



Administration for Community Living

National Institute on Disability, Independent Living, and Rehabilitation Research

Disability and Rehabilitation Research Projects (DRRP) Program: Real Time Pressure Mapping
to Reduce Risk of Pressure Ulcers

HHS-2020-ACL-NIDILRR-DPHF-0396

Application Due Date: 05/11/2020

Disability and Rehabilitation Research Projects (DRRP) Program: Real Time Pressure Mapping
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**Department of Health & Human Services
Administration for Community Living**

ACL Center:	National Institute on Disability, Independent Living, and Rehabilitation Research
Funding Opportunity Title:	Disability and Rehabilitation Research Projects (DRRP) Program: Real Time Pressure Mapping to Reduce Risk of Pressure Ulcers
Announcement Type:	Initial
Funding Opportunity Number:	HHS-2020-ACL-NIDILRR-DPHF-0396
Primary CFDA Number:	93.433
Due Date for Letter of Intent:	04/14/2020
Due Date for Applications:	05/11/2020
Date for Informational Conference Call:	04/02/2020

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or, with <https://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful submission.

Executive Summary

The purpose of NIDILRR's Disability and Rehabilitation Research Projects (DRRP) which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to plan and conduct research, demonstration projects, training, and related activities, including international activities, to develop methods, procedures, and rehabilitation technology that maximize the full inclusion and integration into society, employment, independent living, family support, and economic and social self-sufficiency of individuals with disabilities, especially individuals with the most severe disabilities, and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

Under this particular DRRP priority, the grantee will conduct research and development activities toward sensor-based technologies to detect conditions that are associated with pressure ulcers (pressure, moisture, heat, friction, others) and provide real-time information about these conditions to people with disabilities.

I. Funding Opportunity Description

Background:

Pressure injuries are a common problem that lead to significant costs for people with disabilities and the health care system (Stinson & Crawford, 2015). Approximately 80% of people with spinal cord injuries (SCI) will have at least one pressure injury during their lifetime and 30%

will have more than one (SCI Model Systems, 2009).

While anyone can get a pressure injury, people with spinal cord injuries and other neurological and mobility impairments are at elevated risk because of lack of sensation and extended periods of sitting. Wheelchair users at risk of developing pressure injuries may have a wide variety of medical diagnoses such as SCI, multiple sclerosis, cerebral palsy, spinal bifida, and other neurological and orthopedic conditions that impact mobility and sensation (Stockton, Gebhardt, & Clark, 2009).

People with SCI (or other conditions that lead to limited sensation) do not know that they are experiencing excessive pressure because of impaired sensory feedback. Additionally, there is little or no sense of relief from discomfort experienced with pressure offloading. Wheelchair users must maintain constant attention on the need to reduce pressure across areas at risk. Seat interface pressure mapping could produce powerful behavior change through real-time, immediate information about the need to shift weight or about the effectiveness of a weight shift when it is done (Vos-Draper & Morrow, 2016).

New technologies to assist wheelchair users to self-manage their skin health are needed. Real-time visual feedback has been shown to be effective in developing beneficial habits in wheelchair propulsion (Rice et al., 2013), and it may also be a valuable tool toward better management of skin conditions that can lead to pressure injuries. Other forms of feedback (e.g. haptic or auditory) may also be used to alert wheelchair users to conditions that are conducive to the development of pressure injuries. Sensor technology has progressed to include sensors that are very small and thin (Chen et al., 2014). Large amounts of pressure injury-related data (pressure, moisture, heat, friction) can be collected and analyzed almost instantly and then conveyed to wheelchair users via multiple means, including visual displays on a smartphone, which about 75% of wheelchair users with SCI carry (Vos-Draper & Morrow, 2016).

There is a clear need for effective strategies that provide essential information and feedback to wheelchair users to prompt the need to relieve pressure and address other conditions associated with pressure injuries. These strategies may include devices to train wheelchair users to move frequently, alert them to a problem with seating equipment, or to affirm that weight shifts were effective in redistributing pressure. Prevention behaviors that are not paid attention to through conscious awareness and effort are difficult to maintain, especially if the stimulus is lacking (Vos-Draper & Morrow, 2016). Information and feedback from pressure mapping sensors can let a person know about their seating conditions, and whether they are doing effective pressure releases.

With this DRRP, NIDILRR aims to sponsor research and development activities toward sensor-based technologies to detect conditions that are associated with pressure injuries and provide real-time information about these conditions to people with disabilities.

References:

Chen, L., Tee, B., Chortos, A., Schwartz, G., Tse, V., & Lipomi, D. J. et al. (2014). Continuous wireless pressure monitoring and mapping with ultra-small passive sensors for health monitoring and critical care. *Nature Communications*, 5(1). doi: 10.1038/ncomms6028

NIDILRR Long-Range Plan. (2018). <https://acl.gov/sites/default/files/about-acl/2019-01/NIDILRR%20LRP-2018-2023-Final.pdf>

Rice, I., Pohlig, R., Gallagher, J., & Boninger, M. (2013). Handrim Wheelchair Propulsion Training Effect on Overground Propulsion Using Biomechanical Real-Time Visual Feedback. *Archives of Physical Medicine and Rehabilitation*, 94(2), 256-263. doi: 10.1016/j.apmr.2012.09.014

SCI Model Systems in collaboration with the University of Washington Model Systems Knowledge Translation Center. (2009). *Skin Care & Pressure Sores Part 1: Causes and Risks of Pressure Sores* [Fact sheet]. Retrieved from https://msktc.org/lib/docs/Factsheets/SCI_Skinca re_Series_Causes_and_Risks.pdf

Stinson, M., & Crawford, S. (2015). Wheelchair seating and pressure mapping. In *International Handbook of Occupational Therapy Interventions* (pp. 221-231). Springer, Cham.

Stockton, L., Gebhardt, K. S., & Clark, M. (2009). Seating and pressure ulcers: Clinical practice guideline. *Journal of Tissue Viability*, 18(4), 98-108.

Vos-Draper, T., & Morrow, M. (2016). Seating-Related Pressure Injury Prevention in Spinal Cord Injury: a Review of Compensatory Technologies to Improve In-Seat Movement Behavior. *Current Physical Medicine and Rehabilitation Reports*, 4(4), 320-328. doi: 10.1007/s40141-016-0140-7

Priority: DRRP on Real Time Pressure Mapping to Reduce Risk of Pressure Ulcers

The Administrator of the Administration for Community Living (ACL) establishes a priority for a Disability and Rehabilitation Research Project (DRRP) for Real Time Pressure Mapping to Reduce Risk of Pressure Ulcers. Under this DRRP priority, applicants must propose research and development activities that are aimed at maintaining or improving the independence, community living, and quality of life outcomes of people with disabilities. To contribute to this outcome, the DRRP must:

- (a) Conduct an iterative research and development process to combine and refine existing technology, and develop new technology as needed, to create real-time personal-use mapping of pressure and possibly other conditions that are associated with pressure injuries (including but not limited to moisture, heat, and friction). Research and development activities must make use of advanced sensor technologies to allow users to perceive and react to those conditions associated with pressure injuries. The technology that is developed under this grant must provide feedback to wheelchair users in a way that is motivating and engaging. This feedback may involve visual cues, alarms or other notifications that pressure and possibly other conditions have reached levels that place the user at risk of pressure injuries.
- (b) Partner with people with disabilities, consumer organizations representing people with disabilities, and relevant local, state, and national organizations to ensure the ongoing relevance of proposed activities.
- (c) Focus its research activities in the intervention development and intervention efficacy stages of research, or both. Applicants must justify the need and rationale for research at the proposed stage or stages and describe fully an appropriate methodology or methodologies for the proposed research. NIDILRR's stages of research are defined in Section 1 of this funding opportunity announcement.
- (d) Engage in development activities that culminate in the proof of product or proof of adoption stage of development. Applicants must justify the need and rationale for development at the proposed stage or stages and describe fully an appropriate methodology or methodologies

for the proposed development. NIDILRR's stages of development are defined in Section 1 of this funding opportunity announcement.

(e) Conduct knowledge translation activities (i.e., utilization, dissemination) in order to facilitate stakeholder (e.g., people with disabilities, employers, policymakers, practitioners) use of the knowledge and products that result from the research and development activities conducted under paragraph (a) of this priority.

Stages of research:

(a) Exploration and discovery means the stage of research that generates hypotheses or theories through new and refined analyses of data, producing observational findings and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes of individuals with disabilities, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of individuals with disabilities. Results achieved under this stage of research may inform the development of interventions or lead to evaluations of interventions or policies. The results of the exploration and discovery stage of research may also be used to inform decisions or priorities;

(b) Intervention development means the stage of research that focuses on generating and testing interventions that have the potential to improve outcomes for individuals with disabilities. Intervention development involves determining the active components of possible interventions, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed intervention study. Results from this stage of research may be used to inform the design of a study to test the efficacy of an intervention;

(c) Intervention efficacy means the stage of research during which a project evaluates and tests whether an intervention is feasible, practical, and has the potential to yield positive outcomes for individuals with disabilities. Efficacy research may assess the strength of the relationships between an intervention and outcomes, and may identify factors or individual characteristics that affect the relationship between the intervention and outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support "scaling-up" an intervention to other sites and contexts. This stage of research may include assessing the training needed for wide-scale implementation of the intervention, and approaches to evaluation of the intervention in real-world applications; and

(d) Scale-up evaluation means the stage of research during which a project analyzes whether an intervention is effective in producing improved outcomes for individuals with disabilities when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based intervention in different settings. The project examines the challenges to successful replication of the intervention, and the circumstances and activities that contribute to successful adoption of the intervention in real-world settings. This stage of research may also include well-designed studies of an intervention that has been widely adopted in practice, but lacks a sufficient evidence base to demonstrate its effectiveness.

Stages of development:

(a) Proof of concept means the stage of development where key technical challenges are resolved. Stage activities may include recruiting study participants, verifying product

requirements; implementing and testing (typically in controlled contexts) key concepts, components, or systems, and resolving technical challenges. A technology transfer plan is typically developed and transfer partner(s) identified; and plan implementation may have started. Stage results establish that a product concept is feasible.

(b) Proof of product means the stage of development where a fully-integrated and working prototype, meeting critical technical requirements is created. Stage activities may include recruiting study participants, implementing and iteratively refining the prototype, testing the prototype in natural or less-controlled contexts, and verifying that all technical requirements are met. A technology transfer plan is typically ongoing in collaboration with the transfer partner(s). Stage results establish that a product embodiment is realizable.

(c) Proof of adoption means the stage of development where a product is substantially adopted by its target population and used for its intended purpose. Stage activities typically include completing product refinements; and continued implementation of the technology transfer plan in collaboration with the transfer partner(s). Other activities include measuring users' awareness of the product, opinion of the product, decisions to adopt, use, and retain products; and identifying barriers and facilitators impacting product adoption. Stage results establish that a product is beneficial.

Statutory Authority

29 U.S.C. 764(a)

II. Award Information

Funding Instrument Type:	Grant
Estimated Total Funding:	\$350,000
Expected Number of Awards:	1
Award Ceiling:	\$350,000 Per Budget Period
Award Floor:	\$345,000 Per Budget Period
Length of Project Period:	60-month project period with five 12-month budget periods

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2021 from the list of approved but unfunded applicants from this competition.

III. Eligibility Information

1. Eligible Applicants

States; public or private agencies, including for-profit agencies; public or private organizations, including for-profit organizations; IHEs; and Indian tribes and tribal organizations.

2. Cost Sharing or Matching

Cost Sharing / Matching Requirement: No

3. Responsiveness and Screening Criteria

Application Responsiveness Criteria

To be considered for review under this grant opportunity, applications must be directly responsive to each of the detailed requirements under the Priority heading in Section I. These requirements include research and development activities at specific stages, partnerships with relevant stakeholders, and dissemination and utilization activities – all toward sensor-based technologies to detect conditions that are associated with pressure injuries, and provision of real-time information about these conditions to people with disabilities.

Application Screening Criteria

We will screen all applications and will reject any applications that:

- Are submitted after the established deadline;
- Propose a budget that exceeds \$350,000 in any single budget year;
- Propose a project period that exceeds 60 months.

The Project Narrative section of the application must be double-spaced, on 8 1/2" X 11" pages with 1" margins on both sides, and a standard font size of not less than 12. The project narrative must not exceed 75 double-spaced pages. For project narratives that exceed 75 double-spaced pages, NIDILRR will instruct reviewers to disregard all of the content on the pages beyond the 75th page.

IV. Application and Submission Information

1. Address to Request Application Package

Application materials can be obtained from <https://www.grants.gov/> or <https://www.acl.gov/grants/applying-grants>

Please note, ACL requires applications for all announcements to be submitted electronically through <https://www.grants.gov> in Workspace. Grants.gov Workspace is the standard way for organizations and individuals to apply for federal grants in Grants.gov. An overview and training on Grants.gov Workspace can be found here at: <https://www.grants.gov/web/grants/applicants/workspace-overview.html>

The Grants.gov (<https://www.grants.gov>) registration process can take several days. If your organization is not currently registered with <https://www.grants.gov>, please begin this process immediately. **For assistance with <https://www.grants.gov>, please contact support@grants.gov or 800-518-4726 between 7:00 a.m. and 9:00 p.m. Eastern Time.**

- At the <https://www.grants.gov> website, you will find information about submitting an application electronically through the site, including the hours of operation. ACL strongly recommends that you do not wait until the application due date to begin the

application process because of the time involved to complete the registration process.

- All applicants must have a DUNS number (<http://fedgov.dnb.com/webform/>) and be registered with the System for Award Management (SAM, <https://sam.gov/SAM/>) and maintain an active SAM registration until the application process is complete, and, should a grant be made, throughout the life of the award. **Effective June 11, 2018, when registering or renewing your registration, you must submit a notarized letter appointing the authorized Entity Administrator. Please be sure to read the FAQs located at www.sam.gov to learn more.** Applicants should allot sufficient time prior to the application deadline to finalize a new, or renew an existing registration. This action should allow you time to resolve any issues that may arise. Failure to comply with these requirements may result in your inability to submit your application or receive an award. Maintain documentation (with dates) of your efforts to register or renew at least two weeks before the deadline. See the SAM frequently asked questions for Grantees at: <https://sam.gov/SAM/pages/public/loginFAQ.jsf>.

Note: Once your SAM registration is active, allow 24 to 48 hours for the information to be available in Grants.gov before you can submit an application through Grants.gov. This action should allow you time to resolve any issues that may arise. Failure to comply with these requirements may result in your inability to submit your application or receive an award.

- **Note:** Failure to submit the correct EIN suffix can lead to delays in identifying your organization and access to funding in the Payment Management System.
- Effective October 1, 2010, HHS requires all entities that plan to apply for and ultimately receive Federal grant funds from any HHS Operating/Staff Division (OPDIV/STAFFDIV) **or receive subawards directly from the recipients of those grant funds** to:

1. Register in SAM prior to submitting an application or plan;
2. Maintain an active SAM registration with current information at all times during which it has an active award or an application or plan under consideration by an OPDIV; and
3. Provide its DUNS number in each application or plan to submit to the OPDIV.

Additionally, all first-tier subaward recipients must have a DUNS number at the time the subaward is made.

- Since October 1, 2003, the Office of Management and Budget has required applicants to provide a Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements. It is entered on the SF 424. It is a unique, **nine-digit identification number**, which provides unique identifiers of single business entities. The DUNS number is *free and easy* to obtain.
- Organizations can receive a DUNS number at no cost by calling the dedicated toll-free DUNS Number request line at 866-705-5711.
- You must submit all documents electronically, including all information included on the SF424 and all necessary assurances and certifications.
- **Your application must comply with any page limitation requirements described in this Program Announcement.**
- After you electronically submit your application, you will receive an automatic

acknowledgement from <https://www.grants.gov> that contains a <https://www.grants.gov> tracking number. The Administration for Community Living will retrieve your application form from <https://www.grants.gov>.

U.S. Department of Health and Human Services
Administration for Community Living
Brian Bard
NIDILRR
Phone Number: (202) 795-7298
E-mail: brian.bard@acl.hhs.gov

2. Content and Form of Application Submission

Letter of Intent

Due Date for Letter of Intent: **04/14/2020**

Due to the nature of this DRRP competition, NIDILRR is requesting all potential applicants to submit a letter of intent (LOI). These letters will assist NIDILRR in selecting reviewers for this competition. The submission is not mandatory, and the content of the LOI will not be peer reviewed or otherwise used to rate an applicant's application.

Each LOI should be limited to a maximum of four pages and include the following information: (1) the title of the proposed project, the name of the applicant, the name of the Project Director or Principal Investigator (PI), and the names of partner institutions and entities; (2) a brief statement of the vision, goals, and objectives of the proposed project and a description of its proposed activities at a sufficient level of detail to allow NIDILRR to select potential peer reviewers; (3) a list of proposed project staff including the Project Director or PI and key personnel; (4) a list of individuals whose selection as a peer reviewer might constitute a conflict of interest due to involvement in proposal development, selection as an advisory board member, co-PI relationships, etc.; and (5) contact information for the Project Director or PI. Submission of a LOI is not a prerequisite for eligibility to submit an application.

NIDILRR will accept the LOI via email. The LOI must be sent to Megan Alvarado at megan.alvarado@acl.hhs.gov.

Project Narrative

The project narrative portion of your application is where you describe your proposed project and address the general requirements for DRRPs and the review criteria. Each applicant must limit the project narrative to the equivalent of no more than 75 pages, using the following standards:

- A page is 8.5" x 11", on one side only, with 1" margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative. You are not required to double space titles, headings, footnotes, references,

and captions, or text in charts, tables, figures, and graphs. Use a font that is not less than size 12.

- Use one of the following fonts: Times New Roman, Courier, Courier New or Arial.
- Include all critical information in the project narrative, minimizing the need for additional appendices.
- Ensure that you attach .PDF files only for any attachments to your application. While you are able to attach files to your application in formats other than PDF, non-PDF files are converted into PDF format before reviewers see and evaluate your application. The conversion to PDF format may not maintain your original formatting. Therefore to ensure the integrity of your application documents -- we strongly recommend that you attach only PDF files as you submit your application.

NOTE: The page limit does not apply to the Application for Federal Assistance (SF 424), the budget narrative, the forms, the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the project narrative section.

For project narratives that exceed 75 double-spaced pages, NIDILRR will instruct reviewers to disregard all of the content on the pages beyond the 75th page.

Applicants should provide a Work Plan in their project narrative. The Work Plan should cover all five (5) years of the project period. The Work Plan should include a statement of the project's overall goal(s), anticipated outcome(s), and the major tasks that are proposed to achieve the goal and outcome(s). For each major task, the work plan should identify timeframes involved and the lead person responsible for the task. Please use the "Project Work Plan- Sample Template" format as a reference and resource, if desired. You can find this sample template in the Appendix section of this Funding Opportunity Announcement.

The following application components are not considered part of the Project Narrative section and do not count against an applicant's 75-page limit for the project narrative.

Table of Contents

The table of contents shows where and how the important sections of your proposal are organized. While the application will be submitted electronically, the reviewers may use printed copies during the review process. The table of contents will assist reviewers in more efficiently and effectively evaluating your application.

Summary/Abstract

The one-page abstract should be a comprehensive description of what the whole (all years) project is, not a description of the competency of the institution or project director. It is not an executive summary. It can be single or double-spaced.

Resume/ Vitae

Vitae of staff or consultants should include information that is specifically pertinent to this proposed project.

Budget Narrative/Justification

This part requires an itemized budget breakdown for each project year and the basis for estimating the costs of personnel salaries, benefits, project staff travel, materials and supplies, consultants and subcontracts, indirect costs, and any other projected expenditures. The SF 424A Budget document in the application kit does not contain adequate space for applicants to provide a full 5-year budget by "object class category." Applicants should use the budget justification section to provide a detailed budget for each proposed year of activity.

The Budget Narrative/Justification can be provided using the format "Budget Narrative/Justification - Sample Format" included in this document. Applicants are encouraged to pay particular attention to this document, which provides an example of the level of detail sought. A combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding is required. This information will be uploaded in the "Budget Narrative/Justification" section under the "Optional" category. The checkbox next to "Budget Narrative/Justification" **must** be selected in order to upload your documentation.

Please provide an itemized budget breakdown for each project year. The Appendix section of this Funding Opportunity Announcement includes a sample format for your budget narrative/justification.

Letters of Commitment from Key Participating Organizations and Agencies

Please include letters of commitment from Key Participating Organizations and Agencies after the Budget Narrative/Justification. Also, please submit an appendix that lists every collaborating organization and individual named in the application, including staff, consultants, contractors, and advisory board members. We will use this information to screen for conflicts of interest with reviewers.

Data Management Plan

NIDILRR requires applicants to include a Data Management Plan in the application. NIDILRR will review the data management plans of potential awardees for completeness and compliance before making the awards. The Data Management Plan does not count against the page limitation described in this FOA and is not subject to evaluation and scoring by the peer review panel. The Data Management Plan is a separate requirement from the Data and Safety Monitoring Requirement described in Section IV.6 of this document.

The data management plan (DMP) must include the following components:

1. Description of the types and format of data to be collected, and how they will be organized, stored, and preserved.
2. Description of metadata to be included in the data submission to a repository in order to enable meaningful and useful analysis of the data by users who are not part of the research team.
3. Indication of whether the awardee will submit the scientific data to the Interuniversity Consortium for Political and Social Research (ICPSR) or another public data repository. If the data are to be submitted to ICPSR, no further justification is required. If another repository is identified, the awardee must provide a justification of how this repository will provide for a long-term preservation of, and public access to, scientific data in

digital formats resulting from ACL/NIDILRR funded research at no cost. This justification should include a description of the way in which shared digital data will be discoverable, retrievable, and analyzable through the chosen data repository.

4. If applicable, explain why data sharing, long-term preservation, and access cannot be justified.
5. Provide a plan to address the study participants' consent process to enable the de-identified data to be shared broadly for future research.
6. Indicate an estimated cost to implement the data management plan. This cost is allowable as part of the award's direct costs.

For the DMP preparation, applicants may seek technical assistance from the ICPSR. ICPSR is the preferred data repository for archiving and sharing of scientific data generated under NIDILRR awards. ICPSR can be accessed at <https://www.icpsr.umich.edu/icpsrweb/> or contact help@icpsr.umich.edu or 734-647-2200.

NIDILRR recommends that all applicants view a 3-part training video entitled "NIDILRR Data Archiving and Sharing." This training video is available at: <https://dataarchivingandsharing.naric.com/>

3. Submission Dates and Times

Due Date for Applications: **05/11/2020**

Date for Informational Conference Call: 04/02/2020

Pre-Application Meeting: A pre-application teleconference meeting will be held between 1:00 p.m. and 3:00 p.m. (Eastern time) on the date listed above for the informational conference call. Interested parties are invited to participate in the pre-application meeting to discuss the funding priority and to receive information and technical assistance. You must contact Megan.Alvarado@acl.hhs.gov in order to participate in this meeting. NIDILRR staff also will be available to provide information and technical assistance via individual phone consultations from 3:00 p.m. to 4:00 p.m. on the date listed above. Requests for individual consultations during this one-hour window must be made in advance to Megan Alvarado.

Applications must be submitted electronically by 11:59 p.m. Eastern Time on the date listed immediately above for "Due Date for Applications."

Applications that fail to meet the application due date will not be reviewed and will receive no further consideration. You are strongly encouraged to submit your application a minimum of 3-5 days prior to the application closing date. Do not wait until the last day in the event you encounter technical difficulties, either on your end or with <https://www.grants.gov>. Grants.gov can take up to 48 hours to notify you of a successful submission.

When you are submitting your application via Grants.gov, you must (1) be designated by your organization as an Authorized Organization Representative (AOR) and (2) register yourself with Grants.gov as an AOR. Details on these steps are outlined at the following Grants.gov Web page: <https://www.grants.gov/web/grants/register.html>.

After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates

receipt by Grants.gov only.)

If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline because of technical problems with the Grants.gov system, please contact the person listed under Agency Contacts in section VII of this notice and provide a written explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. ACL will contact you after a determination is made on whether your application will be accepted.

Note: We will not consider your application for further review if you failed to fully register to submit your application to Grants.gov before the application deadline or if the technical problem you experienced is unrelated to the Grants.gov system.

Unsuccessful submissions will require authenticated verification from <https://www.grants.gov> indicating system problems existed at the time of your submission. You will be required to provide a submission error notification from <https://www.grants.gov> and/or tracking number in order to substantiate missing the application deadline due to systematic grants.gov problems.

Grants.gov (<https://www.grants.gov>) will automatically send applicants a tracking number and date of receipt verification once the application has been successfully received and validated in <https://www.grants.gov/>.

How to Submit an Application to HHS via Grants.gov

Grants.gov applicants can apply online using Workspace. Workspace is a shared, online environment where members of a grant team may simultaneously access and edit different webforms within an application. For each funding opportunity announcement (FOA), you can create individual instances of a workspace.

Below is an overview of applying on Grants.gov. For access to complete instructions on how to apply for opportunities, refer to: <https://www.grants.gov/web/grants/applicants/apply-for-grants.html>.

- 1) Create a Workspace: Creating a workspace allows you to complete it online and route it through your organization for review before submitting.
- 2) Complete a Workspace: Add participants to the workspace, complete all the required forms, and check for errors before submission.
 - a. Adobe Reader: If you decide not to apply by filling out webforms you can download individual PDF forms in Workspace so that they will appear similar to other Standard or HHS forms. The individual PDF forms can be downloaded and saved to your local device storage, network drive(s), or external drives, then accessed through Adobe Reader.

NOTE: Visit the Adobe Software Compatibility page on Grants.gov to download the appropriate version of the software at: <https://www.grants.gov/web/grants/applicants/adobe-software-compatibility.html>

- b. Mandatory Fields in Forms: In the forms, you will note fields marked with an asterisk and a different background color. These fields are mandatory fields that must be completed to

successfully submit your application

c. Complete SF-424 Fields First: The forms are designed to fill in common required fields across other forms, such as the applicant name, address, and DUNS number. To trigger this feature, an applicant must complete the SF-424 information first. Once it is completed, the information will transfer to the other form

3) Submit a Workspace: An application may be submitted through workspace by clicking the Sign and Submit button on the Manage Workspace page, under the Forms tab. Grants.gov recommends submitting your application package at least 24-48 hours prior to the close date to provide you with time to correct any potential technical issues that may disrupt the application submission.

4) Track a Workspace: After successfully submitting a workspace package, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the package. The number will be listed on the Confirmation page that is generated after submission.

For additional training resources, including video tutorials, refer to: <https://www.grants.gov/web/grants/applicants/applicant-training.html>

4. Intergovernmental Review

This funding opportunity announcement is not subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

5. Funding Restrictions

Note: A recent Government Accountability Office (GAO) report has raised considerable concerns about grantees and contractors charging the Federal government for additional meals outside of the standard allowance for travel subsistence known as per diem expenses. Executive Orders on Promoting Efficient Spending (E.O. 13589) and Delivering Efficient, Effective and Accountable Government (E.O. 13576) have been issued and instruct Federal agencies to promote efficient spending. Therefore, if meals are to be charged in your proposal, applicants should understand such costs must meet the following criteria outlined in the Executive Orders and HHS Grants Policy Statement:

- Meals are generally unallowable except for the following:
 - For subjects and patients under study (usually a research program);
 - Where specifically approved as part of the project or program activity, e.g., in programs providing children's services (e.g., Headstart);
 - When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement; and
 - As part of a per diem or subsistence allowance provided in conjunction with allowable travel.

6. Other Submission Requirements

Protection of Human Subjects

Research activities involving human subjects by awards under these programs are subject to Regulations for the Protection of Human Subjects. You do not need an assurance or IRB approval as a condition of applying for this competition.

If you marked "Yes" for Item 3 on the Supplemental Information for SF 424, you must provide a human subjects "exempt research" or "nonexempt research" narrative. Insert the narrative(s) in the space provided. If you have multiple projects and need to provide more than one narrative, please indicate which project each set of responses addresses.

A. Exempt Research Narrative. If you marked "Yes" for item 3a. and designated exemption number(s), provide the "exempt research" narrative. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination that the designated exemption(s) are appropriate. The narrative must be succinct. In addition, narratives are required for each participating partner if research is being conducted at other sites.

B. Nonexempt Research Narrative. If you marked "No" for item 3a., you must provide the "nonexempt research" narrative. The narrative must address the seven points. Although no specific page limitation applies to this section of the application, be succinct.

Human Subject Requirements for HHS grants. If your proposed project(s) involves research on human subjects, you must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects, unless that research is exempt as specified in the regulation. All awardees and their performance sites engaged in research involving human subjects must have or obtain:

(1) an assurance of compliance with the Regulations, and (2) initial and continuing approval of the research by an appropriately constituted and registered institutional review board. In order to obtain a Federal wide Assurance (FWA) of Protection for Human Subjects, the applicant may complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. To obtain a FWA, contact OHRP at: <https://www.hhs.gov/ohrp>.

Data and Safety Monitoring Requirement

For all proposed clinical trials, NIDILRR is requiring that applicants address the safety of human subjects participating in such trials or studies. This discussion must be identified in the application as a data and safety monitoring plan (Plan) and specifically address the safety of the participants and the validity and integrity of the data produced by the study. The Plan will be reviewed by NIDILRR staff prior to the award of the grant. Furthermore, a data and safety monitoring board (DSMB) is required for all multi-site clinical trials involving interventions that entail potential risk to participants. The data and safety monitoring plan must include a discussion of the DSMB if warranted by the proposed research activity. The Plan does not count against the page limitations described in this FOA and is not subject to the evaluation and scoring by the peer review panel.

V. Application Review Information

1. Criteria

Applications are scored by assigning a maximum of 100 points across the following criteria:

Responsiveness to the Priority Maximum Points:20

(1) The Director considers the responsiveness of the application to an absolute or competitive priority.

(2) In determining the application's responsiveness to the absolute or competitive priority, the Director considers one or more of the following factors:

(i) The extent to which the applicant addresses all requirements of the absolute or competitive priority.

Design of Research Activities Maximum Points:25

(1) The Director considers the extent to which the design of research activities is likely to be effective in accomplishing the objectives of the project.

(2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:

(i) The extent to which the research activities constitute a coherent, sustained approach to research in the field, including a substantial addition to the state-of-the-art.

(ii) The extent to which the methodology of each proposed research activity is meritorious, including consideration of the extent to which:

(A) The proposed design includes a comprehensive and informed review of the current literature, demonstrating knowledge of the state-of-the-art;

(B) Each research hypothesis or research question, as appropriate, is theoretically sound and based on current knowledge;

(C) Each sample is drawn from an appropriate, specified population and is of sufficient size to address the proposed hypotheses or research questions, as appropriate, and to support the proposed data analysis methods;

(D) The source or sources of the data and the data collection methods are appropriate to address the proposed hypotheses or research questions and to support the proposed data analysis methods;

(E) The data analysis methods are appropriate.

(F) Implementation of the proposed research design is feasible, given the current state of the science and the time and resources available.

(G) Input of individuals with disabilities and other key stakeholders is used to shape the proposed research activities.

(H) The applicant identifies and justifies the stage of research being proposed and the research methods associated with the stage.

Design of Development Activities Maximum Points:25

(1) The Director considers the extent to which the design of development activities is likely to be effective in accomplishing project objectives.

(2) In determining the extent to which the design is likely to be effective in accomplishing project objectives, the Director considers one or more of the following factors:

(i) The extent to which the proposed project methodology is meritorious, including consideration of the extent to which

(A) The proposed project shows awareness of the state-of-the-art for current, related products.

- (B) The proposed project employs appropriate concepts, components, or systems to develop the new or improved product;
- (C) The proposed project employs appropriate samples in tests, trials, and other development activities;
- (D) The proposed project conducts development activities in appropriate environments;
- (E) Input from individuals with disabilities and other key stakeholders is obtained to establish and guide proposed development activities;
- (F) The applicant identifies and justifies the stage(s) of development for the proposed project, and activities associated with each stage.

Design of Utilization Activities	Maximum Points:5
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- (1) The Director considers the extent to which the design of utilization activities is likely to be effective in accomplishing the objectives of the project.
- (2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:
 - (i) The extent to which the utilization strategies are likely to be effective.
 - (ii) The extent to which the potential new users of the information or technology have a practical use for the information and are likely to adopt the practices or use the information or technology, including new devices.

Design of Dissemination Activities	Maximum Points:5
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- (1) The Director considers the extent to which the design of dissemination activities is likely to be effective in accomplishing the objectives of the project.
- (2) In determining the extent to which the design is likely to be effective in accomplishing the objectives of the project, the Director considers one or more of the following factors:
 - (i) The extent to which the methods for dissemination are of sufficient quality, intensity, and duration.
 - (ii) The extent to which the materials and information to be disseminated and the methods for dissemination are appropriate to the target population, including consideration of the familiarity of the target population with the subject matter, format of the information, and subject matter.
 - (iii) The extent to which the information to be disseminated will be accessible to individuals with disabilities.

Project Staff	Maximum Points:15
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- (1) The Director considers the quality of the project staff.
- (2) In determining the quality of the project staff, the Director considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.
- (3) In addition, the Director considers one or more of the following:
 - (i) The extent to which the key personnel and other key staff have appropriate training and experience in disciplines required to conduct all proposed activities.

Adequacy and Accessibility of Resources	Maximum Points:5
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- (1) The Director considers the adequacy and accessibility of the applicant's resources to implement the proposed project.

(2) In determining the adequacy and accessibility of resources, the Director considers one or more of the following factors:

(i) The extent to which the applicant is committed to provide adequate facilities, equipment, other resources, including administrative support, and laboratories, if appropriate.

(ii) The extent to which the facilities, equipment, and other resources are appropriately accessible to individuals with disabilities who may use the facilities, equipment, and other resources of the project.

2. Review and Selection Process

As required by 2 CFR Part 200 of the Uniform Guidance, effective January 1, 2016, ACL is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information System

(FAPIIS), <https://www.fapiis.gov> before making any award in excess of the simplified acquisition threshold (currently \$150,000) over the period of performance. An applicant may review and comment on any information about itself that a federal awarding agency has previously entered into FAPIIS. ACL will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed by applicants as described in 2 CFR Section 200.205 Federal Awarding Agency Review of Risk Posed by Applicants ([https:// www.ecfr.gov/ cgi-bin/ text-idx?node=se2.1.200_1205&rgn=div8](https://www.ecfr.gov/cgi-bin/text-idx?node=se2.1.200_1205&rgn=div8)).

Final award decisions will be made by the Administrator of ACL. In making these decisions, the Administrator's primary consideration will be the ranking of applications by the review panel. The Administrator may also consider the reasonableness of the estimated cost to the government considering the available funding and anticipated results and the likelihood that the proposed project will result in the benefits expected. Under 45 CFR part 75, Section 205, item (3) history of performance is an item that is also reviewed. In addition, in making a competitive grant award, the Administrator of ACL also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Health and Human Services 45 CFR part 75.

3. Anticipated Announcement Award Date

Successful applicants will receive an electronic Notice of Award no later than September 30, 2020. All applicants will receive feedback from the peer review process no later than September 30, 2020.

VI. Award Administration Information

1. Award Notices

If your application is successful, we send you a Notice of Award (NOA) or we may send you an

email containing a link to access an electronic version of your NOA. We will notify you if your application is not selected for funding or is not evaluated.

2. Administrative and National Policy Requirements

The award is subject to HHS Administrative Requirements, which can be found in 45 CFR Part 75 and the Standard Terms and Conditions, included in the Notice of Award as well as implemented through the HHS Grants Policy Statement.

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see the appendix for this announcement to review the entire policy and guidelines. A standard term and condition of award will be included in the final notice of award; all applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires the grantees inform their employee in writing of employee whistleblower rights and protections under 41 U.S.C. 4712 in the predominant native language of the workforce.

3. Reporting

(a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 45 CFR part 75 should you receive funding under the competition. This does not apply if you have an exception under 45 CFR part 75.

(b) At the end of your project period, you must submit a final performance report, including financial information, as required in your award's terms and conditions. If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as required under 45 CFR part 75.

All NIDILRR grantees will submit their annual and final reports through NIDILRR's online reporting system and as designated in the terms and conditions of your NOA.

Complying with the Administration for Community Living (ACL) Public Access Plan

Any grants the NIDILRR makes under this priority will be required to comply with the requirements described in the ACL Public Access Plan. ACL's public access requirements apply to peer-reviewed publications and scientific data that result from all NIDILRR-funded projects.

Investigators working on a grant made under this priority will be required to comply with the requirements described in the ACL Public Access Plan. ACL's public access requirements apply to peer-reviewed publications and scientific data that result from all NIDILRR-funded projects.

Peer-reviewed Publications:

Investigators working on a grant made under this priority will be required to report in their annual performance reports and final reports any peer-reviewed manuscripts that have been accepted for publication or articles that have been published. This reporting must include an indication whether their compliance with the ACL Public Access Policy has been achieved by

one of the following two methods:

- The manuscript is being published in a journal with PubMed Central's full-participation status with a 12-month or less embargo period; or
- The final peer-reviewed manuscript has been submitted through the National Institutes of Health Manuscript Submission System (NIHMS) with an embargo period of 12 months or less.

Scientific Data:

Investigators working on a grant made under this priority will be required to describe in their final reports their compliance with the ACL's public access requirements for scientific data. This description must include the location of the data repository where the scientific data are deposited, the Digital Object Identifiers (DOI) associated with the data, and an assurance that the scientific data will be publicly available no later than 24 months after the award's end date.

The final report is due 90 days after an award's end date. Therefore, the data must be deposited at an approved repository by the time you submit your final report. However, it is permissible to delay the sharing of those deposited data for up to 24 months after the award's end date.

A grantee's failure to comply with the ACL public access plan could result in the withholding, suspension, or termination of funding for non-competing continuation awards. Before awarding new grants or contracts, ACL will determine whether prospective awardees are in compliance with the ACL Public Access Plan. If a grantee fails to comply with ACL's public access policy, NIDILRR and the Administrator of ACL may consider this failure to comply as part of the grantee's history of performance when making decisions about future grant awards.

The ACL Public Access Plan is available in the following location: <https://www.acl.gov/sites/default/files/about-acl/2017-06/ACL-PublicAccessPlan-UpdatedJune2017.pdf>.

4. FFATA and FSRS Reporting

The Federal Financial Accountability and Transparency Act (FFATA) requires data entry at the FFATA Subaward Reporting System (<http://www.FSRS.gov>) for all sub-awards and sub-contracts issued for \$25,000 or more as well as addressing executive compensation for both grantee and sub-award organizations.

For further guidance please follow this link to access ACL's Terms and Conditions: <https://www.acl.gov/grants/managing-grant#>

VII. Agency Contacts

Project Officer

Brian Bard

Office: 202-795-7298

Email: brian.bard@acl.hhs.gov

Grants Management Specialist

Marlene Spencer

Office: 202-795-7442

Email: Marlene.Spencer@acl.hhs.gov

VIII. Other Information

Application Elements

- SF 424, required – Application for Federal Assistance (See “Instructions for Completing Required Forms” for assistance).
 - SF 424A, required – Budget Information. (See Appendix for instructions).
 - Separate Budget Narrative/Justification, required (See “Budget Narrative/Justification - Sample Format” for examples and “Budget Narrative/Justification – Sample Template.”)
- NOTE: Applicants requesting funding for multi-year grant projects are REQUIRED to provide a Narrative/Justification for each year of potential grant funding, as well as a combined multi-year detailed Budget Narrative/Justification.
- SF 424B – Assurance, required. Note: Be sure to complete this form according to instructions and have it signed and dated by the authorized representative (see item 18d on the SF 424).
 - Lobbying Certification, required.
 - Proof of non-profit status, if applicable
 - Copy of the applicant’s most recent indirect cost agreement or cost allocation plan, if requesting indirect costs. If any sub-contractors or sub-grantees are requesting indirect costs, copies of their indirect cost agreements must also be included with the application.
 - Project Narrative with Work Plan, required (See “Project Work Plan – Sample Template” for a formatting suggestions).
 - Vitae for Key Project Personnel.
 - Letters of Commitment from Key Partners, if applicable.
- Abstract
 - Supplemental Information Form for the SF-424

NOTE: NIDILRR does not require applicants to submit an organizational capability statement outside of their project narrative. NIDILRR assesses organizational capability via the peer review process, including application criteria to project staff, and the adequacy and accessibility of applicant resources.

The Paperwork Reduction Act of 1995 (P.L. 104-13)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The project description and Budget Narrative/Justification is approved under OMB control number 0985-0018. Public reporting burden for this collection of information is estimated to average 10 hours per

response, including the time for reviewing instructions, gathering and maintaining the data needed and reviewing the collection information.

Appendix

Accessibility Provisions for All Grant Application Packages and Funding Opportunity Announcements

Recipients of federal financial assistance (FFA) from HHS must administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age and, in some circumstances, religion, conscience, and sex. This includes ensuring programs are accessible to persons with limited English proficiency. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see <https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html> and <http://www.hhs.gov/ocr/civilrights/understanding/section1557/index.html>.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. HHS provides guidance to recipients of FFA on meeting their legal obligation to take reasonable steps to provide meaningful access to their programs by persons with limited English proficiency. Please see <https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html> and <https://www.lep.gov>. For further guidance on providing culturally and linguistically appropriate services, recipients should review the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care at <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=2&lvlid=53>.
- Recipients of FFA also have specific legal obligations for serving qualified individuals with disabilities. Please see <http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html>.
- HHS funded health and education programs must be administered in an environment free of sexual harassment. Please see <https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html>; <https://www2.ed.gov/about/offices/list/ocr/docs/shguide.html>; and <https://www.eeoc.gov/eeoc/publications/upload/fs-sex.pdf>.
- Recipients of FFA must also administer their programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws. Collectively, these laws prohibit exclusion, adverse treatment, coercion, or other discrimination against persons or entities on the basis of their consciences, religious beliefs, or moral convictions. Please see <https://www.hhs.gov/conscience/conscience-protections/index.html> and <https://www.hhs.gov/conscience/religious-freedom/index.html>.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at <https://www.hhs.gov/ocr/about-us/contact-us/index.html> or call 1-800-368-1019 or TDD 1-800-537-7697.

Instructions for Completing Required Forms

This section provides step-by-step instructions for completing the four (4) standard Federal forms required as part of your grant application, including special instructions for completing Standard Budget Forms 424 and 424A. Standard Forms 424 and 424A are used for a wide variety of Federal grant programs, and Federal agencies have the discretion to require some or all of the information on these forms. ACL does not require all the information on these Standard Forms. Accordingly, please use the instructions below in lieu of the standard instructions attached to SF 424 and 424A to complete these forms.

a. Standard Form 424

1. **Type of Submission:** (REQUIRED): Select one type of submission in accordance with agency instructions.

- Preapplication
- Application
- Changed/Corrected Application – If ACL requests, check if this submission is to change or correct a previously submitted application.

2. **Type of Application:** (REQUIRED) Select one type of application in accordance with agency instructions.

- New
- Continuation
- Revision

3. **Date Received:** Leave this field blank.

4. **Applicant Identifier:** Leave this field blank

5a **Federal Entity Identifier:** Leave this field blank

5b. **Federal Award Identifier:** For new applications leave blank. For a continuation or revision to an existing award, enter the previously assigned Federal award (grant) number.

6. **Date Received by State:** Leave this field blank.

7. **State Application Identifier:** Leave this field blank.

8. **Applicant Information:** Enter the following in accordance with agency instructions:

a. **Legal Name:** (REQUIRED): Enter the name that the organization has registered with the System for Award Management (SAM), formally the Central Contractor Registry. Information on registering with SAM may be obtained by visiting the Grants.gov website (<https://www.grants.gov>) or by going directly to the SAM website (www.sam.gov).

b. Employer/Taxpayer Number (EIN/TIN): (REQUIRED): Enter the Employer or Taxpayer Identification Number (EIN or TIN) as assigned by the Internal Revenue Service. In addition, we encourage the organization to include the correct suffix used to identify your organization in order to properly align access to the Payment Management System.

c. Organizational DUNS: (REQUIRED) Enter the organization's DUNS or DUNS+4 number received from Dun and Bradstreet. Information on obtaining a DUNS number may be obtained by visiting the Grants.gov website (<https://www.grants.gov>). Your DUNS number can be verified at <https://fedgov.dnb.com/webform/>.

d. Address: (REQUIRED) Enter the complete address including the county.

e. Organizational Unit: Enter the name of the primary organizational unit (and department or division, if applicable) that will undertake the project.

f. Name and contact information of person to be contacted on matters involving this application: Enter the name (First and last name required), organizational affiliation (if affiliated with an organization other than the applicant organization), telephone number (Required), fax number, and email address (Required) of the person to contact on matters related to this application.

9. Type of Applicant: (REQUIRED) Select the applicant organization "type" from the following drop down list.

A. State Government B. County Government C. City or Township Government D. Special District Government E. Regional Organization F. U.S. Territory or Possession G. Independent School District H. Public/State Controlled Institution of Higher Education I. Indian/Native American Tribal Government (Federally Recognized) J. Indian/Native American Tribal Government (Other than Federally Recognized) K. Indian/Native American Tribally Designated Organization L. Public/Indian Housing Authority M. Nonprofit with 501C3 IRS Status (Other than Institution of Higher Education) N. Nonprofit without 501C3 IRS Status (Other than Institution of Higher Education) O. Private Institution of Higher Education P. Individual Q. For-Profit Organization (Other than Small Business) R. Small Business S. Hispanic-serving Institution T. Historically Black Colleges and Universities (HBCUs) U. Tribally Controlled Colleges and Universities (TCCUs) V. Alaska Native and Native Hawaiian Serving Institutions W. Non-domestic (non-US) Entity X. Other (specify)

10. Name of Federal Agency: (REQUIRED) Enter U.S. Administration for Community Living

11. Catalog of Federal Domestic Assistance Number/Title: The CFDA number can be found on page one of the Program Announcement.

12. Funding Opportunity Number/Title: (REQUIRED) The Funding Opportunity Number and title of the opportunity can be found on page one of the Program Announcement.

13. Competition Identification Number/Title: Leave this field blank.

14. Areas Affected by Project: List the largest political entity affected (cities, counties, state etc.)

15. Descriptive Title of Applicant's Project: (REQUIRED) Enter a brief descriptive title of the project (This is not a narrative description).

16. Congressional Districts Of: (REQUIRED) 16a. Enter the applicant's Congressional District, and 16b. Enter all district(s) affected by the program or project. Enter in the format: 2 characters State Abbreviation – 3 characters District Number, e.g., CA-005 for California 5th district, CA-012 for California 12th district, NC-103 for North Carolina's 103rd district. If all congressional districts in a state are affected, enter "all" for the district number, e.g., MD-all for all congressional districts in Maryland. If nationwide, i.e. all districts within all states are affected, enter US-all. See the below website to find your congressional district:

<https://www.house.gov/>

17. Proposed Project Start and End Dates: (REQUIRED) Enter the proposed start date and final end date of the project. **If you are applying for a multi-year grant, such as a 3 year grant project, the final project end date will be 3 years after the proposed start date.** In general, all start dates on the SF424 should be the 1st of the month and the end date of the last day of the month of the final year, for example 7/01/2014 to 6/30/2017. The Grants Officer can alter the start and end date at their discretion.

18. Estimated Funding: (REQUIRED) If requesting multi-year funding, enter the full amount requested from the Federal Government in line item 18.a., as a multi-year total. For example and illustrative purposes only, if year one is \$100,000, year two is \$100,000, and year three is \$100,000, then the full amount of federal funds requested would be reflected as \$300,000. The amount of matching funds is denoted by lines b. through f. with a combined federal and non-federal total entered on line g. Lines b. through f. represents contributions to the project by the applicant and by your partners during the total project period, broken down by each type of contributor. The value of in-kind contributions should be included on appropriate lines, as applicable.

NOTE: Applicants should review cost sharing or matching principles contained in Subpart C of 45 CFR Part 75 or 45 CFR Part 92 before completing Item 18 and the Budget Information Sections A, B and C noted below.

All budget information entered under item 18 should cover the total project period. For sub-item 18a, enter the federal funds being requested. Sub-items 18b-18e is considered matching funds. The dollar amounts entered in sub-items 18b-18f must total at least 1/3 of the amount of federal funds being requested (the amount in 18a). For a full explanation of ACL's match requirements, see the information in the box below. For sub-item 18f (program income), enter only the amount, if any, that is going to be used as part of the required match. Program Income submitted as match will become a part of the award match and recipients will be held accountable to meet their share of project expenses even if program income is not generated

during the award period.

There are two types of match: 1) non-federal cash and 2) non-federal in-kind. In general, costs borne by the applicant and cash contributions of any and all third parties involved in the project, including sub-grantees, contractors and consultants, are considered **matching funds**. Examples of **non-federal cash match** includes budgetary funds provided from the applicant agency's budget for costs associated with the project. Generally, most contributions from sub-contractors or sub-grantees (third parties) will be non-federal in-kind matching funds. Volunteered time and use of third party facilities to hold meetings or conduct project activities may be considered in-kind (third party) donations.

NOTE: Indirect charges may only be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. State governments should enter the amount of indirect costs determined in accordance with HHS requirements. **If indirect costs are to be included in the application, a copy of the approved indirect cost agreement or cost allocation plan must be included with the application. Further, if any sub-contractors or sub-grantees are requesting indirect costs, a copy of the latest approved indirect cost agreements must also be included with the application, or reference to an approved cost allocation plan.**

19. Is Application Subject to Review by State Under Executive Order 12372

Process? Please refer to IV. Application and Submission Information, 4. Intergovernmental Review to determine if the ACL program is subject to E.O. 12372 and respond accordingly.

20. Is the Applicant Delinquent on any Federal Debt? (Required) This question applies to the applicant organization, not the person who signs as the authorized representative. If yes, include an explanation on the continuation sheet.

21. Authorized Representative: (Required) To be signed and dated by the authorized representative of the applicant organization. Enter the name (First and last name required) title (Required), telephone number (Required), fax number, and email address (Required) of the person authorized to sign for the applicant. A copy of the governing body's authorization for you to sign this application as the official representative must be on file in the applicant's office. (Certain federal agencies may require that this authorization be submitted as part of the application.)

Standard Form 424A

NOTE: Standard Form 424A is designed to accommodate applications for multiple grant programs; thus, for purposes of this ACL program, many of the budget item columns and rows are not applicable. You should only consider and respond to the budget items for which guidance is provided below. Unless otherwise indicated, the SF 424A should reflect a multi-year budget.

Section A - Budget Summary

Line 5: Leave columns (c) and (d) blank. Enter TOTAL Federal costs in column (e) and total non federal costs (including third party in-kind contributions and any program income to be used as part of the grantee match) in column (f). Enter the sum of columns (e) and (f) in column (g).

Section B - Budget Categories

Column 1: Enter the breakdown of how you plan to use the Federal funds being requested by object class category.

Column 2: Enter the breakdown of how you plan to use the non-Federal share by object class category.

Column 5: Enter the total funds required for the project (sum of Columns 1 and 2) by object class category.

Section C - Non-Federal Resources

Column A: Enter the federal grant program.

Column B: Enter in any non-federal resources that the applicant will contribute to the project.

Column C: Enter in any non-federal resources that the state will contribute to the project.

Column D: Enter in any non-federal resources that other sources will contribute to the project.

Column E: Enter the total non-federal resources for each program listed in column A.

Section D - Forecasted Cash Needs

Line 13: Enter Federal forecasted cash needs broken down by quarter for the first year only.

Line 14: Enter Non-Federal forecasted cash needs broken down by quarter for the first year.

Line 15: Enter total forecasted cash needs broken down by quarter for the first year.

Note: This area is not meant to be one whereby an applicant merely divides the requested funding by four and inserts that amount in each quarter but an area where thought is given as to how your estimated expenses will be incurred during each quarter. For example, if you have initial startup costs in the first quarter of your award reflect that in quarter one or you do not expect to have contracts awarded and funded until quarter three, reflect those costs in that quarter.

Section E – Budget Estimates of Federal Funds Needed for Balance of the Project (i.e. subsequent years 2, 3, 4 or 5 as applicable).

Column A: Enter the federal grant program

Column B (first): Enter the requested year two funding.

Column C (second): Enter the requested year three funding.

Column D (third): Enter the requested year four funding, if applicable.

Column E (forth): Enter the requested year five funding, if applicable.

Section F – Other Budget Information

Line 21: Enter the total Indirect Charges

Line 22: Enter the total Direct charges (calculation of indirect rate and direct charges).

Line 23: Enter any pertinent remarks related to the budget.

Separate Budget Narrative/Justification Requirement

Applicants requesting funding for multi-year grant programs are REQUIRED to provide a combined multi-year Budget Narrative/Justification, as well as a detailed Budget Narrative/Justification for each year of potential grant funding. A separate Budget Narrative/Justification is also REQUIRED for each potential year of grant funding requested.

For your use in developing and presenting your Budget Narrative/Justification, a sample format with examples and a blank sample template have been included in these Attachments. In your Budget Narrative/Justification, you should include a breakdown of the budgetary costs for all of the object class categories noted in Section B, across three columns: Federal; non-Federal cash; and non-Federal in-kind. Cost breakdowns, or justifications, are required for any cost of \$1,000 or for the thresholds as established in the examples. The Budget Narratives/Justifications should fully explain and justify the costs in each of the major budget items for each of the object class categories, as described below. Non-Federal cash as well as, sub-contractor or sub-grantee (third party) in-kind contributions designated as match must be clearly identified and explained in the Budget Narrative/Justification. The full Budget Narrative/Justification should be included in the application immediately following the SF 424 forms.

Line 6a: **Personnel:** Enter total costs of salaries and wages of applicant/grantee staff. Do not include the costs of consultants, which should be included under 6h Other.

In the Justification: Identify the project director, if known. Specify the key staff, their titles, and time commitments in the budget justification.

Line 6b: **Fringe Benefits:** Enter the total costs of fringe benefits unless treated as part of an approved indirect cost rate.

In the Justification: If the total fringe benefit rate exceeds 35% of Personnel costs, provide a breakdown of amounts and percentages that comprise fringe benefit costs, such as health

insurance, FICA, retirement, etc. A percentage of 35% or less does not require a breakdown but you must show the percentage charged for each full/part time employee.

Line 6c: Travel: Enter total costs of all travel (local and non-local) for staff on the project. **NEW:** Local travel is considered under this cost item not under Other. Local transportation (all travel which does not require per diem is considered local travel). Do not enter costs for consultant's travel - this should be included in line 6h.

In the Justification: Include the total number of trips, number of travelers, destinations, purpose (e.g., attend conference), length of stay, subsistence allowances (per diem), and transportation costs (including mileage rates).

Line 6d: Equipment: Enter the total costs of all equipment to be acquired by the project. For all grantees, "equipment" is nonexpendable tangible personal property having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. If the item does not meet the \$5,000 threshold, include it in your budget under Supplies, line 6e.

In the Justification: Equipment to be purchased with federal funds must be justified as necessary for the conduct of the project. The equipment must be used for project-related functions. Further, the purchase of specific items of equipment should not be included in the submitted budget if those items of equipment, or a reasonable facsimile, are otherwise available to the applicant or its subgrantees.

Line 6e: Supplies: Enter the total costs of all tangible expendable personal property (supplies) other than those included on line 6d.

In the Justification: . For any grant award that has supply costs in excess of 5% of total direct costs (Federal or Non-Federal), you must provide a detailed break down of the supply items (e.g., 6% of \$100,000 = \$6,000 – breakdown of supplies needed). If the 5% is applied against \$1 million total direct costs (5% x \$1,000,000 = \$50,000) a detailed breakdown of supplies is not needed. Please note: any supply costs of \$5,000 or less regardless of total direct costs does not require a detailed budget breakdown (e.g., 5% x \$100,000 = \$5,000 – no breakdown needed).

Line 6f: Contractual: Regardless of the dollar value of any contract, you must follow your established policies and procedures for procurements and meet the minimum standards established in the Code of Federal Regulations (CFR's) mentioned below. Enter the total costs of all contracts, including (1) procurement contracts (except those which belong on other lines such as equipment, supplies, etc.). Note: The 33% provision has been removed and line item budget detail is not required as long as you meet the established procurement standards. Also include any awards to organizations for the provision of technical assistance. Do not include payments to individuals on this line. Please be advised: A subrecipient is involved in financial assistance activities by receiving a sub-award and a subcontractor is involved in procurement activities by receiving a sub-contract. Through the recipient, a subrecipient performs work to accomplish the public purpose authorized by law. Generally speaking, a sub-contractor does not seek to accomplish a public benefit and does not perform substantive work on the project. It

is merely a vendor providing goods or services to directly benefit the recipient, for example procuring landscaping or janitorial services. In either case, you are encouraged to clearly describe the type of work that will be accomplished and type of relationship with the lower tiered entity whether it be labeled as a subaward or subcontract.

In the Justification: Provide the following three items – 1) Attach a list of contractors indicating the name of the organization; 2) the purpose of the contract; and 3) the estimated dollar amount. If the name of the contractor and estimated costs are not available or have not been negotiated, indicate when this information will be available. The Federal government reserves the right to request the final executed contracts at any time. If an individual contractual item is over the small purchase threshold, currently set at \$100K in the CFR, you must certify that your procurement standards are in accordance with the policies and procedures as stated in 45 CFR Part 75 for states, in lieu of providing separate detailed budgets. This certification should be referenced in the justification and attached to the budget narrative.

Line 6g: **Construction:** Leave blank since construction is not an allowable costs for this program.

Line 6h: **Other:** Enter the total of all other costs. Such costs, where applicable, may include, but are not limited to: insurance, medical and dental costs (i.e. for project volunteers this is different from personnel fringe benefits), non-contractual fees and travel paid directly to individual consultants, postage, space and equipment rentals/lease, printing and publication, computer use, training and staff development costs (i.e. registration fees). If a cost does not clearly fit under another category, and it qualifies as an allowable cost, then rest assured this is where it belongs.

Note: A recent Government Accountability Office (GAO) report number 11-43, has raised considerable concerns about grantees and contractors charging the Federal government for additional meals outside of the standard allowance for travel subsistence known as per diem expenses. If meals are to be charged towards the grant they must meet the following criteria outlined in the Grants Policy Statement:

- *Meals are generally unallowable except for the following:*
- *For subjects and patients under study(usually a research program);*
- *Where specifically approved as part of the project or program activity, e.g., in programs providing children's services (e.g., Headstart);*
- *When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement;*
- *As part of a per diem or subsistence allowance provided in conjunction with allowable travel; and*
- *Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances (Note: the sole purpose of the grant award is to hold a conference).*

In the Justification: Provide a reasonable explanation for items in this category. For

example, individual consultants explain the nature of services provided and the relation to activities in the work plan or indicate where it is described in the work plan. Describe the types of activities for staff development costs.

Line 6i: **Total Direct Charges:** Show the totals of Lines 6a through 6h.

Line 6j: **Indirect Charges:** Enter the total amount of indirect charges (costs), if any. If no indirect costs are requested, enter "none." Indirect charges may be requested if: (1) the applicant has a current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency; or (2) the applicant is a state or local government agency. **State governments should enter the amount of indirect costs determined in accordance with DHHS requirements.** An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. Indirect Costs can only be claimed on Federal funds, more specifically, they are to only be claimed on the Federal share of your direct costs. Any unused portion of the grantee's eligible Indirect Cost amount that are not claimed on the Federal share of direct charges can be claimed as un-reimbursed indirect charges, and that portion can be used towards meeting the recipient match.

Line 6k: **Total:** Enter the total amounts of Lines 6i and 6j.

Line 7: **Program Income:** As appropriate, include the estimated amount of income, if any, you expect to be generated from this project that you wish to designate as match (equal to the amount shown for Item 15(f) on Form 424). **Note:** Any program income indicated at the bottom of Section B and for item 15(f) on the face sheet of Form 424 will be included as part of non-Federal match and will be subject to the rules for documenting completion of this pledge. If program income is expected, but is not needed to achieve matching funds, **do not** include that portion here or on Item 15(f) of the Form 424 face sheet. Any anticipated program income that will not be applied as grantee match should be described in the Level of Effort section of the Program Narrative.

c. Standard Form 424B – Assurances (required)

This form contains assurances required of applicants under the discretionary funds programs administered by the Administration for Community Living. Please note that a duly authorized representative of the applicant organization must certify that the organization is in compliance with these assurances.

d. Certification Regarding Lobbying (required)

This form contains certifications that are required of the applicant organization regarding lobbying. Please note that a duly authorized representative of the applicant organization must attest to the applicant's compliance with these certifications.

Proof of Nonprofit Status (as applicable)

Non-profit applicants must submit proof of non-profit status. Any of the following constitutes

acceptable proof of such status:

- A copy of a currently valid IRS tax exemption certificate.
- A statement from a State taxing body, State attorney general, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.
- A certified copy of the organization's certificate of incorporation or similar document that clearly establishes non-profit status.

Indirect Cost Agreement

Applicants that have included indirect costs in their budgets must include a copy of the current indirect cost rate agreement approved by the Department of Health and Human Services or another federal agency. This is optional for applicants that have not included indirect costs in their budgets.

Budget Narrative/Justification - Sample Format

NOTE: Applicants requesting funding for a multi-year grant program are REQUIRED to provide a detailed Budget Narrative/Justification for EACH potential year of grant funding requested.

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel	\$47,700	\$23,554	\$0	\$71,254	Federal Project Director (name) = .5 FTE @ \$95,401/yr = \$47,700 Non-Fed Cash Officer Manager (name) = .5FTE @ \$47,108/yr = \$23,554 Total 71,254
Fringe Benefits	\$17,482	\$8,632	\$0	\$26,114	Federal Fringe on Project Director at 36.65% = \$17,482 FICA (7.65%) Health (25%) Dental (2%) Life (1%) Unemployment (1%) Non-Fed Cash Fringe on Office Manager at 36.65% = \$8,632

					FICA (7.65%) Health (25%) Dental (2%) Life (1%) Unemployment (1%)
Travel	\$4,707	\$2,940	\$0	\$7,647	Federal Local travel: 6 TA site visits for 1 person Mileage: 6RT @ .585 x 700 miles \$2,457 Lodging: 15 days @ \$110/day \$1,650 Per Diem: 15 days @ \$40/day \$600 Total \$4,707 Non-Fed Cash Travel to National Conference in (Destination) for 3 people Airfare 1 RT x 3 staff @ \$500 \$1,500 Lodging: 3 days x 3 staff @ \$120/day \$1,080 Per Diem: 3 days x 3 staff @ \$40/day \$360 Total \$2,940
Equipment	\$10,000	\$0	\$0	\$10,000	No Equipment requested OR: Call Center Equipment Installation = \$5,000 Phones = \$5,000 Total \$10,000
Supplies	\$3,700	\$5,670	\$0	\$9,460	Federal 2 desks @ \$1,500 \$3,000 2 chairs @ \$300 \$600 2 cabinets @ \$200 \$400 Non-Fed Cash 2 Laptop computers \$3,000

					Printer cartridges @ \$50/month \$300 Consumable supplies (pens, paper, clips etc...) @ \$180/month \$2,160 Total \$9,460
Contractual	\$30,171	\$0	\$0	\$30,171	(organization name, purpose of contract and estimated dollar amount) Contract with AAA to provide respite services: 11 care givers @ \$1,682 = \$18,502 Volunteer Coordinator = \$11,669 Total \$30,171 <i>If contract details are unknown due to contract yet to be made provide same information listed above and: A detailed evaluation plan and budget will be submitted by (date), when contract is made.</i>
Other	\$5,600	\$0	\$5,880	\$11,480	Federal 2 consultants @ \$100/hr for 24.5 hours each = \$4,900 Printing 10,000 Brochures @ \$.05 = \$500 Local conference registration fee (name conference) = \$200 Total \$5,600 In-Kind Volunteers 15 volunteers @ \$8/hr for 49 hours = \$5,880
Indirect Charges	\$20,934	\$0	\$0	\$20,934	21.5% of salaries and fringe = \$20,934 IDC rate is attached.
TOTAL	\$140,294	\$40,866	\$5,880	\$187,060	

Budget Narrative/Justification - Sample Template

NOTE: Applicants requesting funding for a multi-year grant program are REQUIRED to

provide a detailed Budget Narrative/Justification for EACH potential year of grant funding requested.

Object Class Category	Federal Funds	Non-Federal Cash	Non-Federal In-Kind	TOTAL	Justification
Personnel					
Fringe Benefits					
Travel					
Equipment					
Supplies					
Contractual					
Other					
Indirect Charges					
TOTAL					

Project Work Plan - Sample Template

NOTE : Applicants requesting funding for a multi-year grant program are REQUIRED to provide a Project Work Plan for EACH potential year of grant funding requested.

Goal:

Measurable Outcome(s):

* Time Frame (Start/End Dates by Month in Project Cycle)

Major Objectives	Key Tasks	Lead Person	1*	2*	3*	4*	5*	6*	7*	8*	9*	10*	11*	12*
1.														
2.														
3.														
4.														
5.														
6.														

project in the future. The expected **products** are marketing and outreach materials, caregiver training, respite worker training, a Respite Online searchable database, two new Caregiver Resource Centers (CRC), an annual Respite Summit, a respite voucher program and 24/7 telephone information and referral services.

Instructions for Completing the "Supplemental Information for the SF-424" Form

1. Project Director.

Name, address, telephone and fax numbers, and e-mail address of the person to be contacted on matters involving this application. Items marked with an asterisk (*) are mandatory.

2. Novice Applicant. Select "Not Applicable To This Program."

3a. Human Subjects Research. Check "**No**" if research activities involving human subjects are not planned at any time during the proposed project period. The remaining parts of Item 3 are then not applicable. Check "**Yes**" if research activities involving human subjects are planned at any time during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution. Check "**Yes**" even if the research is exempt from the regulations for the protection of human subjects.

3b. Human Subjects Research. "**Yes**" if all the research activities proposed are designated to be exempt from the regulations. Check the exemption number(s) corresponding to one or more of the six exemption categories listed in I. B. "Exemptions." In addition, follow the instructions in II. A. "Exempt Research Narrative" below.

Check "**No**" if some or all of the planned research activities are covered (not exempt). In addition, follow the instructions in II. B. "Nonexempt Research Narrative" in the attached page entitled "Definitions for U.S. Department of Education Supplemental Information for the SF-424."

3b. Human Subjects Assurance Number. If the applicant has an approved Federal Wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services, that covers the specific activity, insert the number in the space provided. (A list of current FWAs is available at: <http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>) If the applicant does not have an approved assurance on file with OHRP, enter "None." In this case, the applicant, by signature on the SF-424, is declaring that it will proceed to obtain the human subjects assurance upon request by the designated NIDILRR official. If the application is recommended/selected for funding, the designated NIDILRR official will request that the applicant obtain the assurance within 30 days after the specific formal request.

3c. Human Subjects Narratives. If applicable, please attach your "Exempt Research" or "Nonexempt Research" narrative to your submission of the Supplemental Information for the

SF-424 form as instructed in item II, "Instructions for Exempt and Nonexempt Human Subjects Research Narratives," below.

Note about Institutional Review Board Approval. NIDILRR does not require certification of Institutional Review Board approval with the application. However, if an application that involves non-exempt human subjects research is recommended/selected for funding, the designated NIDILRR official will request that the applicant obtain and send the certification to NIDILRR within 30 days after the formal request. **No covered human subjects research can be conducted until the study has NIDILRR clearance for protection of human subjects in research.**

I. Definitions and Exemptions

A. Definitions.

—Research

"a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Activities which meet this definition constitute research whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

—Human Subject

"a living individual about whom an investigator (whether professional or student) conducting research information." (1) *If an activity involves obtaining information about a living person by manipulating that person or that person's environment, or by communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met.* (2) *If an activity involves obtaining private information about a living person in such a way that the information can be **directly or indirectly linked to** that individual), the definition of human subject is met.*

B. Exemptions.

Research activities in which the **only** involvement of human subjects will be in one or more of the following six categories of **exemptions** are not covered by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. ***If an educational practice is being introduced to the site and is not widely used for similar populations, it is not covered by this exemption.***

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. ***If the subjects are children, exemption 2 applies only to research involving educational tests and observations of public behavior when the investigator(s) do not***

participate in the activities being observed. Exemption 2 does not apply if children are surveyed or interviewed or if the research involves observation of public behavior and the investigator(s) participate in the activities being observed. [Children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law or jurisdiction in which the research will be conducted.]

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under section (2) above, if the human subjects are elected or appointed public officials or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. *[This exemption applies only to retrospective studies using data collected before the initiation of the research.]*

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs. *[The standards of this exemption are rarely met because it was designed to apply only to specific research conducted by the Social Security Administration and some Federal welfare benefits programs.]*

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome food without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

II. Instructions for Exempt and Nonexempt Human Subjects Research Narratives

If the applicant marked “Yes” for Item 3.b. of the Supplemental Information for the SF 424, the applicant must attach a human subjects “exempt research” or “nonexempt research” narrative to the Supplemental Information for the SF-424 form. If you have multiple projects and need to provide more than one narrative, be sure to label each set of responses as to the project they address.

A. Exempt Research Narrative.

If you marked “Yes” for item 3.b. and designated exemption numbers(s), attach the “exempt research” narrative to the Supplemental Information for the SF-424. The narrative must contain sufficient information about the involvement of human subjects in the proposed research to allow a determination by NIDILRR that the designated exemption(s) are appropriate. The narrative must be succinct.

B. Nonexempt Research Narrative.

If you marked “No” for item 3.b. you must attach the “nonexempt research” narrative to the Supplemental Information for the SF-424. The narrative must address the following seven points. Although no specific page limitation applies to this section of the application, be succinct.

(1) Human Subjects Involvement and Characteristics: Provide a detailed description of the proposed involvement of human subjects. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, subpopulation. Explain the rationale for the involvement of special classes of subjects, such as children, children with disabilities, adults with disabilities, persons with mental disabilities, pregnant women, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

(2) Sources of Materials: Identify the sources of research material obtained from individually living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Recruitment and Informed Consent: Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

(4) Potential Risks: Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

5) Protection Against Risk: Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of the subjects.

(6) Importance of the Knowledge to be Gained: Discuss the importance of the knowledge gained or to be gained as a result of the proposed research. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

(7) Collaborating Site(s): If research involving human subjects will take place at collaborating site(s) or other performance site(s), name the sites and briefly describe their involvement or role in the research.