUMAN SUBJECTS:** Proposals calling for use of human subjects must be reviewed by the University’s Institutional Review Board (IRB). Human subjects review and approval must be obtained either before the proposal is submitted or before a deadline set by the sponsoring agency. In many cases

non-competing continuation proposals do not have a grace period and must have human subjects approval prior to submission. If the grant is awarded, ORS will not assign a University account number and research cannot begin until the human subjects protocol has been approved. Human subjects “Guidelines” are available from the Office of Regulatory Affairs (Ext 8-2614).

Human gene transfer protocols and recombinant vaccine trials must be reviewed by Penn’s Institutional Biosafety Committee. Consult the Office of Environmental Health and Radiation Safety (EHRS) web site at [http://www.ehrs.upenn.edu/protocols/bio\\_humans.html](http://www.ehrs.upenn.edu/protocols/bio_humans.html) or call EHRS (215) 898-4453) for details.

- b. **ANIMAL CARE REVIEW**: Proposals involving the use of vertebrate animals must be reviewed by the Institutional Animal Care and Use Committee (IACUC). Committee approval is required before the proposal is submitted or before a deadline date set by the sponsoring agency. In many cases non-competing continuation proposals do not have a grace period and must have IACUC approval prior to submission. ORS will not process a proposal until the IACUC protocol has been submitted for review. If the grant is awarded, ORS will not assign a University account number and research cannot begin until the IACUC protocol has been approved. Animal care Guidelines are available from the Office of Regulatory Affairs (Ext. 8-2614). EHRS, under the auspices of the University Environmental Health and Safety Committee and the Radiation Safety Committee, approves the use of biohazards, radioactive materials and certain hazardous chemicals in animal research at the University. Investigators intending to administer or treat live animals with hazardous materials must submit a copy of their animal protocol review form ([Form A](#)) to EHRS for review and approval before the IACUC will give its full approval to the protocol. **To expedite the review process, a copy of Form A should be simultaneously submitted to EHRS in addition to the form submitted to ORA. This may be done electronically by emailing Form A to [biohazreg@ehrs.upenn.edu](mailto:biohazreg@ehrs.upenn.edu).**
- c. **EXPERIMENTAL DRUG AND DEVICE TESTING**: Clinical trial protocols must receive the approval of the IRB, and if appropriate, the Radioactive Drug Research Committee. For information, contact the Office of Regulatory Affairs (Ext. 8-2614).
- d. **RADIOACTIVE DRUG RESEARCH**: The research use of radioactive drugs is to be referred to the Radioactive Drug Research Committee for clearance. “Guidelines” are available from EHRS (215-898-7187).
- e. **RADIATION SAFETY**: The use of radio nuclides and radiation producing equipment at the University is under surveillance of the Radiation Safety Committee. The Radiation Safety Committee establishes policy with respect to use of sources of radiation in the University of Pennsylvania and certain affiliated institutions. Under the direction of the Committee, EHRS provides consultation, technical support services, monitoring surveillance and administers a program to establish compliance

with federal, state and local regulations and laws governing use of sources of radiation. Due to government regulations and required licensure, the procurement of radioactive materials requires prior approval by the Radiation Safety Committee. Other sources of radiation (x-ray equipment, accelerators, electron microscopes for example) are subject to regulations and standards for equipment, its installation (which may require substantial structural shielding), procedures for safe use, standards for personal exposure, and registration of the equipment with the Commonwealth of Pennsylvania.

Information on licenses and the proper use of radioactive material is to be found in the EHRS “Users Guide” which is available on the [www.ehrs.upenn.edu/](http://www.ehrs.upenn.edu/). By following the “Users Guide” and consulting with EHRS during grant proposal preparation, a researcher will be able to facilitate the licensing process and will obtain other services such as advice about potential costs for the disposal of radioactive materials and personnel dosimetry. Also, by having completed the EHRS licensing process prior to the award of a grant, researchers will avoid delays in initiating a research project if licensing has not been finalized. Please contact EHRS at extension 215-898-7187 for more information.

f. Select Agents: Certain restricted biological agents and toxins have been designated as "[select agents](#)" the US Department of Health and Human Services (CDC) and US Department of Agriculture (APHIS). Possession, use and transfer of these restricted agents must be registered with EHRS and the appropriate federal authorities before they are brought to Penn’s campus. EHRS is responsible for coordinating the federal registration process for all Penn investigators. Consult the [EHRS website](#) for more information or contact EHRS at (215-) 898-4453).

g. Chemical and Biological Safety: EHRS is the operational group of the Environmental Health and Safety Committee and its subcommittee, the Institutional Biosafety Committee (IBC). As such, EHRS facilitates compliance with proposed and existing laws, regulations and guidelines associated with the use of chemically and biologically hazardous materials and harmful physical agents. Proposals which involve the *in vitro* generation of recombinant DNA must be registered and approved by the IBC through OEHS. Proposals involving the use of carcinogens, reproductive hazards and acutely toxic chemicals must comply with guidelines described in the University’s “[Chemical Hygiene Plan](#)”

[http://ehrs.upenn.edu/programs/labsafety/labsafety\\_manual.html](http://ehrs.upenn.edu/programs/labsafety/labsafety_manual.html)

Proposals involving the use of infectious agents must comply with guidelines outlined in the University’s Biological Safety Manual  
[http://ehrs.upenn.edu/programs/bio/bio\\_manual.html](http://ehrs.upenn.edu/programs/bio/bio_manual.html)

A comprehensive list of infectious agents, their risk groups and recommended containment levels may be found in the [Biological Safety Manual](#). Investigators whose proposals involve the use of human blood, blood products, tissues and certain body fluids [University’s Exposure Control Plan](#) must complete the <http://ehrs.upenn.edu/programs/bio/ecp/default.html>. The completed plan must

be readily accessible to the laboratory for all employees to reference. For more information contact EHRIS (215-898) 898-4453 or [biohazreg@ehrs.upenn.edu](mailto:biohazreg@ehrs.upenn.edu)).

## 29. APPROVAL CERTIFICATIONS:

- a. Principal Investigators are responsible for verifying that all proposal information is accurate and complete. PI's must disclose any significant financial interests and agree to accept responsibility for scientific and technical conduct of the project and for provision of required technical reports if a grant or contract is awarded as a result of the proposal. PI's certify that all personnel will have signed a Participation Agreement prior to the initiation of the project. If an award is made as a result of the proposal the Principal Investigator is responsible for administering it in accordance with the policies of the sponsor and the University.
- b. Business Administrators are responsible for verifying that the financial and administrative information contained in the proposal is accurate and complete.
- c. Department Chairs have a general responsibility for promoting the scholarly and research activities of their department. They review applications for research projects for their appropriateness and transmit approved proposals through the appropriate dean to ORS, making sure that the human, fiscal and space demands of all projects are in the best interests of their departments and the University. A departmental Chair's signature is required for each department with significant involvement in the proposal.
- d. Dean of the School: The Dean's review relates to the substance and merit of the proposal, as well as, the budget, the salaries, and employment of present and proposed personnel, and any other aspect of the proposal which may effect the teaching, research, and use of space and facilities of the responsibility center and the University. The Dean's approval of less than the negotiated indirect cost rate indicates his/her acceptance of reduced indirect cost recovery according to Sponsored Projects Policy No. 2116 to the responsibility center. Once approved and endorsed, the proposal is transmitted to ORS for University approval. A Dean's signature is required for each school involved in the proposal.