

SECTION 10: GLOSSARY

The following glossary is a compilation of frequently used terms pertaining to grants, contracts, fellowships, and research involving human subjects or animals. *Italicized words within a definition indicate separate glossary entries.* Comments and suggestions are greatly appreciated.

Acronyms:

CFR:	Code of Federal Regulations
DAW:	US Division of Animal Welfare
DHHS:	US Department of Health and Human Services
eRA:	Electronic Research Administration
F&A:	Facilities and Administration rate
FDA:	Food and Drug Administration
FWA:	Federal Wide Assurance
IACUC:	Institutional Animal Care and Use Committee
IRB:	Institutional Review Board
NEH:	National Endowment for the Humanities
NIH:	National Institutes of Health
NSF:	National Science Foundation
PD:	Project Director
PHS:	US Public Health Service
PI:	Principal Investigator
RFP:	Request for Proposal
OHRP:	US Office of Human Research Protections (formerly OPRR)
OLAW:	US Office of Laboratory Animal Welfare (IACUC matters)
OPRR:	US Office for Protection from Research Risks (IRB matters)
USDA:	US Department of Agriculture

Anonymity: As used in consent forms, the term assures that there is no method of linking data to any individual. See also *confidentiality*.

Assurance: A formal binding statement certifying compliance with federal or state regulations such as those pertaining to a drug free workplace or the protection of humans or animals in research. See also *federal wide assurance*.

Audit: The funder may reserve the right to verify that its money has been spend according to the terms of the grant, contract, or other agreement. Auditors may be sent by the funder as part of a site visit to conduct a financial review.

Authorized Institutional Official: A designated senior officer with legal authority to sign grant agreements, contracts, and other such documents. The Dean of the Graduate School is an official signatory for sponsored projects.

Award: A funded grant or fellowship.

Budget: A detailed account of the monies required to implement and successfully complete a project indicating the source of the funding (internal or external), budget categories (such as equipment or salary), and time line (for multi-year projects).

Capital Support: Funds collected for buildings, construction, or equipment.

Certification: A funding agency, especially a federal funding agency, may require the University to formally file an assurance of compliance to receive certification for a specific topic, such as the protection of human subjects.

Code of Federal Regulations (CFR): The codification of federal rules which have been published in the Federal Register. Regulations are cited by title, part, and section number so that 45 CFR 46.117 refers to:

- ◆ Title 45: Public Welfare
- ◆ Code of Federal Regulations
- ◆ Part 46: Protection of Human Subjects
- ◆ Section 117: Documentation of informed consent.

Common Rule: The federal regulations on the protection of human subjects, codified by the DHHS in 45 CFR 46, have been accepted as a common rule by sixteen other federal departments and agencies, including the National Science Foundation and the Department of Education. Institutions receiving funding from any of these federal sources must comply with the Rule.

Compliance: A funding agency will often request compliance statements (agreements to comply with certain standards) from the University as a condition of eligibility. Some common compliance statements related to grants and contracts ensure a drug free workplace and equal opportunity employment. See also *assurance, certification, conflict of interest/commitment, and disclosure*.

Confidentiality: As used in consent forms, the term ensures that data will be coded to protect the identity of the individual; in this case, the data could be linked to individuals through a guarded master list, usually available to the researcher only. See also *anonymity*.

Conflict of Commitment: The PI should ensure that the amount of time to be spent on a funded project does not conflict with university or other obligations.

Conflict of Interest: The PI should ensure that funded projects would not result in inappropriate personal gain or an inappropriate advantage to colleagues and associates. The perception of conflict is as damaging as actual conflict. A Disclosure of Interests Form should be completed for each proposal.

Consent Form: For IRB purposes, human subjects involved in research in most cases must sign a consent form indicating their willingness to participate in the project. The form must be written in language easily understandable by the participants and should state the expected duration and type of participation by the subject as well as other standard clauses. See also *informed consent*. See **Section 8.11** in this guide.

Consultant: A person hired to provide specific advice or services for a set fee. Fringe benefits are not applied to the fee.

Contract: A legal agreement of a predetermined amount to conduct specific research, provide services, or deliver a product to the funding agency.

Collaborative Venture: Many grants (and some contracts and fellowships) request collaboration between different institutions such as a university and a municipal school district or company. For fellowships, the collaboration may be between scholars in the same field or interdisciplinary fields. Collaborative grants and contracts are awarded to one designated institution, which then distributes funds to the remaining collaborators. The grant/contract must be submitted for internal approval whether JCU is the main grantee or a secondary collaborator.

Copyright: If applicable, grants, contracts, and other agreements should include protection of any copyrights for which the researcher would be eligible. See also *intellectual property, patent, and publication rights*.

Cost-Sharing: Many grants require that the funded institution provide some monetary support for the project. The University may offer in-kind costs such as release time for faculty, secretarial support, some supplies, or the use of computer time or rooms, as a cost-share requirement in lieu of actual monies.

Deadline: The date required by the funding agency for either (1) a postmark or (2) delivery date. It is important to indicate the type of deadline on the internal approval form. The Graduate School and Grants Administration office should be notified in advance of the deadline to allow for careful processing of the proposal.

Department of Health and Human Services (DHHS): The federal agency that oversees the OHRP.

Direct Costs: When preparing a proposal budget, direct costs are those which can be directly applied to the project, such as consultant fees, photocopying of materials, supplies, and salaries of project personnel. See also *indirect costs*.

Director, Sponsored Research: The JCU resource person responsible for guiding proposal development and award management. Reporting to the Dean of The Graduate School, oversees the IRB and IACUC Administrator.

Disclosure: A PI may be required to supply a disclosure statement listing any significant financial interests (including those of spouse and dependent children) which may be affected by the funded research. See also *conflict of interest/commitment*.

Division of Animal Welfare (DAW): The federal agency that oversees IACUC matters. Formerly reporting to DHHS's OPRR, as of March 2000, the division was elevated to the Office of Laboratory Animal Welfare (OLAW).

Drug-Free Workplace: Most federal funding agencies require grant seeking institutions to certify their status as a drug free workplace in accordance with the Drug-Free Workplace Act of 1988.

Electronic Research Administration (eRA): The electronic submission of applications and reports for grants and contracts. The National Science Foundation is an eRA institution requiring that grant transactions such as proposal submission and final reporting occur via the Internet.

Endowment: Money contributed to provide a continuing income for support or maintenance. The endowment may be general or specified for a particular project.

Expedited Review (of IRB application): "Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research" (Penslar G-4) [Federal Policy 45 CFR 46.110].

Expenditures: Specified line items spent from funds. The PI initiates and tracks expenditures. The Senior Accountant in the Business Office can assist in compiling expenditure reports.

Facilities and Administration rate (F&A): Same as *indirect costs*.

FastLane: The National Science Foundation electronic research administration website located at www.fastlane.nsf.gov to create, edit, and submit proposals, budgets, and reports to NSF.

Federal Wide Assurance (FWA): An IRB which is registered with OHRP may apply for a FWA to allow receipt of funded awards for human research activities from several federal agencies such as the NIH. NB: JCU does not hold a FWA and therefore may be ineligible to apply for some federal grants.

Fellowship: An award made directly to an individual for independent research purposes in a specified area. Awards may be made from a federal source (e.g., the NEH) or private agency (e.g., the Getty Trust, the Newberry Library). Resident fellowships may pay travel expenses to the granting institution, room and board, and salary for the duration of the fellowship. Non-resident fellowships may pay some travel expenses to research sites and salary for the duration of the fellowship. Salary can either be a portion of the salary or a full replacement depending on the granting organization. Fellowship research is expected to result in a publishable work. Duration may range anywhere from a few weeks to an academic year or more.

Financial Report: A report covering a specified time (such as a fiscal year) detailing actual expenditures and income for a particular project.

Final Report: Most funding agencies require a written and financial report to be completed by the PI at the end of the project. The amount and type of information varies by agency. The Business Office can assist in the preparation of the final financial report.

Fiscal Year: A fixed 12-month budget period for accounting purposes. JCU's fiscal year runs from June 1 to May 31. The funder may request reports based on a different fiscal year.

Food and Drug Administration (FDA): The FDA regulations for the use of human subjects in biomedical situations are codified in 21 CFR 50 and §56.

Full Board Review (of IRB applications): "Review of proposed research at a convened meeting at which a majority of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting" (Penslar G-5) [Federal Policy 45 CFR 46.108].

Funder: The organization awarding a grant or fellowship. Same as *sponsor*.

Graduate School Dean: The Graduate School Dean, as Coordinator of Sponsored Research and Faculty Development, serves ex officio as the Chair of the Committee on Research and Service, Chair of the Summer Course Development Fellowship Committee, Chair of the Institutional Review Board for

the Protection of Human Subjects, and Co-chair of the Institutional Animal Care & Use Committee. The Dean is an official signatory of grants and contracts for the University.

Grant: Funding made available for a specific research project based on a proposal submitted by a principal investigator. Grants are made to an institution for use by the principal investigator.

Grantee: The institution receiving an award on behalf of the PI.

Guidelines: Depending on the agency, the written guidelines may detail specific instructions on eligibility requirements, proposal format and content, budget concerns, and deadlines and other submission requirements. Some agencies use guideline adherence as a method of weeding proposals.

Human Subjects: For IRB purposes, “individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information” (Penslar G-6) [Federal Policy 45 CFR 46.102(f)].

Indirect Costs: Costs associated with administering a project such as accounting services, space and utilities, maintenance, sponsored project administration, and library resources. Some agencies have a cap on the indirect cost rate; other agencies disallow any indirect costs charged to the grant. Indirect costs may be used as a portion of the cost-share. Also known as overhead and facilities and administration costs. See **Section 3.9.2** in this guide for federal guidelines.

Informed Consent: “A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25]” (Penslar G-6). See also *consent form*.

In-Kind Costs: Many grants require that the funded institution provide some monetary support for the project. The University may offer in-kind costs such as release time for faculty, secretarial support, some supplies, or the use of computer time or rooms as a cost-share requirement in lieu of actual monies.

Institutional Animal Care and Use Committee (IACUC): The committee reviews research proposals involving the use of animals to ensure ethical treatment such as the minimization of pain and distress. Equipment and facilities

may be inspected. No animal research may take place without review and approval by the committee.

Institutional Review Board (IRB): “A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research” (Penslar G-7) [Federal Policy 45 CFR 46.102(g), §108, and §109]. The board oversees research involving human subjects to protect the rights of individuals by guarding privacy; reducing risk; ensuring the validity of the project and its design; and evaluating the appropriateness of the consent form. No research involving human subjects may take place without review and approval by the board.

Intellectual Property: To protect academic freedom, intellectual results of research should be guaranteed to allow for public distribution, generally by publishing or presenting the results of the work. See also *copyright*, *patent*, and *publication rights*.

Internal Approval: JCU personnel seeking external funding, whether grants, contracts, or fellowships, should complete an appropriate internal approval form by detailing the budget section and securing all appropriate signatures.

Internal Research: Research undertaken to provide information for in-house use where the results will not be disseminated outside the University.

Letter of Intent: This notification by the PI to the funding agency on a possible forthcoming proposal should include a brief summation of the project and preliminary budget. Agencies may require a letter of intent for planning purposes or to weed out undesirable projects. Same as *pre-proposal* and *white paper*.

Matching Funds: Agencies may require that the requesting institution match grant monies either with capital contributions or in-kind costs. See also *cost-sharing*.

Minimal Risk: “A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests ” (Penslar G-8) [Federal Policy 45 CFR 46.102(i)]. This definition does not apply to some special populations, such as prisoners.

Misconduct in Science: Integrity of research is achieved by maintaining high ethical standards of professional behavior and scholarship. Misconduct includes, but is not limited to, plagiarism, falsification or fabrication of data, dishonesty in presentation or publication of research results, and violations of the ethical treatment of humans or animals. The IRB and the IACUC address concerns of misconduct with regard to humans and animals, respectively.

Office of Human Research Protections (OHRP): As of June 2000, the federal office now responsible for implementing DHHS regulations governing research involving human subjects (45 CFR 46) and reporting to the US Department of Health and Human Services. Formerly known as the OPRR.

Office of Laboratory Animal Welfare (OLAW): As of March 2000, the federal office now responsible for animal-related functions such as implementing and interpreting the Public Health Service Policy on Humane Care and Use of Laboratory Animals. Formerly known as DAW.

Office for Protection from Research Risks (OPRR): The federal office originally responsible for implementing DHHS regulations governing research involving human subjects (45 CFR 46) and reporting to the National Institute of Health, an agency of the Public Health Service, Department of Health and Human Services. Now elevated to the Office of Human Research Protections reporting directly to DHHS.

Overhead: Same as *indirect costs*.

Patent: The rights of the University and researcher should be protected in the conception or development of any patentable material or processes. See also *copyright, intellectual property, and publication rights*.

Pre-proposal: See *letter of intent*.

Principal Investigator (PI): The individual applying for grants, fellowships, or contracts, or the individual submitting a research application to the IACUC or the IRB. The PI is responsible for writing the grant or fellowship, securing internal approval, and carrying out any funded projects. Same as *project director, investigator, and researcher*.

Privacy: For IRB purposes, the “control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others” (Penslar G-11).

Program Officer: The resource person at the funding agency who can provide information on specific grant programs. For funded grants, the program officer oversees the project for the funding agency.

Project Director (PD): Same as *principal investigator*.

Protocol: A detailed description of a research study including design, implementation, and analysis.

Proposal: A narrative describing a research project written for submission to a funding agency usually accompanied by a project budget.

Publication Rights: Grants, contracts, and other agreements should include protection of the publication rights of the researcher to publish project reports on a timely basis and to present project reports at conferences. The sponsor may receive advance notice of publication or presentation material for the purpose of patent protection. See also *intellectual property*, and *patent*.

Request for Proposal (RFP): Notice from a funding agency of a new grant opportunity usually listing program description, deadlines, and eligibility requirements.

Research: For IRB purposes, “a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge ” (Penslar G-13) [Federal Policy 45 CFR 46.102(d)].

Risk: For IRB purposes, “the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant” (Penslar G-13). See also *minimal risk*.

Site Visit: The funder may request to review a project on campus (facilities and personnel) to ensure the project is being conducted according to the terms of the contract or grant. An audit may be requested at the same time.

Sponsor (agency): The organization funding a grant, contract, or fellowship. Same as *funder*.

Sponsor (JCU): A JCU employee who agrees to support (1) a collaborative grant or contract or (2) research on campus to be conducted by a JCU student or by a member of an outside organization.

Subcontract: A legal agreement to transfer part of a grant or contract from the awarded institution to another organization. Terms and conditions of the original contract/grant apply to the subcontract as well.

White Paper: Slightly longer version of a *letter of intent*.

REFERENCE

Penslar, Robin Levin. *Protecting Human Research Subjects: Institutional Review Board Guidebook*. Second edition. Washington, DC: U.S. Dept. of Health and Human Services, Public Health Service, National Institutes of Health, Office of Extramural Research, Office for Protection from Research Risks: 1993.

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