

(b) Conducting training, technical assistance, and dissemination activities to increase utilization of research and evaluative study findings related to self-directed care of individuals living with SMI to promote and co-occurring conditions, health management, and employment.

### Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

**Absolute priority:** Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

**Competitive preference priority:** Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (45 CFR part 75); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (45 CFR part 75).

**Invitational priority:** Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (45 CFR part 75).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

**Note:** This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

**Electronic Access to This Document:** The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). At this site you can view this document, as well as all other documents of ACL published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced

search feature at this site, you can limit your search to documents published by the Department.

Dated: June 22, 2015.

**John Tschida,**

*Director, National Institute on Disability, Independent Living, and Rehabilitation Research.*

[FR Doc. 2015-15745 Filed 6-25-15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Applications for New Awards; National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)—Rehabilitation Research and Training Centers

**AGENCY:** Administration for Community Living, Department of Health and Human Services.

**ACTION:** Notice.

#### Overview Information

National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR)—Rehabilitation Research and Training Centers (RRTC)—Self-Directed Care to Promote Recovery, Health, and Wellness for Individuals with Serious Mental Illness.

Notice inviting applications for new awards for fiscal year (FY) 2015.

*Catalog of Federal Domestic Assistance (CFDA) Number:* 84.133B-4.

#### DATES:

*Applications Available:* June 26, 2015.

**Note:** On July 22, 2014, President Obama signed the Workforce Innovation Opportunity Act (WIOA). WIOA was effective immediately. One provision of WIOA transferred the National Institute on Disability and Rehabilitation Research (NIDRR) from the Department of Education to the Administration for Community Living (ACL) in the Department of Health and Human Services. In addition, NIDRR's name was changed to the Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). For FY 2015, all NIDILRR priority notices will be published as ACL notices, and ACL will make all NIDILRR awards. During this transition period, however, NIDILRR will continue to review grant applications using Department of Education tools. NIDILRR will post previously-approved application kits to [grants.gov](http://grants.gov), and NIDILRR applications submitted to [grants.gov](http://grants.gov) will be forwarded to the Department of Education's G-5 system for peer review. We are using Department of Education application kits and peer review systems during this transition year in order to provide for a smooth and orderly process for our applicants.

Because of HHS policy, there are changes in the way that NIDILRR will award and oversee grants that are made on behalf of other agencies. These changes apply for this priority because SAMHSA, specifically the Center for Mental Health Services, provides funding for activities carried out under the award. These changes are reflected in the final notice, the Notice Inviting Applications, and the grant application kit.

*Date of Pre-Application Meeting:* July 17, 2015.

*Deadline for Notice of Intent to Apply:* July 31, 2015.

*Deadline for Transmittal of Applications:* August 25, 2015.

### Full Text of Announcement

#### I. Funding Opportunity Description

**Purpose of Program:** The purpose of 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. The Program's activities are designed to 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).

#### *Rehabilitation Research and Training Centers*

The purpose of the RRTCs, which are funded through the Disability and Rehabilitation Research Projects and Centers Program, is to achieve the goals of, and improve the effectiveness of, services authorized under the Rehabilitation Act through well-designed research, training, technical assistance, and dissemination activities in important topical areas as specified by NIDILRR. These activities are designed to benefit rehabilitation service providers, individuals with disabilities, family members, policymakers and other research stakeholders. Additional information on the RRTC program can be found at: <http://www2.ed.gov/programs/rrtc/index.html#types>.

**Priorities:** There are two priorities for the grant competition announced in this notice. The General RRTC Requirements priority is from the notice of final priorities for the Rehabilitation Research

and Training Centers, published in the **Federal Register** on February 1, 2008 (73 FR 6132). Priority two is from the notice of final priority for this program, published elsewhere in this issue of the **Federal Register**.

**Absolute Priorities:** For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, these priorities are absolute priorities. Under 45 CFR part 75 we consider only applications that meet these program priorities.

These priorities are:

**Priority 1—General RRTC Requirements.**

**Note:** The full text of this priority is included in the notice of final priorities for the Rehabilitation Research and Training Centers, published in the **Federal Register** on February 1, 2008 (73 FR 6132) and in the application package for this competition.

**Priority 2—RRTC on Self-Directed Care to Promote Recovery, Health, and Wellness for Individuals with Serious Mental Illness.**

**Note:** The full text of this priority is included in the notice of final priority published elsewhere in this issue of the **Federal Register** and in the application package for this competition.

**Program Authority:** 29 U.S.C. 762(g) and 764(b)(2).

**Applicable Regulations:** (a) The Department of Health and Human Services General Administrative Regulations in 45 CFR part 75 (b) Audit Requirements for Federal Awards in 45 CFR part 75 Subpart F; (c) 45 CFR part 75 Non-procurement Debarment and Suspension; (d) 45 CFR part 75 Requirement for Drug-Free Workplace (Financial Assistance); (e) The regulations for this program in 34 CFR part 350; The notice of final priorities for the RRTC Program published in the **Federal Register** on February 1, 2008 (73 FR 6132); and (g) The notice of final priority for this program, published elsewhere in this issue of the **Federal Register**.

## II. Award Information

**Type of Award:** Discretionary grants.

**Estimated Available Funds:** \$875,000.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2015 and any subsequent year from the list of unfunded applicants from this competition.

**Maximum Award:** \$875,000 (\$300,000 from CMHS and \$575,000 from NIDILRR).

Applicants must submit a two-part proposal. One part must describe tasks and funds utilization carried out for the

CMHS portion of the project and the other part must describe the tasks and funds utilization for the NIDILRR part. We will reject any application that proposes a budget exceeding the Maximum Amount for the CMHS portion. We will reject any application that proposes a budget exceeding the Maximum Amount for the NIDILRR portion. The Administrator of the Administration for Community Living may change the maximum amount through a notice published in the **Federal Register**.

**Estimated Number of Awards:** 1.

The Department is not bound by any estimates in this notice.

**Project Period:** 60 months.

We will reject any application that proposes a project period exceeding 60 months. The Administrator of the Administration for Community Living may change the project period through a notice published in the **Federal Register**.

## 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:** This competition does not require cost sharing or matching.

## IV. Application and Submission Information

1. **Address to Request Application Package:** You can obtain an application package via grants.gov, or by contacting Marlene Spencer: U.S. Department of Health and Human Services, 400 Maryland Avenue SW., Room 5133, PCP, Washington, DC 20202–2700. Telephone: (202) 245–7532 or by email: [marlene.spencer@acl.hhs.gov](mailto:marlene.spencer@acl.hhs.gov). The application package will contain instructions for preparing the two-part application.

If you request an application from Marlene Spencer, be sure to identify this competition as follows: CFDA number 84.133B–4.

2. **Content and Form of Application Submission:** Requirements concerning the content of an application, together with the forms you must submit, are in the application package for the competition announced in this notice.

**Notice of Intent to Apply:** Due to the open nature of the RRTC priority announced here, and to assist with the selection of reviewers for this competition, NIDILRR is requesting all potential applicants submit a letter of intent (LOI). 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 optional LOI via mail (through the U.S. Postal Service or commercial carrier) or email, by July 31, 2015. The LOI must be sent to: Marlene Spencer, U.S. Department of Health and Human Services, 550 12th Street SW., Room 5133, PCP, Washington, DC 20202; or by email to: [marlene.spencer@acl.hhs.gov](mailto:marlene.spencer@acl.hhs.gov).

For further information regarding the LOI submission process, contact Marlene Spencer at (202) 245–7532.

**Page Limit:** The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you limit Part III to the equivalent of no more than 100 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 either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to Part I, the cover sheet; Part II, the budget section, including the narrative budget justification; Part IV, the assurances and certifications; or the one-page abstract, the resumes, the

bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative section (Part III).

**Note:** 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 help us screen for conflicts of interest with our reviewers.

An applicant should consult NIDRR's Long-Range Plan for Fiscal Years 2013–2017 (78 FR 20299) (Plan) when preparing its application. The Plan is organized around the following research domains: (1) Community Living and Participation; (2) Health and Function; and (3) Employment.

**3. Submission Dates and Times:**

*Applications Available:* June 26, 2015.

*Date of Pre-Application Meeting:*

Interested parties are invited to participate in a pre-application meeting and to receive information and technical assistance through individual consultation with NIDILRR staff. The pre-application meeting will be held on July 17, 2015. Interested parties may participate in this meeting by conference call with NIDILRR staff from the Administration for Community Living between 1:00 p.m. and 3:00 p.m., Washington, DC time. NIDILRR staff also will be available from 3:30 p.m. to 4:30 p.m., Washington, DC time, on the same day, by telephone, to provide information and technical assistance through individual consultation. For further information or to make arrangements to participate in the meeting via conference call or to arrange for an individual consultation, contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

*Deadline for Notice of Intent to Apply:* July 31, 2015.

*Deadline for Transmittal of Applications:* August 25, 2015.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail delivery if you qualify for an exception to the electronic submission requirement, please refer to section IV. **7. Other Submission Requirements of this notice.**

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed

**under FOR FURTHER INFORMATION**

**CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

**4. Intergovernmental Review:** This program is not subject to Executive Order 12372.

**5. Funding Restrictions:** We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

**6. Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:** To do business with the Department of Health and Human Services, you must—

a. Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

b. Register both your DUNS number and TIN with the System for Award Management (SAM) (formerly the Central Contractor Registry (CCR)), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet. A DUNS number can be created within one-to-two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data entered into the SAM database by an entity. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

**Note:** Once your SAM registration is active, you will need to allow 24 to 48 hours for the

information to be available in Grants.gov and before you can submit an application through Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at [www.SAM.gov](http://www.SAM.gov). To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, we have prepared a SAM.gov Tip Sheet, which you can find at: <http://www2.ed.gov/fund/grant/apply/sam-faqs.html>.

In addition, if 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: [www.grants.gov/web/grants/register.html](http://www.grants.gov/web/grants/register.html)

**7. Other Submission Requirements:** Applications for grants under this competition must be submitted electronically unless you qualify for an exception to this requirement in accordance with the instructions in this section.

**a. Electronic Submission of Applications.**

Applications for grants under the priority for a RRRTC on Self-Directed Care to Promote Recovery, Health, and Wellness for Individuals with Serious Mental Illness, CFDA Number 84.133B–4, must be submitted electronically using the Governmentwide Grants.gov Apply site at [www.Grants.gov](http://www.Grants.gov). Through this site, you will be able to download a copy of the application package, complete it offline, and then upload and submit your application. You may not email an electronic copy of a grant application to us.

We will reject your application if you submit it in paper format unless, as described elsewhere in this section, you qualify for one of the exceptions to the electronic submission requirement and submit, no later than two weeks before the application deadline date, a written statement to the Department that you qualify for one of these exceptions. Further information regarding calculation of the date that is two weeks before the application deadline date is provided later in this section under *Exception to Electronic Submission Requirement*.

You may access the electronic grant application for the RRTC on Self-

Directed Care to Promote Recovery, Health, and Wellness for Individuals with Serious Mental Illness competition at [www.Grants.gov](http://www.Grants.gov). You must search for the downloadable application package for this competition by the CFDA number. Do not include the CFDA number's alpha suffix in your search (e.g., search for 84.133, not 84.133B).

Please note the following:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

- Applications received by Grants.gov are date and time stamped. Your application must be fully uploaded and submitted and must be date and time stamped by the Grants.gov system no later than 4:30:00 p.m., Washington, DC time, on the application deadline date. Except as otherwise noted in this section, we will not accept your application if it is received—that is, date and time stamped by the Grants.gov system—after 4:30:00 p.m., Washington, DC time, on the application deadline date. We do not consider an application that does not comply with the deadline requirements. When we retrieve your application from Grants.gov, we will notify you if we are rejecting your application because it was date and time stamped by the Grants.gov system after 4:30:00 p.m., Washington, DC time, on the application deadline date.

- The amount of time it can take to upload an application will vary depending on a variety of factors, including the size of the application and the speed of your Internet connection. Therefore, we strongly recommend that you do not wait until the application deadline date to begin the submission process through Grants.gov.

- You should review and follow the Education Submission Procedures for submitting an application through Grants.gov that are included in the application package for this competition to ensure that you submit your application in a timely manner to the Grants.gov system. You can also find the Education Submission Procedures pertaining to Grants.gov under News and Events on the Department's G5 system home page at <http://www.G5.gov>.

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following

forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must upload any narrative sections and all other attachments to your application as files in a PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.

- Your electronic application must comply with any page-limit requirements described in this notice.

- 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, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

- We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System:* 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 date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along

with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

*Exception to Electronic Submission Requirement:* You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or

- You do not have the capacity to upload large documents to the Grants.gov system; and

- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Patricia Barrett, U.S. Department of Health and Human Services, 400 Maryland Avenue SW., Room 5142, Potomac Center Plaza (PCP), Washington, DC 20202-2700. FAX: (202) 245-7323.

Your paper application must be submitted in accordance with the mail instructions described in this notice.

b. *Submission of Paper Applications by Mail.*

If you qualify for an exception to the electronic submission requirement, you may mail (through the U.S. Postal Service or a commercial carrier) your application to the Department. You

must mail the original and two copies of your application, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.133B-4), 550 12th Street SW., Room 7041, Potomac Center Plaza, Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Administrator of the Administration for Community Living of the U.S. Department of Health and Human Services.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

**Note for Mail of Paper Applications:** If you mail your application to the Department—

(1) You must indicate on the envelope and—if not provided by the Department—in Item 11 of the SF 424 the CFDA number, including suffix letter, if any, of the program under which you are submitting your application; and

(2) The Application Control Center will mail to you a notification of receipt of your grant application. If you do not receive this notification within 15 business days from the application deadline date, you should call the U.S. Department of Education Application Control Center at (202) 245-6288.

## V. Application Review Information

1. *Selection Criteria:* The selection criteria for this program are from 34 CFR 350.54 and are listed in the application package.

2. *Review and Selection Process:* Final award decisions will be made by the Administrator, ACL. In making these decisions, the Administrator will take into consideration: Ranking of the review panel; reviews for programmatic and grants management compliance; 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 Section 75.205, item (3) history of performance is an item that is reviewed.

In addition, in making a competitive grant award, the Administrator of the Administration for Community Living 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. *Special Conditions:* Under 45 CFR part 75 the Administrator of the Administration for Community Living may impose special conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 45 CFR part 75, as applicable; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

## 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 may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the NOA. The NOA also incorporates your approved application as part of your binding commitments under the grant.

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 directed by the Administrator of the Administration for Community Living. 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 directed by the Administrator of the Administration for Community Living 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. The Administrator of the Administration for Community Living may also require more frequent performance reports under 45 CFR part 75. For specific requirements on reporting, please go to [www.ed.gov/fund/grant/apply/appforms/appforms.html](http://www.ed.gov/fund/grant/apply/appforms/appforms.html).

(c) *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 see the following link: [http://www.acl.gov/Funding\\_Opportunities/Grantee\\_Info/FFATA.aspx](http://www.acl.gov/Funding_Opportunities/Grantee_Info/FFATA.aspx).

If you receive a multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information. Annual and Final Performance reports will be submitted through NIDILRR's online Performance System and as designated in the terms and conditions of your NOA. At the end of your project period, you must submit a final performance report, including financial information.

Note: NIDILRR will provide information by letter to successful grantees on how and when to submit the report.

4. *Performance Measures:* To evaluate the overall success of its research program, NIDILRR assesses the quality of its funded projects through a review of grantee performance and accomplishments. Each year, NIDILRR examines a portion of its grantees to determine:

- The number of products (e.g., new or improved tools, methods, discoveries, standards, interventions, programs, or devices developed or tested with NIDILRR funding) that have been judged by expert panels to be of high quality and to advance the field.

- The average number of publications per award based on NIDILRR-funded research and development activities in refereed journals.

- The percentage of new NIDILRR grants that assess the effectiveness of interventions, programs, and devices using rigorous methods.

NIDILRR uses information submitted by grantees as part of their Annual Performance Reports for these reviews.

5. *Continuation Awards*: In making a continuation award, the Administrator of the Administration for Community Living may consider, under 45 CFR part 75, the extent to which a grantee has made "substantial progress toward meeting the objectives in its approved application." This consideration includes the review of a grantee's progress in meeting the targets and projected outcomes in its approved application, and whether the grantee has expended funds in a manner that is consistent with its approved application and budget. In making a continuation grant, the Administrator also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department. Continuation funding is also subject to availability of funds.

## VII. Agency Contact

### FOR FURTHER INFORMATION CONTACT:

Patricia Barrett, U.S. Department of Health and Human Services, 400 Maryland Avenue SW., Room 5142, PCP, Washington, DC 20202-2700. Telephone: (202) 245-6211 or by email: [patricia.barrett@acl.hhs.gov](mailto:patricia.barrett@acl.hhs.gov).

If you use a TDD or a TTY, call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

## VIII. Other Information

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Dated: June 22, 2015.

**John Tschida,**

*Director, National Institute on Disability, Independent Living, and Rehabilitation Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-1887]

#### Source Data Capture From Electronic Health Records: Using Standardized Clinical Research Data

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Center for Drug Evaluation and Research (CDER) is interested in supporting demonstration projects to test the capability and evaluate performance of using an end-to-end Electronic Health Record (EHR)-to-Electronic Data Capture (EDC) single-point data capture approach, using established data and implementation standards in a regulated clinical research environment. A demonstration project should ideally test the use of a standards-based technology solution to enable the collection of related healthcare and clinical research information within a single system and workflow. Stakeholders may include regulated industry, EHR and EDC vendors, academic medical centers, and other interested parties.

**DATES:** Submit either electric or written requests for participation in the demonstration project by August 10, 2015.

**ADDRESSES:** Submit written requests for single copies of the documents to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring,

MD 20993-002, 301-796-5333, [ronald.fitzmartin@fda.hhs.gov](mailto:ronald.fitzmartin@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

The information systems, as well as the underlying data models, that define both clinical care and clinical research are widely disparate. This was not an issue for the conduct of clinical research prior to use of EHRs or EDC because data were captured on paper case report forms. However, much has changed in the past decade for clinical research where EDC systems are now ubiquitous for the capture of clinical trials data. Similarly, EHRs have had widespread adoption and are rapidly becoming a standard part of clinical care.

In 2013, FDA published a final guidance on "Electronic Source Data in Clinical Investigations" which encourages use of electronic source data in the conduct of clinical trials intended for inclusion in investigational and new drug applications. The electronic capture of data from EHRs and healthcare devices, such as electrocardiogram management systems, digital imaging and mobile health devices, as well as electronic Patient Reported Outcomes Instruments has the potential to improve the reliability, quality, traceability, provenance and integrity of data from electronic source to regulatory submission.

Demonstration projects should assess and report value and challenges of the EHR-to-EDC single-point capture of source data in a clinical research environment. Streamlining clinical research at the source may open up opportunities to improve clinical trial design and execution, speed the cycle of clinical research and get medicines to market faster.

Specifically, the use of a standards-based technology solution in clinical trials has the potential to:

- Eliminate duplication of data by capturing and transmitting electronic source data;
- auto-populate the electronic study forms from EHRs;
- reduce transcription errors and improve the quality of data;
- encourage entering source data at the point of care;
- facilitate remote monitoring of data to reduce the number of onsite visits by regulated biopharmaceutical industry;
- improve site monitoring to minimize the need for cross-reference data in multiple sources;
- make it easier for investigators to conduct clinical research;
- facilitate the inspection and reconstruction of clinical investigations by FDA; and