IRB Approval of Research Using Survey Procedures

Kerry Agnitsch, Office for Responsible Research October 1, 2009

Key Definitions (per 45 CFR 46.102(d) & (f):

Research—a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

Human Subject—a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject [e.g., surveys, interviews, focus groups, etc.].

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

IRB approval is needed for projects that collect data <u>about a living individual</u> for <u>research purposes</u> and that involve <u>interaction</u> or <u>intervention</u> with an individual or collection of <u>identifiable or private</u> <u>information</u>.

Interaction	Intervention	Private and Identifiable
Surveys (mail, phone,	Usability studies	Student records
online, etc.)	Taste tests	Medical records
Interviews	Exercise trials	Employment records
Focus groups	Food/dietary supplement trials	Observation of private activities (i.e.,
Educational tests	Drawing blood or other	non-public meetings)
Observation (sometimes)	specimens	Existing data that contains identifiers
		_

IRB approval is needed for projects that include surveys if the survey is conducted for research purposes and is used to obtain information about an individual

	Requires IRB Approval	Does not require IRB approval
How will the data be used?	A program evaluation where survey results will be generalized beyond the specific program, used to test theories or hypotheses, published or presented in academic venues, etc.	A program evaluation where survey results are applicable only to the program and will be used solely for purposes of evaluating or improving that program.
What information will be gathered?	Surveys that collect background information, demographic information, thoughts, feelings, personality traits, choices, opinions, attitudes, perceptions, behaviors, etc. Examples:	Surveys that collect factual information about an issue, organization, etc.
	A survey asking school superintendents about their educational and employment background, their thoughts and opinions about their job, etc.	A survey asking school superintendents to provide <u>only</u> factual information about the school district
	A survey of business owners or employees asking for demographic or background information (e.g., age, educational attainment, gender, race, etc.) and/or opinions about their job, their workplace)	A survey asking business owners or employees for <u>only</u> factual information about their business.

GRANT COORDINATOR MEETING 10/1/09 SPONSORED PROGRAMS ACCOUNTING (SPA)

COMPUTER PURCHASES ON FEDERAL FUNDING

The purchase of computers and peripherals from federal funds is something auditors examine closely and often results in disallowances if not handled properly. Use the following information to assist you in determining whether or not these types of purchases should be placed on federal or federal flow-thru funding.

Does the item cost \$5,000 or more? If yes, then the purchase would be classified as equipment. Computers are usually considered general purpose equipment per OMB Circular A-21. Equipment purchases must be approved in advance by the awarding agency with ample justification given as to why the item is necessary. If the computer is not primarily used for the research project, it should not be paid for with federal or federal flow-thru funds. If the computer was not listed in the approved proposal budget, then rebudgeting is necessary before SPA will approve the web requisition.

If the computer costs less than \$5,000, then the purchase would be considered a material and supply cost which is addressed in OMB Circular A-21 under Sections F.6 and J.27(a) and (c). Because computers (and related printers and secondary monitors) can be used for many activities including unrelated correspondence, preparing instructional materials, and other non-project related activities, auditors usually classify these expenses as office supplies and consider them to be unallowable charges to federal funds.

If the computer is necessary for the project and will be used 100% of the time on project related activities, then the purchase may be allowable on federal funds. Examples where you might have justification to purchase a computer on federal funds would be if research was being done in a remote off-campus location which required the purchase of a dedicated laptop, or if you were purchasing a computer to act as a front end to a piece of equipment. In these cases where you have adequate justification and the sponsor does not disallow computer purchases in their terms and conditions, the purchase would be allowable as a direct charge. Please be sure to have documentation in the file explaining why the computer was necessary to the project and that it is being used solely on the project. Documentation is key in case of an audit.

Whenever possible, it is best to anticipate these types of purchases at the proposal stage and include computers in your proposal budget with appropriate justification.

US DEPARTMENT OF JUSTICE FINANCIAL REVIEW UPDATE

Last year, the US Department of Justice (DOJ) conducted a site visit at ISU on August 12, 2008. The purpose of the site visit was to perform routine grant financial monitoring and provide technical assistance for grants awarded by the Department of Justice. The visit included a review of three DOJ grants.

At the September 2008 Grant Coordinator Meeting, the preliminary results of the review were presented. These preliminary results included:

- An employee was paid beyond the end date of the award
- Rebudgeting was not requested for budget categories that exceeded 10% of the total budget:

Items budgeted as equipment posted to the supplies budget line

Salary costs incurred were in excess of budget by more than 10% of the award

• Travel costs were questioned for two domestic travel events in which the traveler did not depart from Iowa and was no longer an ISU employee

Final Findings/Results:

- \$395 in salary and fringe benefits were incurred after the award period. These funds were paid back to the sponsor. A revised final financial report was submitted.
- The DOJ guidelines allow for the movement of dollars between approved budget categories of up to 10% of the total award amount. When cumulative changes exceed 10% of the total award amount, prior approval from the awarding agency is required. For one award, ISU incurred expenditures on individual budget categories that exceeded 10% of the total award amount without obtaining sponsor approval. The cumulative budget modifications amounted to \$49,338 or 25% of the award amount.

ISU requested rebudgeting after the award ended. On July 14, 2009, ISU received formal approval of the rebudget request. Had ISU not received rebudget approval, \$49,338 in expenses would have been deemed to be unallowable and would have been repaid to the sponsor.

Lessons learned:

- For awards that do not terminate at the end of a month, please review employee salary paid from grant funds to ensure that they are not paid beyond the end date of the award.
- Periodically review the Sponsored Programs Financial Reports to identify if rebudgeting is needed. If rebudgeting is needed, please submit a request for rebudgeting prior to the end date of the award.

NIH KIRSCHSTEIN NRSA AWARDS

NIH Ruth L. Kirschstein National Research Service Awards (NRSA)

Individual Fellowships and Institutional Research Training Grants

NIH Kirschstein-NRSA Individual Fellowship awards begin with: F30, F31, F32, F33

NIH Kirschstein-NRSA Institutional Research Training Grants award begin with: T32, T34, T35

All Kirschstein-NRSA recipients are required to pursue their research training full time, defined as 40 hours per week. The recipient may submit a written request to NIH to permit less than full time training, but cannot get Kirschstein-NRSA support if their training effort is less than 50%. Stipends are provided as a subsistence allowance for Kirschstein-NRSA recipients to help defray living expenses during the research training experience. The stipend is not provided as a condition of employment with either the federal government or the sponsoring institution (ISU). Kirschstein-NRSA's have a maximum stipend level and NIH will provide funding for stipends based on the stipend level at the time of the award. The recipient will need to be paid the exact amount of stipends as awarded.

Employee benefits are not allowed on Kirschstein-NRSA grants. Because these awards are not provided as a condition of employment it is inappropriate and unallowable to charge grants for the cost of employee benefits such as FICA, workers compensation, and unemployment insurance. Health insurance is an allowable cost only if applied to all people in a similar training status.

Instead of paying the recipient a fellowship stipend, many departments will pay the recipient via the ISU payroll system. If the recipient is being paid through payroll, an alternative account number will need to be provided to SPA so that the payroll benefits are not charged to the NIH account. Benefits must be paid from an unrestricted source. If health insurance is provided, health insurance benefits can be transferred to the NIH account on a monthly or quarterly basis. If transferring health insurance benefits quarterly, please be aware of the 90 day cost transfer rule.

When tuition, fees, and insurance are awarded as a separate budget item, these funds may not be rebudgeted into any other budget category without written prior approval from the NIH awarding office.

If the Kirschstein-NRSA recipient leaves before the end of the award period, they will be required to notify NIH prior to departure and then complete a Termination Notice (Form PHS 416-7). This form will need the signatures of the fellow, the PI, and OSPA before submission to NIH.

If your department receives a Ruth L. Kirschstein National Research Service Award, please be aware of these guidelines. The full guidelines for Ruth L. Kirschstein National Research Service Awards can be found in the NIH Grants Policy Statement. The link to the most recent GPS is: http://grants.nih.gov/grants/policy/nihgps_2003/nihgps_2003.pdf

E-VERIFY

Implementation of E-Verify was delayed until September 8th, 2009. The final rule was published November 14th, 2008 under Federal Acquisition Regulation (FAR) Case 2007-013, Employment Eligibility Verification (http://edocket.access.gpo.gov/2008/pdf/E8-26904.pdf). The E-Verify system administered by the Department of Homeland Security in conjunction with the U.S. Social Security Administration is used to verify the work eligibility of employees. Beginning September 8th, all federal contracts must include a provision mandating the use of E-Verify on all employees (new or existing) assigned to perform work under a federal contract. This rule is applicable to federal contracts above \$100,000 with a performance period longer than 120 days, and is not applicable to grants or cooperative agreements.

The E-Verify program must be extended by Congress or it will expire on September 30th, 2009. It is believed that the program will be extended. Per Lea Henderson, ISU HR Services, ISU will register on October 1st, 2009 and will initially only E-Verify new hires. When ISU receives its first federal contract with the E-Verify FAR clause, ISU plans to change its registration to a Federal Contractor. It is anticipated that ISU will then E-Verify all new hires as well as current employees hired after 11-6-1986 at that time.

Additional E-Verify information is available on the ISU HR Services Records Management website under Information and Instructions at: http://www.hrs.iastate.edu/hrs/records.

MISCELLANEOUS UPDATES

- 1. SPA Fax Number Change to (515) 294-3401
- 2. Draft B-base Summer Salary Guidelines Under Discussion