Great Lakes Center for Occupational Health and Safety
School of Public Health West
University of Illinois at Chicago
2121 West Taylor Street
Chicago, Illinois 60612-7260

DATE: February 1, 2022

The **Great Lakes Center for Occupational Health and Safety (GLC-OHS)** at the University of Illinois Chicago is soliciting proposals for the next round of Pilot Project Research Training funds. The funds are intended for new occupational safety & health investigators in Fiscal Year (FY) 2022-2023. The availability and amount of funding for this initiative is contingent on the Pilot Project award provided by the National Institute for Occupational Safety and Health (NIOSH).

Application and complete information at: https://glcohs.uic.edu/research-2/pilot-project-grants/

The purpose of the awards is to provide research training that will prepare new researchers for more comprehensive investigations by supporting new, short-term (1-year) projects that will:
1) Develop research expertise & capacity in ERC research trainees & new investigators in occupational health;
2) Support investigators in establishing new occupational health-related research areas; and,
3) Encourage established investigators from other fields to apply their expertise to National Occupational Research Agenda (NORA) sectors and topics.

For more information about NORA and NIOSH research goals, go to: https://www.cdc.gov/nora/default.html, and https://www.cdc.gov/niosh/programs/prioritygoals.html. In addition, GLC-OHS is interested in projects that promote the NIOSH Total Worker Health® initiative. The Total Worker Health (TWH) approach advocates for a holistic understanding of the factors that contribute to worker well-being. Scientific evidence now supports what many safety and health professionals, as well as workers themselves, have long suspected - that risk factors in the workplace can contribute to health problems previously considered unrelated to work. For more information about TWH, go to: http://www.cdc.gov/niosh/twh/ and http://www.cdc.gov/niosh/twh/totalhealth.html.

Categories of pilot/small projects include, but are not limited to, projects that:
- Provide initial support to develop innovative approaches/lines of investigation in the program areas;
- Allow exploration of possible innovative new directions in occupational safety and health (OSH) sciences;
- Stimulate investigators from other fields to apply their expertise to OSH issues;
- Develop new mechanisms for external or multi-ERC collaborative partnerships to address emerging safety and health concerns;
- Provide initial support for a translational/research to practice project;
- Support trainee capstone projects;
- Provide descriptive preliminary data and are hypothesis generating.

The awards are intended to provide investigators with the resources needed to develop pilot information about a research hypothesis, with the expectation that investigators will subsequently develop fully formed extramural research applications on the basis of this pilot information.

Preference will be given to proposals from the following states in the GLC-OHS's region: Illinois, Indiana, Wisconsin, and Missouri.

Application instructions provided in this document are detailed and specific, and the procedures that you follow here are very similar to requirements for most federal award applications. Therefore, this application process will help you prepare other proposals in the future.

Proposal applications must address a NORA priority area. Proposal **considerations of interest** include:
- Research capacity building in trainees and new investigators;
- Regional occupational safety & health needs;
- Participation of multiple stakeholders, including employers, employees, labor unions, professional trade associations, private non-for-profit organizations, and academia;
- Workplace intervention and intervention effectiveness;
- Scientific merit; and,

- Multi-disciplinary approaches.

Questions concerning applications and instructions may be addressed to:
Salvatore Cali, Research Coordinator, Email: scali@uic.edu (Inquiries by e-mail preferred).

DEADLINE AND COPIES REQUIRED
GLC-OHS requires ONE (1) COMPLETE ELECTRONIC COPY (in one pdf file of the entire application, budget, budget justification, & proposal narrative and attachments), signed by the department head, principal investigator, and mentor. The electronic file(s) may be sent to Mr. Cali by email (scali@uic.edu), and may be in pdf format, but please provide the proposal abstract in a separate word processing format for UIC's internal convenience. Applications must be received on or before 5:00 pm CST, Wednesday**, April 6, 2022** at the email address above. Late applications will not be accepted.

ELIGIBILITY
Eligible: New occupational safety & health investigators, including investigators from other disciplines who have recently begun targeting occupational safety & health topics. Applicants are limited to junior faculty, new investigators, or research trainees. NIOSH has traditionally defined research training as being at the PhD candidate level with the objective of helping to prepare trainees for research careers, although this program has funded well-prepared proposals from other innovative researchers.
Not eligible: Tenured faculty, RO1 investigators, and non-junior faculty members are not eligible as principal investigators. NIOSH Trainees are not eligible for personal salary support from pilot projects, but may use funds for other research-related expenditures. Previously funded projects are not eligible for renewal, although previously funded projects or investigators with new or advanced hypotheses may be considered for a second award.

TYPES AND CATEGORIES OF SUPPORT
Three to five awards ranging from $6,000 to a maximum of $20,000 are available per project, with completion of all funded expenditures and substantial completion of project objectives by June 30, 2023 required. **Funds must be utilized by June 30, 2023, or they will be forfeited, as there is no mechanism for continuing funding beyond that date.** These projects must be relevant to a NORA sector or topic and may not be renewed. The availability and amount of funding for this initiative is contingent on the Pilot Project award provided by NIOSH. It should be noted that NIOSH strongly recommends that individual salary costs be minimized.

FORMAT OF APPLICATION
The application form provided with these instructions must be completed. In addition to the application form, a maximum of ten (10) pages of text for the full research narrative can be attached to the application form. No more than ten pages of proposal narrative will be accepted. Narrative elements include items 1 through 6 below, and should be organized as follows:

1. Introduction/background;
2. Objectives;
3. Description of methods and survey tools if applicable;
4. Expected outcomes/contribution to field/significance;
5. Anticipated difficulties and approaches to overcoming them;
6. References.

The **appendix** is an additional item that is not subject to the 10-page limit, and must include the following elements:

- Budget: You may use the Budget Proposal Worksheet provided on the application website or an equivalent spreadsheet. (Please have your business manager review your budget!)
- Budget justification in an attached budget justification that addresses:
  a) Key Personnel- List all personnel names, organization and project duties
  b) Salaries and Wages
  c) Fringe Benefits
  d) Travel; note that prior Program Grant Official (PGO) approval is needed for each case of foreign travel involved. Prior approval may be a lengthy process, on the order of months.
  e) Consultants; generally should be specifically named in the proposal.

f) General Services, which includes copying, supplies, etc. Note: Meal & refreshment expenses require prior approval and are generally only allowed for participants in group settings, such as focus groups.
g) Equipment
h) Tuition Remission (Note: Within the University of Illinois system, student tuition remission will not be charged for these grants, so do not include that cost; for other applicants, please include such charges)
i) Facilities and Administration (F&A) Allocation (Indirect) (Note: Limited to 8% by NIOSH)

- Timeline for the proposed research;
- External Funding Plan: A description of how the results will be leveraged into external applications, a time-line for proposal grant submission to external funding agency (specify), and a plan for expanding the work as a line of research;
- NIH Biosketch for the Principle Investigator, co-investigators, and mentors (See templates and sample biosketch at https://grants.nih.gov/grants/forms/biosketch.htm)
- Letters of Support from collaborators;
- Certificate of completion of continuing education from your institution in a human subjects protection program dated within the last two (2) years for all investigators, even if this application does not include human subjects research. See https://research.uic.edu/human-subjects-irbs/education-training/ for information about UIC's program. In addition, all investigator and key research personnel are required to complete a CITI Information Privacy and Security (IPS) course (or an equivalent at their home institution) before their involvement in the research (link is at the same url).
- A brief plan that addresses the selection of human subject study participants that is likely to pass Internal Review Board (IRB) application. For this application, pilot project applicants do not need to submit an IRB compliance application to their IRB before the research proposal is reviewed for funding eligibility. However, the pilot project reviewers do want to see a plan that demonstrates that the researchers have considered ethical standards for human research protections. See some of the Guiding Principles for Ethical Research at this site: https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research. If applicable, also address inclusion of women, minorities and children. See the GRANTS POLICY STATEMENT REGARDING ETHICAL CONDUCT IN RESEARCH in this document for more information.
- Research involving vertebrate animals must follow the instructions in this document: https://grants.nih.gov/grants/olaw/VAChecklist.pdf.
- In accordance with the new Federal regulations regarding Financial Conflicts of Interests (COI) the University (UIC) may not expend funds from many federal and non-federal sponsors (including NIOSH) until requirements of the regulation have been met by Investigators and senior/key research personnel named on the funding proposal. Information is available at: https://research.uic.edu/compliance/coi/fcoi/. Upon successful completion of a training option, the UIC Training Learning Management System (LMS) will provide a certificate of completion for COI training;
- Survey instruments (if applicable) should also be included in the Appendix.

RESEARCH INVOLVING HUMAN SUBJECTS

Among the challenges that new researchers face is the time and effort required to comply with requirements relative to the protection of human subjects. If the proposed project involves research involving human subjects in any way, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human research participants. Assurance must be provided that demonstrates that the project will be subject to initial and continuing reviews by an appropriate institutional review board. Please read the GLC-OHS's Research Policy attached to these instructions. It is strongly recommended that applicants familiarize themselves with the policy statement and with the human subjects review process at their sponsoring organization.

All ERC pilot/small projects, including those being conducted by or with other institutions, that involve human subjects must be reviewed and approved by an IRB in advance of project funding to ensure protection of the rights and welfare of human subjects. (See 45 Code of Federal Regulations 46.) The IRB must be registered with the DHHS Office of Human Research Protections and have completed a Federal-wide Assurance (See https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-and-fwa-status/index.html for a list of registered institutions). Documentation of IRB approval of protocols, as well as copies of currently approved consent forms,

must be provided to the GLC-OHS prior to the award. "IRB Approval" means full, final IRB approval **that includes approval documentation of the same project description, exact title as the proposal, and PI name as provided on the pilot project application**. Project protocols must comply with all applicable Federal and State regulations.

Awards will not be made available until Mr. Cali receives documentation of human subjects review or exemption reviews and approves the required documentation. Previous awards under this program have been disallowed or delayed because grantees did not begin their human subjects review application promptly. Therefore, applicants must provide a letter of completed review within two months (60 days) of the notification of funding recommendation or the award recommendation will be withdrawn. Please contact Mr. Cali if you have questions about requirements relative to the protection of human subjects.

PROPOSAL REVIEW

Review will be conducted in late April or early May. Although review comments may be provided earlier, formal award announcements cannot be made until NIOSH officially awards the funds to UIC, usually in late June.

For all proposals, after scientific review is complete, eligible applicants will be ranked in order of overall merit. Investigators with proposals that are recommended for funding will be notified, but actual award will not be made until the completion of recommendations or requirements set by the scientific review committee. For proposals that involve research on human subjects, one of these conditions will be a successful review of protection of Human Subject protocols by an organization that has an Assurance of Compliance with the Office for Human Research Protections per U.S. Department of Health and Human Services (HHS) requirements. Documentation of compliance must be received by Mr. Cali before awards will be made available.

POLICY REGARDING OTHER SUPPORT

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts are not included.

Do not confuse Research Support with Other Support. Though they sound similar, these items are distinctly different. As part of the biosketch section of the application, Research Support highlights your accomplishments, and those of your colleagues, as scientists. This information will be used by the reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualification of the research team. In contrast, Other Support information must be addressed on the application form (Page 4). The Principal Investigator should include a statement on other support specific to this research project. The GLC-OHS will request additional and/or up-to-date information if the award is recommended after peer review. This information will be used to ensure that the proposed research does not have significant overlap because of funding from other sources.

Significant overlap, whether scientific, budgetary, or commitment of individual effort greater than 100 percent or 12 person months, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source. Commitment overlap occurs when a person's time commitment exceeds 100 percent or 12 person months, whether or not salary support is requested in the application. Although information regarding other support is only requested for Senior/ Key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent. The PI for this project should state the estimated percentage of time commitment that will be expended on the project, even if the PI is not requesting salary support. Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely

related in two or more applications or awards, regardless of the funding source. Resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the PI, and GLC-OHS staff.

PROPOSALS FOR RESEARCH AT OR INVOLVING FOREIGN PERFORMANCE SITES

Projects involving research at foreign performance sites are discouraged for a number of reasons, including IRB approvals required at both your institution and in the performance site country, and prior Program Grant Official (PGO) approval for each case of foreign travel involved. Review of such projects has proven to be very time-consuming (on the order of 6 months) and not consistent with the usual short time frame for pilot projects. Proposed projects also must have a clear justification for the relevance to worker protection issues in the U.S. given the focus of the OSH Act on the U.S. workforce.

RESEARCH AT INSTITUTIONS OTHER THAN THE UNIVERSITY OF ILLINOIS:

GLC-OHS strongly encourages proposals from institutions outside of the University of Illinois (UI) system. However, it should be noted that it is necessary to establish a sub-contract between UI and other institutions. This usually takes a few months, so non-UI proposals should factor this delay into their project. Project completion after the preferred one-year project period is allowed, but all funds must be utilized within the one-year period without exception.

In order to be consistent with the GLC-OHS Program requirements from CDC/ NIOSH, some additional requirements may be included in sub-contracts with other institutions. These requirements will address data sharing, invention reporting (patentable), and property inventory related to the award.

OTHER SPECIAL REQUIREMENTS

Research funded by GLC-OHS must also meet DHHS and NIH requirements regarding inclusion of women, minorities, and children, and use of animal subjects, and use of funds for lobbying activities.

BUDGET GUIDELINES

Request the minimum amount of funds that will allow you to conduct the research. Justify each item clearly. Indirect costs will be allowed to a maximum of 8% of direct costs excluding equipment and tuition and/or tuition remission. Applications that include matching funds should detail those funds on the application budget worksheet.

- Note: UIC NIOSH trainees cannot receive additional personnel funding under this grant.
- Note: Receipt of federal funds includes certain restrictions on purchase of food, refreshments, etc. Please ensure that your proposal budget complies with these restrictions.
- Note: Many organizations have strict documentation requirements for compensation of research participants; contact your business manager for clarification of such restrictions.
- Note: Please have your business manager review your final budget.

Be sure to include personnel fringe benefits and indirect costs as part of the budget. Check with your employer's business office to confirm fringe rates; indirect costs are capped at 8% for these awards. It is not necessary to add tuition remission charges to the budget for research assistants at UIC for these awards. Other institutions may have tuition charges that must be included in the budget but are not included in the calculation of indirect costs.

All fund awards must be utilized in full by June 30, 2023, the end of the fiscal year, as there is no mechanism to extend the award beyond that date.

REVIEW PROCESS

Proposals will be reviewed by a subcommittee of occupational safety and health professionals. The full committee includes representatives from Industrial Hygiene, Occupational Health Nursing, Occupational Medicine, Occupational Safety, Occupational and Environmental Epidemiology, and Agricultural Safety and Health. The subcommittee reviewing individual proposals in detail will include representatives most appropriate to the proposal. Investigators will receive a priority score and written critique of the proposal.

REVIEW CRITERIA

In their written critiques, reviewers will be asked to comment on each of the following criteria. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

Significance: Does this study address an important occupational safety and health problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods, and analyses of occupational safety and health adequately developed, well integrated, well-reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

Investigators: Are the investigators appropriately trained and well suited to carry out this occupational safety and health work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA:

- Relevance to occupational safety and health by contributing to achievement of research objectives described in NORA.
- Potential contribution to applied technical knowledge in the identification, evaluation, and/or control of occupational safety and health hazards.
- Magnitude of the problem in terms of numbers of workers affected.
- Severity of the disease or injury in the worker population.
- Likelihood that the proposed work can be accomplished in one year.
- Preference will be given to proposals from the following states in the GLC-OHS's region: Illinois, Indiana, Wisconsin, and Missouri.

Previously funded projects are not eligible for renewal, although previous projects that lead to new, related hypotheses might be considered. Previous year award recipients may apply for funding to further a line of research initiated by a previous award by explaining current project progress, and indicating the purpose of the additional funding. A 2nd year proposal should explore a hypothesis that is distinctly different, advanced, or compelling from the previous year so as to stand alone as a separate project. However, priority will generally be given to new applicants.

ADMINISTRATION OF AWARDS:

Investigators with proposals that are recommended for funding by the review committee will be notified (usually in late May or early June) so as to help investigators prepare, but formal award notice will not be made until the completion of recommendations or requirements set by the scientific review committee and until GLC-OHS receives written funding notice from NIOSH (In the past, this notice has arrived after July 1). The amount of prospective funding and recommendations/ requirements will be provided to the PI by e-mail. Once recommendations or requirements are completed, e-mail notice of award will be provided.

UIC will establish award accounts for UIC recipients and subcontracts for non-UIC recipients. Accounts will be managed by award recipients and/or their business offices. Recipients will be required to provide periodic reporting of research progress and expenditures. Prior written approval must be obtained from the Research Committee before modifications are made to the budget or research focus. Allowable expenditures must be incurred only within the project period. Award decisions will be announced by July 1, 2022 or earlier if possible, but note that in previous years, the official notice of award has been delayed pending notice of award from NIOSH to UIC.

A final project report is required within 30 days of the end of the project funding period. Additionally, post-project completion reports may be requested periodically that provide information about publications, presentations, and other project outcomes for 1 to 3 years after projects are completed.

PUBLICATIONS AND PRESENTATIONS:
NIOSH-funded research presentations and publications are required to include an acknowledgement and disclaimer. Typical disclaimer wording is as follows: "This publication (or journal article, presentation, etc.) was supported by Grant # xxxx from NIOSH. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of NIOSH."

GRANTS POLICY STATEMENT REGARDING ETHICAL CONDUCT IN RESEARCH (HUMAN SUBJECTS)

The GLC-OHS requires that applicants for funding from us follow the U.S. Department of Health and Human Services (HHS) regulations for protection of human subjects involved in HHS-funded research. The HHS requirements are presented here. These requirements were taken from NIH Grants Policy Statement, Part II: Terms and Conditions of NIH Grant Awards-Part 2 of 7.

HHS regulations for the protection of human subjects, at 45 CFR Part 46, implement section 491(a) of the PHS Act and provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by NIH or other HHS components. They stipulate that the applicant/grantee, whether domestic or foreign, is responsible for safeguarding the rights and welfare of human subjects involved in NIH grant-supported research activities. Subpart A of the HHS regulations constitutes the Federal policy (common rule) for the protection of human subjects.

Applicant organizations proposing to involve human subjects in research must file (or have previously filed) a written Assurance of Compliance with the Office for Human Research Protections, HHS (OHRP) setting forth the commitment of the organization to establish appropriate policies and procedures for the protection of human subjects. Affiliated organizations or organizations that will serve as other performance sites for the grant-supported research must also file an Assurance. OHRP is responsible for approving the Assurance, which may be a Multiple Project Assurance (MPA), a Single Project Assurance (SPA), or other type of Assurance, as appropriate. OHRP may also negotiate an Inter-Institutional Amendment if employees of an organization with an MPA routinely conduct their grant-supported research at an affiliated institution, thereby avoiding the need for an SPA for each separate project performed at such sites.

NIH will not award any grant for research involving human subjects unless the organization is operating under an approved Assurance and, if operating under an MPA, provides certification, as part of its application, that an appropriate Institutional Review Board (IRB) has, within 12 months of the budget period start date, reviewed and approved the proposed activity in accordance with the regulatory requirements. SPA organizations must provide certification of IRB approval to OHRP as part of the SPA. In addition, no human subjects may be involved in research at an affiliated institution prior to approval by OHRP of an applicable Assurance for that organization. If an MPA organization submits an application with the knowledge that human subjects may be involved within the project period, but definite plans are not set forth in the application, the research activity must be reviewed and approved by an IRB and a certification submitted to NIH before human subjects may be involved in covered research activities supported by the award.

No individual may receive NIH grant funds for covered research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an applicable written Assurance or the individual makes other arrangements with OHRP.

For purposes of this public policy requirement, the definitions at 45 CFR 46.102 apply. A "human subject" is defined as 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. The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR 46.

"Research" is defined as "systematic investigation designed to develop or contribute to generalizable knowledge." Unless an activity is "exempt" (see 45 CFR 46.101), any activity meeting the regulatory definition of "research" constitutes research for purposes of applying the regulations, even if supported by a grant that might have as its overall purpose an activity that is not primarily research. (For example, some training programs may include research activities.) OHRP should also be consulted if there is any question concerning the classification of research as exempt or nonexempt.

The GLC-OHS will not award any grant for research involving human subjects unless the organization demonstrates compliance with the above HHS requirements. No individual may receive grant funds from the GLC-OHS for covered research involving human subjects unless the individual is affiliated with or sponsored by an organization that assumes responsibility for the research under an applicable written Assurance or the individual makes other arrangements with OHRP.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Inclusion of Women and Minorities in Research Involving Human Subjects

It is the policy of the CDC and NIH, as well as the GLC-OHS, to ensure that individuals of both sexes and the various racial and ethnic groups will be included in supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

Inclusion of Children as Participants in Research Involving Human Subjects

It is the policy of NIH and the GLC-OHS that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, including research conducted and supported by the GLC-OHS, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and updated in 2015, and is available at the following URL address: https://grants.nih.gov/grants/guide/notice-files/not98-024.html

Animal Subjects

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant (as well as each subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC and NIH supported activities, including those supported by the GLC-OHS, must file (or have on file) the Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC).

Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds, including awards by the GLC-OHS, for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of PHS appropriated funds (including funds from the GLC-OHS), shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Prohibition on use of CDC Funds for Certain Gun Control Activities

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control. Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a Member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence Members of Congress with regard to specific legislation or appropriation by Congress. In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the new language in the CDC's Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.