NOFO Informational Meeting Transcript - Components B and C

Understanding and Promoting Resources and Opportunities for People with Autism and Fragile X Syndrome and Their Families Across the Lifespan

NOFO DD26-0025

Informational Meeting held May 27, 2026

Reader note: This is a cleaned AI generated transcript intended for readability, not a certified verbatim transcript.

OPENING AND MEETING LOGISTICS

A link to the recording will be posted on the NOFO webpage after the call. You can follow the webinar content using the PDF version of the NOFO available on Grants.gov. We have also included reference page numbers from the NOFO throughout the presentation.

Please mute your phone lines and speakers and submit any questions you have in the chat box. We will answer questions at the end of the presentation and also post them on the NOFO webpage.

Welcome to the informational call for potential applicants for NOFO DD26-0025, Understanding and Promoting Resources and Opportunities for People with Autism and Fragile X Syndrome and Their Families Across the Lifespan. This portion of the call focuses specifically on Components B and C.

AGENDA AND OVERVIEW OF THE NOFO

The call will include multiple members of the team discussing different parts of the NOFO. We will begin with a summary of the NOFO, award information, and eligibility information.

This NOFO aims to better understand the resources and opportunities that people with autism or fragile X syndrome and their families need in areas including education, transition into young adulthood, services, and supports. The goal is to reduce morbidity and mortality and improve long-term outcomes, including health and well-being.

CDC will fund three components under this NOFO. Component A focuses on autism. Components B and C focus on fragile X syndrome. This is a five-year cooperative agreement broken into five 12-month budget periods. There will be up to three awards for Component B and one award for Component C. Applicants may apply for all three components if they have the capacity.

BACKGROUND AND HISTORY OF FRAGILE X RESEARCH

Mark Schweizer provided background on fragile X syndrome.

The population for Component B is people with fragile X syndrome. Fragile X syndrome is a genetic disorder caused by a mutation in the FMR1 gene, which affects production of the FMRP protein needed for brain development. It is the most prevalent known cause of inherited intellectual disability and the most common monogenic, or single-gene, cause of autism.

Fragile X syndrome affects about 1 in 7,000 males and 1 in 11,000 females. Males generally have more severe symptoms because they have only one X chromosome. People with fragile X syndrome more often have developmental delays, learning disabilities, and a variety of social and behavioral problems compared with their peers.

Fragile X syndrome has no cure. However, early diagnosis and intervention may have a significant impact on the health and well-being of people living with fragile X syndrome.

HISTORY OF FORWARD AND FORWARD-MARCH

The work began with FORWARD as a pilot from 2008 to 2011. FORWARD then developed into a larger project that included many instruments and assessments from 2012 to 2021. The current FORWARD-MARCH project began in 2021 and is scheduled to end in 2026.

COMPONENT B: FAST FORWARD - PURPOSE

Fast Forward will collect information on demographics, symptoms, co-occurring conditions, service and support needs, and other needs and experiences of people with fragile X syndrome and their families. The data will guide practices to increase access to services and supports and improve health and other outcomes for people with fragile X syndrome and their families.

Component B applicants must provide evidence of access to a clinic-based sample of children, adolescents, and adults ages 0 through 40 with a fragile X syndrome full mutation diagnosis. Applicants must demonstrate the ability and capacity to collect data and access clinical records for a minimum of 200 unique people with a fragile X syndrome full mutation diagnosis.

COMPONENT B: STRATEGY 1 - DATA COLLECTION AND MANAGEMENT

The first strategy for Component B is to recruit a minimum of 200 unique clinic-based participants ages 0 through 40 with a fragile X full mutation diagnosis. Data will be collected through caregiver surveys and from existing clinical records. Applicants will manage, clean, and share de-identified data with CDC.

Awardees are expected to conduct all recruitment, enrollment, survey administration, and data collection activities in the timeframe specified by CDC. Awardees will need to establish access to contact, clinic, and genetic information. Previous participation in FORWARD or FORWARD-MARCH is not required.

Awardees will confirm contact information for eligible participants, provide caregiver surveys to recruited individuals, collect data from existing clinical records, and conduct enrollment calls for those who have not responded to survey invitations.

Awardees should meet regularly with other recipients and CDC coordinating staff to ensure standardized data collection methods, discuss study progress, and troubleshoot any problems related to study implementation.

REDCAP AND CAREGIVER SURVEY ADMINISTRATION

A REDCap data collection system designed by CDC will be used to ensure uniform data collection. Awardees are expected to install and maintain the system by providing IT infrastructure, updating local REDCap systems, and ensuring effective user operation of the system.

The caregiver survey will be programmed in REDCap and administered using a mobile-friendly format to facilitate participant access and ease of completion. Awardees should ensure active participation with a goal of data completion for 50 participants per year. Participant incentives, consistent with applicable grant regulations and guidance, should be issued upon survey completion.

DATA MANAGEMENT PLAN AND DATA SECURITY

Applicants need to submit a data management plan with their application. The data management plan should be updated as needed and resubmitted to CDC for annual review.

Awardees will be required to host and use R, a free and open-source software program, for data management. Awardees should provide R training for staff members if needed and ensure local expertise for troubleshooting.

Awardees should provide training on confidentiality, data collection and management procedures, and data quality assurance and control. Data access should be restricted to investigators affiliated with Fast Forward.

Awardees will clean data in R using CDC-developed programs and ensure that all personally identifiable information is removed. Awardees will work with CDC to facilitate data exchange. All de-identified data will be shared through Secure File Transfer Protocol (SFTP). A subset of the finalized pooled data may be made available for public use, consistent with CDC policies and applicable law.

COMPONENT B: STRATEGY 2 - PUBLIC HEALTH PRODUCTS

The second strategy for Component B is to translate data into high-quality public health products in a timely manner. These products may be peer-reviewed publications or other products such as summaries, data summaries, infographics, or professional trainings.

The activities, performance measures, frequency, and start dates are included in the NOFO. In brief, there are performance measures associated with each activity. These include reporting the number of eligible participants, providing clinic demographics to aid in refining recruitment projections, reporting the number of eligible participants and other metrics in consultation with CDC, and reporting the criteria used.

The initial eligibility and criteria reporting will occur once at the beginning of the study. Updating clinic demographic information to refine projections will occur quarterly. Reporting the number of eligible participants will occur monthly.

During data collection, awardees will report monthly on key participation and completion milestones, as well as any challenges or barriers to data collection and proposed actions to overcome those barriers.

For management of collected data, awardees will provide the status of confidentiality training completion annually, ensure that at least one site representative is present on all

fragile X calls monthly, and participate in principal investigator calls as needed. Principal investigator calls are projected to occur monthly.

For cleaning and sharing data, local instances of the REDCap database will be used. Uploading and transferring de-identified data via SFTP to CDC is projected to occur monthly. Completing data cleaning and submitting de-identified data files to CDC will occur once.

Each Component B site will be expected to develop at least one public health product. These may include peer-reviewed publications, professional trainings, summaries, infographics, or similar products. Sites will also report any resource needs and opportunities as needed.

COMPONENT C: FRAGILE X INFORMATION DISSEMINATION

Amy Alexander introduced Component C, Fragile X Information Dissemination.

The outcome of Component C is to strengthen partnerships with organizations that support people with fragile X syndrome and their families. Each activity focuses on a different audience. One focuses on support for families. The second focuses on support through and for healthcare providers.

The activities include dissemination of knowledge gained from previously funded data collections, such as FORWARD-MARCH, and are separate from Component B. Outreach for fragile X syndrome, a rare genetic disorder, is best and most efficiently achieved by an entity focused on the mission and with established connections to the community nationwide.

Clinics may be involved in the dissemination strategy, but activities are not limited to clinics. Component C will not be involved with Component B activity management or monitoring.

COMPONENT C: STRATEGY AND ACTIVITIES

The primary strategy for Component C is to disseminate information to specific audiences. Activity 1 will focus on disseminating information to people with fragile X syndrome, their families, and associated communities. Activity 2 will focus on providing information to healthcare providers.

Dissemination activities may include identifying priorities, gaps in information, education needs, and communication needs; developing or adapting programs, products, or tools for the focused audiences; developing a dissemination plan; disseminating information; evaluating and continuously improving information dissemination to both audiences; and ensuring products are responsive to diverse audiences and communication needs.

Recipients must share information and materials with CDC and incorporate current evidence for successful communication and dissemination into all proposed activities.

Component C applicants must demonstrate the ability and capacity to identify and reach people with fragile X syndrome and their families and communities across the United States. Applicants must also be able to reach healthcare providers, specifically those treating patients with fragile X syndrome; generate new communication materials; and continually identify resources for healthcare providers, people with fragile X syndrome, their families, and communities.

Applicants should quantify metrics of impact, such as tracking and reporting use of disseminated information.

The activities, performance measures, frequencies, and start dates are outlined in the NOFO. Performance measures include describing identified needs; itemizing and describing products and plans for creating additional products; providing statistics and qualitative feedback, if available, on reach and outcomes of information dissemination; providing information on barriers or facilitators to information dissemination; and providing a status update for all activities undertaken. The frequency for these activities will be annual.

APPLICATION SUBMISSION PROCEDURES

A letter of intent from potential applicants is requested but optional. This allows CDC to estimate the number of applications and plan for the review. The letter of intent may be sent to CBK9@cdc.gov and should include the NOFO number and title, the organization's name and address, a contact name, phone number and email address, and the components for which the applicant plans to apply.

The application includes a project narrative, limited to 20 pages, including the background and approach, evaluation and performance measurement plan, and organizational capacity. Applicants also need to submit a budget narrative, which is not scored, and may submit attachments as needed.

The budget narrative supports information provided in Standard Form 424A. It explains and justifies the costs in the budget and includes the listed budget categories. Budget items specific to Component B and Component C are included in the NOFO.

REVIEW AND SELECTION PROCESS

After applications are submitted by the June 15 deadline, the Office of Grants Services will conduct an initial review for eligibility and completeness. Applications that are not responsive will not advance to the next phase of review.

A panel outside CDC's Division of Human Development and Disability will review applications using the scoring criteria outlined in the NOFO. A separate review is also conducted to assess the risk that recipients will not manage federal funds prudently.

An objective review panel will review each application and assign points for each section. Background and approach are worth 45 points total. The evaluation and performance measurement plan is worth 20 points. Organizational capacity is worth 35 points.

The slides that follow provide additional details about point assignments within each section. Those details are also included in the NOFO.

FUNDING DECISIONS AND NOTIFICATIONS

Applications will be funded in order by the rank determined by the review panel. CDC considers merit review results as key, but they are not the only factor. CDC may fund applications out of rank order to ensure demographic and geographic representativeness or based on applicants' ability to access participant health records or contact information.

Applicants may be funded in whole or in part, may be funded at a lower amount than requested, or may be approved but not funded during this fiscal year. The number of awards is subject to available funds and agency and program priorities.

If awarded, CDC will email a Notice of Award to the authorized official. CDC will also notify applicants if an application is found not responsive or unsuccessful.

KEY DATES AND CONTACTS

The deadline for the optional letter of intent is June 1. Applications are due before midnight on June 15. The tentative date for awards to be issued is August 31, and the projected project start date is September 30.

The project officer is the presenter who provided the application information. Robin Bryant will serve as the Grants Management Officer for this project. Questions about submissions should be directed to the Grants.gov Help Desk.

Questions about Components B and C may be submitted after the call to the FORWARD mailbox at forward@cdc.gov by June 9. Questions and answers, as well as the slides and recording from the call, will be posted to the NOFO webpage.

QUESTION AND ANSWER SESSION

Question: Is it within the scope of the NOFO to use Component B and/or Component C funding to fund referrals from non-Component B fragile X specialty clinics and/or participation on an advisory board to assist with project design and dissemination of recruitment information and project results to the community? These efforts would ensure geographic representation and enhance reach to both families and healthcare providers treating these individuals across the country.

Answer: The scope for Component B is focused on the three clinics' patients and, as stated in the NOFO, includes information from medical records. The intention of the NOFO is that Component B participants be patients at that clinic. Advisory boards to discuss dissemination of materials could potentially be within the scope of Component C.

Question: Can a Component B application have a subcontract with a second fragile X clinic that combines to have the 200 patients?

Answer: There are no restrictions on subcontracts.

Question: Where will the REDCap database be created and housed? Should applicants include housing REDCap at one or all Component B sites?

Answer: CDC is developing the REDCap database, but awardees will house it locally. Each site is expected to host its own version.

Follow-up question: Could one site host REDCap and have sections for the other sites?

Answer: The expectation is that each site will host its own version locally. CDC will not provide support for a centralized site-hosted model across multiple awardees.

Question: Can sites use the current FORWARD-MARCH questionnaires and forms? Are there other specific forms CDC has in mind for the adult population? Will there be a planning period at the beginning of Component B grants to decide what will be collected?

Answer: CDC has already been working on the data collection instruments so that the appropriate Office of Management and Budget approvals can be obtained and the REDCap database can be ready when funding begins. Sites should be able to begin implementation when funding begins.

Follow-up question: Will sites have input into what is used?

Answer: There may be an opportunity for refinement, which would be discussed with awardees.

Follow-up question: Does the application need to specify exactly which questions will be collected?

Answer: No. The subject areas have already been identified and submitted to OMB. They are in the public record and are also described in the NOFO and presentation.

Follow-up question: Should applicants propose using prior FORWARD questionnaires?

Answer: No. The intent is to streamline and focus the questions and substantially reduce participant burden from prior versions of FORWARD.

Question: What does it mean that activities cannot include research?

Answer: CDC determined that the activities described in the NOFO are non-research because CDC considers them surveillance of a defined population. Each awarded site may still need to go through its own institutional research determination. An institution may determine that the project is research locally, but as long as the activities being conducted are the ones CDC determined to be non-research, that is not an issue.

Follow-up question: The NOFO says research is not permitted. Can you explain further?

Answer: The data collection, data analysis, and other activities outlined for Components B and C are determined by CDC not to be research. Anything proposed that is consistent with what is requested in the NOFO is not considered research by CDC.

Question: Is CDC going to provide the R scripts and support for R?

Answer: Yes. CDC is transitioning to using only R and not providing support for SAS. Support will be provided in R, which is free.

Question: Will sites have input into what is in the REDCap database?

Answer: The REDCap database is being developed based on draft surveys that have already been developed. There will be an opportunity for review and potential revisions as needed with recipients, particularly regarding tracking and related processes.

Question: Has CDC decided what the surveys will be? Applicants may want to know in order to align their plans.

Answer: CDC can provide the Federal Register notice for the questionnaire to give applicants an idea of the content. The notice does not include the actual questions, but the types of questions are generally described in the NOFO. The subject areas are described to the extent applicants are expected to know them for their applications.

Question: Will there be an opportunity to track longitudinal data from previous FORWARD projects?

Answer: Funded clinics are not required to have been previous FORWARD participants. However, there is nothing that would preclude analyses of data over time if one or more funded clinics has data from previous rounds of FORWARD.

Question: For Component C, does the partnership with organizations providing support include medical, psychological, and other clinical organizations?

Answer: Component C did not specify that level of detail. The main concern is the ability to disseminate information to families, communities, and clinicians. Component C would not preclude partnerships with medical, psychological, or other clinical organizations if those organizations can provide that reach.

Question: For clinical data housed at clinics, will data be entered into REDCap by a person, or is an extraction from electronic medical records expected?

Answer: It is not a large amount of clinical data, and an electronic medical record extraction is not expected. If extraction from an EMR is easier for a site, there is nothing preventing that, but manual entry by clinic staff is acceptable and expected.

Question: Strategy 2 requires one product to be produced and disseminated to stakeholders. Is that one per year per site, one per site, or one per year?

Answer: The requirement is one per site over the whole grant period, at a minimum.

Question: Are letters of support required to document access to patients, or are they only required if access needs to be documented through another entity?

Answer: If an applicant is a clinic and can demonstrate access to clinic records, a letter is not needed. Letters would be relevant when needed to document access.

Question: A data management plan is required, as is budgeting for data management. Other than using a CDC-provided database and CDC-provided R scripts, what elements of data management is CDC asking for from Component B applicants?

Answer: The data management plan is described on page 42 of the NOFO. Applicants can describe confidentiality training, maintaining a secure server, restricting access to investigators associated with Fast Forward, and the ability to host REDCap. If the applicant's organization does not already have REDCap access, there may be costs associated with that. Applicants can also describe use of SFTP to securely transfer data.

Follow-up question: Should the plan describe continuous data monitoring, data queries, and accurate refinement of data entry?

Answer: That would be helpful. Prior iterations of studies have shown that completeness of data can be a problem over time, so addressing completeness and quality monitoring may be part of the data management plan.

Question: For budgeting purposes, will each site need a data manager and/or statistician? Will each site only manage day-to-day upload of data into REDCap? Will CDC manage any part of the data, or is data management up to each site?

Answer: CDC will manage data from each site as they are brought together for the final dataset. Uploads are anticipated to occur at least monthly to ensure data are coming in regularly. Sites will be responsible for cleaning data before upload using cleaning code provided by CDC. Sites will also be expected to maintain the most updated version of the REDCap database on their systems. A data manager or epidemiologist would be needed at each site for those processes.

The NOFO also notes that each site needs an actively involved principal investigator, at least 50% effort for a project coordinator or project manager, a qualified clinician to review medical records, and anticipated additional staffing for epidemiologic and data management support.

Question: Can data be used for publications as they are collected, or will sites need to wait until a cleaned dataset from CDC is available for analysis?

Answer: CDC does not anticipate releasing a partial dataset during the study. The completed dataset will be cleaned and available for analysis shortly after the conclusion of the study.

Follow-up question: Will fragile X participating clinics and other fragile X experts then be allowed to use the data to publish?

Answer: Yes. The datasets from the study will be shared back with sites after the conclusion of the study. The data should not be used for publication as it is being collected.

Question: The institution may consider this research and require consent forms and IRB review. Is that acceptable?

Answer: Yes. CDC will work with each recipient in whatever way is needed by that site.

Question: CDC stated that Component C awardees cannot be involved in managing or monitoring any part of Component B. If the Component C awardee has been involved in past projects, is there a role they can play at each site to help?

Answer: The clarification is that Component C activities and funding are completely separate from Component B. Component C is separate from Component B activities. However, if there were an appropriate role for an organization or clinic, such as a justified subcontract that added strength to a Component B application, the NOFO would not preclude that.

Question: The NOFO outlines categories, order, and hierarchy of sections for the grant. Should applicants use that outline instead of a traditional aims, background, preliminary data, and research plan format?

Answer: Yes. Applicants should use the format specified in the NOFO.

Question: Will Fast Forward data from this grant opportunity be unavailable for use until the end of the grant period?

Answer: CDC does not anticipate releasing an interim dataset. The Fast Forward data will not be available until the end of the grant period, depending on when data collection ends.

Follow-up question: For Component B products and Component C dissemination activities, educational materials, and similar products, should the data used come from past FORWARD project data?

Answer: For Component C, products are not limited to FORWARD data. Any good information that is available, including FORWARD data, may be included. The primary thrust of Component C is to increase the amount of information available to families and providers.

Question: Do Component B products have to be linked to information gathered in this grant, or can they come from past FORWARD projects, other projects, or information useful to the community in one of the NOFO's specified areas of interest?

Answer: Component B products do not have to be linked to data collected during this grant. Because the new Fast Forward data will not be available until later, products may use past FORWARD projects, other projects, or other informative content within the NOFO's areas of interest.

CLOSING

Participants were encouraged to submit any additional questions to the FORWARD mailbox. CDC will update the FAQ document and post it to the NOFO webpage. The call ended with thanks to participants.