



HUNTINGTON'S DISEASE SOCIETY OF AMERICA CENTERS OF EXCELLENCE 2019 Program Description

DATES AND DEADLINES

Online submission of Letter of Interest	<i>due by</i>	September 14, 2018
Invitation to submit application	<i>distributed no later than</i>	September 28, 2018
Completed application for funding	<i>due by</i>	November 30, 2018
Letters of Designation	<i>by</i>	Early February 2019*

*All grants are retroactive to January 1, 2019

MISSION

The goal of the HDSA Center of Excellence (COE) program is to increase access to the best possible multi-disciplinary clinical care and services for individuals affected by Huntington's disease (HD) and their families through a geographically diverse network of local and/or regional clinical centers. In addition to clinical and social services, the Centers will provide professional and lay education in the geographic areas they serve, are involved in HD clinical research and work with HDSA locally and nationally in its efforts to continually improve the lives of those affected by HD and their families.

OBJECTIVES

- To design a US standard for best practice multidisciplinary care in the management of HD and to provide services for families with HD.
- To select and support institutions that excel with regard to: knowledge and experience in HD, education of HD in their local community, establishment of a multidisciplinary care team for HD, and involvement with HD clinical research.
- To directly support HDSA in accomplishing its mission by developing and maintaining relationships throughout the HDSA local, regional and national community, including among the COE network.

CLINICAL AND SOCIAL SERVICES

HDSA Centers of Excellence provide comprehensive multidisciplinary clinical service for families affected by HD. Services are centered around an organized HD clinic in which an individual's clinical care needs are defined, plans are made to fulfill those needs, and follow-up is provided to continually optimize clinical management. While attending to the individual, needs will be considered in the context of the family unit impacted by HD.

Based on the size and scope of clinics within the HDSA Center of Excellence program as determined by the levels of criteria, services may be readily available on campus or provided at off-site facilities at the discretion of the Center. Responsibility for the treatment plan should be retained by the Center so that HD families will benefit from the Center's expertise. Individuals should be seen annually or semi-annually at the Center of Excellence for HD treatment management; the personnel at a Center of Excellence does not replace the primary care provider (PCP) and is expected to work in concert with the PCP.

Core COE personnel must have established and demonstrated expertise in caring for a person with HD. Depending on the level of services offered, HDSA Centers of Excellence will be categorized as Level 1, 2 or 3. Requirements are briefly summarized in the following table and expanded below. Click on the left column to jump to details.

Table of Basic Expectations for HDSA Centers of Excellence:

	Level 1	Level 2	Level 3
Patient base at time of application	150	75	25
Minimum HD-specific clinic time	1 full day/month	1 full day/month	1 half day/month
Prior Support	Substantial track record prior to award	Substantial track record prior to award	Not required
Relationship with partner clinic that expands geographic access to care	Required	Not required	Not required
Administration	Neurologist/psychiatrist director or co-director, Operations Committee, Center Advisory Board		
Clinical Services	<u>Level 1</u> Required onsite: clinic director, neurologist, genetic counselor, social worker, nurse, research personnel, triage line. Required onsite or on campus: psychiatrist, psychologist, physical therapist, occupational therapist, speech-language pathologist, nutritionist	<u>Level 2</u> Required onsite: clinic director, neurologist, social worker, nurse, research personnel, triage line. Required onsite or on campus: genetic counselor, psychiatrist, psychologist, physical therapist, occupational therapist, speech-language pathologist, nutritionist	<u>Level 3</u> Required onsite: clinic director, neurologist, social worker, triage line. Required by community referral or may be provided on site/on campus: genetic counselor, psychiatrist, psychologist, physical therapist, occupational therapist, speech-language pathologist, nutritionist
Genetic counseling requirements	On clinic days AND outside of clinic hours		On clinic days OR outside of clinic hours
Mental health requirements	Must be able at all times to refer a patient for follow-up mental health needs		
Research	Direct participation required; HSG site		Must be able to refer to research studies
Education	Education in care of persons with HD for medical professionals, families, and broader community		
Expectations for Community Participation and Training	Center Director: 2 HDSA sponsored events annually. Social worker: Professional Training Day at HDSA Annual Convention. Other Center staff: Encouraged to attend at least 1 HDSA sponsored event annually.		
Long Term Care	Provide in-services to LTC facilities and assist in identifying placement in long term care facilities for HD patients and families		
Social support	Must provide HD patients and families a connection to HDSA support groups.		
Indigent Care	Procedures must be in place for providing care to those without insurance or the ability to pay.		
Collaboration with HD Community	Education, LTC In-services, public dissemination of information, connection to HDSA support groups		

DESIGNATION AND PROGRESS REPORTS

Designation as a Level 1 or 2 HDSA Center of Excellence is valid for three years. Therefore, Level 1 and 2 Clinics *do not* have to re-apply each year unless changes occur in their partnership or if they desire to be considered for a higher level of funding. To maintain funding and designation, current Level 1 and 2 COEs must complete an annual progress report to HDSA by November 30, 2018. In year 3, a more extensive annual review will be required of Level 1 and 2 COEs that includes documentation including a letter of interest in a new three-year award. Progress report templates will be provided to each Level 1 and 2 COE.

In any year in which an unsatisfactory Progress Report is submitted or upon failure to deliver the services or adhere to the terms and conditions delineated in the letter of award, HDSA reserves the right to suspend the Center of Excellence designation and grant funding until such time as identified deficiencies have been satisfactorily addressed. Said deficiencies must be resolved within 90 days of suspension or the HDSA Center of Excellence designation will be revoked and the grant terminated.

Designation as a Level 3 HDSA Center of Excellence is valid for one year. An annual Progress Report is NOT required of Level 3 Centers. Instead, each Level 3 Center must re-apply annually for maintenance of designation. It is in the re-application that HDSA expects to be updated on progress since the previous year. Level 3 Centers may apply for a higher level of funding at another level at the end of any annual grant cycle if they meet the minimum standards required for that level.

LEVEL 3 designees MUST re-apply annually to continue as an HDSA Center of Excellence

GRANT PROCESS

Based upon the qualifications submitted in the online Letter of Interest, eligible prospective Centers will be invited by HDSA to submit a written application for review by the HDSA Center Programs Education and Advisory Committee (CPEAC). A site visit by representatives of HDSA may be a part of the renewal/re-designation process. To complete an online Letter of Interest, please go to www.hdsa.org/19COELOI.

To prepare your site for the application process, the following information will be required:

- A. Region and population:** Description of the region and population that is currently served and any potential changes that might result from the continuing or new presence of an HDSA Center of Excellence. If seeking a regional designation, this section should include how the entities will deliver services within the delineated catchment area and should contain supporting documentation from the partnering entity.
- B. Description of the HD clinic.** Information including history, location, frequency, billing, insurance acceptance practices, arrangements for seeing patients without means, and typical follow-up frequency. What change, if any, would occur as a result of becoming an HDSA Center of Excellence. For regional designations, this information will be included in Part 11. Grants are available only to existing clinics for support and expansion; grants are not intended to be seed funding to establish new expertise.
- C. Clinical Services:** Description of how access to each service is provided. Elaboration on the strengths and weaknesses of the clinic, future goals and what changes, if any, would occur as a result of becoming an HDSA Center of Excellence. If your clinic offers telemedicine, a brief description of the program and its use.
- D. Outreach:** Description of any efforts in place or that you would propose to help extend services to additional families and to institutionalized patients.
- E. Education:** Description of how your team contributes to educating healthcare professionals, HD families, and the public. For initial applications, describe what changes, if any, would occur as a result of becoming an HDSA Center of Excellence.
- F. Administration:** Refer to the program description for the proposed Operations Committee and Center Advisory Board. Provide specific information about your proposed Operations Committee and Center Advisory Board, including names, contact information and affiliation with clinic.

- G. Supporting Material:** Include the following supporting materials – curriculum vitae of core Center personnel, a list of members of your multidisciplinary team and information about additional on campus providers to whom you refer HD patients. For Level 3 applicants, a roster of community based providers to whom you refer HD patients is required. Letter of support from Center Advisory Board is required at renewal only.
- H. Relationship with HDSA:** Description of any contributions the proposed Center of Excellence would make to the local HDSA community, specifically chapter/affiliate relationships and activities.
- I. Budget:** Provide a budget in tabular form followed by specific justifications of each budget item. Major categories include personnel, services, supplies, and travel. Personnel should include percentage of effort and a breakdown of base pay and fringe benefits. Please note: HDSA allows no more than 5% of any grant to be used for administrative expenses. Level 1 applicants should include detailed information about funding for their partner site(s) in the area provided.
- J. Other support and institutional commitment:** Describe other support you receive for your HD services, including grants or donations that cover salaries, administrative support and/or space. Will your institution contribute any new resources as a result of becoming an HDSA Center of Excellence?
- K. Funding Plan:** Historically, most Centers of Excellence have been awarded 50-90% of the annual amount requested in their application. Please describe your plans to support your center if you do not receive full funding.
- L. Terms and Conditions:** The Terms and Conditions document must be signed by an official authorized to sign on behalf of the institution. The prospective Center of Excellence director or co-director are not acceptable signers. Please submit the Terms and Conditions document to your institution upon receipt of the Application Package so there is adequate time to process and return it to HDSA prior to the deadline for submission of your application

REVIEW AND SCORING OF APPLICATIONS

Applications will be reviewed by the HDSA Center Programs & Education Advisory Committee (CPEAC). All applications will be scored, using the following five individual criteria:

1. The quality of the overall application/services
2. Geographic diversity
3. Unique offerings or particular characteristics that add to the HD clinic
4. Use of funds and proper distribution of budget
5. Miscellaneous (e.g., HD community citizenship, research)

More than 50 percent of the emphasis will be placed on the first criterion which is the overall quality and completeness of the application and HD services provided at the prospective Center. The scoring of applications is part of an internal review process used by CPEAC to determine outcomes. Therefore, scores will not be shared with any site submitting an application for designation as an HDSA Center of Excellence, regardless of whether the site is given COE designation.

DECISION NOTIFICATION

Applicants will be notified by e-mail after a designation decision has been made by CPEAC and no later than early February 2019. If a clinic is designated as an HDSA Center of Excellence, an award letter will be sent to the Center's medical director. Information regarding branding materials and corresponding media package will be included. If a clinic does not receive the HDSA Center of Excellence designation, a letter detailing areas for improvement in future applications will be sent to the Center's medical director.

*All awards will be retroactive to January 1, 2019. If you have any questions about the HDSA Center of Excellence program please direct them to Dr. George Yohrling, Senior Director, Mission and Scientific Affairs at gyohrling@hdsa.org or by calling 212-242-1968 x211.

Full Eligibility Requirements and Expectations for HDSA Centers of Excellence

Patient Base

Reported patient numbers should reflect individual patients, not individual visits. Numbers may include tele-neurology patients. Centers of all levels must have a proven record of new patients seeking care annually. *At the time of application* for HDSA Center of Excellence status:

- Level 1 applicants should serve a minimum HD patient base of 150. Each Level 1 Partner Site must serve a minimum patient base of 10.
- Level 2 applicants should serve a minimum HD patient base of 75.
- Level 3 applicants should serve a minimum HD patient base of 25.

Clinic Time

HDSA Centers of Excellence hold regular organized multidisciplinary HD clinics.

- Level 1: equivalent to at least one full day per month.
- Level 2: equivalent to at least one full day per month.
- Level 3: equivalent to at least one half day per month.

Prior Support

Level 1 and 2 HDSA Center of Excellence applicants should have a substantial track record of institutional support for HD or movement disorder clinic prior to the award. This is not necessary for Level 3 applicants.

Level 1 Clinic Partnership

A Level 1 HDSA Center of Excellence must have established a formal partnership with other HD clinic(s) within a specific region as delineated in their application and award. Each HDSA Center of Excellence Partner Site that is associated with a Level 1 Center of Excellence:

- Must expand geographic access to HD care
- Must be outside of the applicant's university or hospital system
- Must contribute a letter of support to the Level 1 application
- Must have a minimum of 10 HD patients at time of application
- Must be an established movement disorder clinic or HD clinic staffed by professionals with knowledge of HD
- Must provide access to or offer HD genetic testing
- Must offer lay, professional and community HD education
- Must provide access to or information about HD research and clinical trial opportunities

Level 2 and 3 Centers of Excellence are not expected to have partnerships with additional sites.

Administration

Clinic Directorship

All HDSA Centers of Excellence are usually led by a medical director or co-director who is either a neurologist or psychiatrist well-qualified in the movement disorder field with expertise in HD. While it is strongly preferable that the HDSA Center of Excellence Director be a licensed physician, consideration will be given to a qualified professional who has demonstrated and documented expertise in Huntington's disease. In those instances where the Director is not a physician, then the co-Director must be a licensed physician with expertise in HD.

Operations Committee

An Operations Committee (3-4 persons) comprised of a Center Director and other senior Center professionals is required at all HDSA Centers of Excellence. This Committee:

- Selects and supervises employed personnel

- Manages relationships with collaborating professionals
- Notifies HDSA of personnel changes in HD team within 30 days of change
- Oversees Center operations
- Is responsible for timely and proper reporting
- Operations Committee meets a minimum of once a year

Center Advisory Board:

A Center Advisory Board is required at all HDSA Centers of Excellence and should include representatives from local HDSA chapters or affiliates and/or the local HD community, HD family members, local business leaders, and the Center director as a non-voting member. This board:

- Provides feedback on whether the needs of the local HD community are being met
- Meets at least once per year to assess programs and services delivered by the Center of Excellence prior to submission of an annual Progress Report or application for designation
- Provides a letter of support at annual renewal

Clinical Services and Multidisciplinary Team

Level 1 and 2 HDSA Centers of Excellence are expected to have a full multidisciplinary team with comprehensive care available on clinic days, including access to ancillary providers, without requiring a separate appointment day. Level 3 HDSA Centers of Excellence are expected to have core personnel in clinic on clinic day, but may refer patients to community based providers for ancillary services.

Level 1:

The following providers **must** be present onsite at the primary site on clinic days. See note below for required staff for partner sites on clinic days.

- clinic director
- neurologist
- genetic counselor compliant with the 2015 HDSA [protocol](#)
- social worker (minimum MSW, licensed and HIPAA compliant)
- nurse
- research personnel to facilitate participation in onsite clinical studies
- service triage or “help line” personnel such as a clinic coordinator, social worker, nurse, or other identified staff person to coordinate scheduling and ensure timely access to needed services

Additional providers must be available on clinic days and can be either in the clinic or on campus (within walking distance or a short drive):

- HD-experienced psychiatrist or neuropsychiatrist
- psychologist or neuropsychologist
- physical therapist
- occupational therapist
- speech-language pathologist
- nutritionist

On HD clinic days patients in a Level 1 Center of Excellence should have access to these services on the same day for an initial evaluation.

NOTE: Level 1 partner sites are not required to have a nurse onsite. Clinical study referrals can be made by the social worker or any personnel familiar with opportunities for research participation. Partner sites may also provide ancillary services (PT, OT, SLP, nutrition, psychology/psychiatry) either on campus or by referral to a community based provider with the expectation that the service is provided within one week of the clinic appointment.

Level 2:

The following providers **must** be present onsite on clinic days.

- clinic director
- neurologist
- social worker (minimum MSW, licensed and HIPAA compliant)
- nurse
- research personnel to facilitate participation in onsite clinical studies
- service triage or “help line” personnel such as a clinic coordinator, social worker, nurse, or other identified staff person to coordinate scheduling and ensure timely access to needed services

Additional providers must be available on clinic days and can be either in the clinic or on campus (within walking distance or a short drive):

- genetic counselor compliant with the 2015 HDSA [protocol](#)
- HD-experienced psychiatrist or neuropsychiatrist
- psychologist or neuropsychologist
- physical therapist
- occupational therapist
- speech-language pathologist
- nutritionist

On HD clinic days patients in a Level 2 Center of Excellence should have access to these services on the same day for an initial evaluation.

Level 3:

The following providers **must** be present onsite on clinic days.

- clinic director
- neurologist
- social worker (minimum MSW, licensed and HIPAA compliant)
- service triage or “help line” personnel such as a clinic coordinator, social worker, nurse, or other identified staff person to coordinate scheduling and ensure timely access to needed services

Additional providers must be available by community referral. HDSA encourages Level 3 Centers of Excellence to provide all services on clinic day either in clinic or on campus if possible.

- genetic counselor compliant with the 2015 HDSA [protocol](#)
- HD-experienced psychiatrist or neuropsychiatrist
- psychologist or neuropsychologist
- physical therapist
- occupational therapist
- speech-language pathologist
- nutritionist

On HD clinic days, a Level 3 HDSA Center of Excellence is encouraged but not required to provide patients access to these services on the same day for an initial evaluation.

Genetic Counseling and Testing

Genetic counseling and testing for persons at-risk for Huntington’s disease is a vital part of the mission of the HDSA Center of Excellence program. All Centers of Excellence, regardless of funding level, are required to provide access to this service either during clinic, on a separate day or by patient needs (see above for requirements by Level). HDSA Centers of Excellence must follow the [2015 HDSA protocol for genetic testing](#). Since the majority of at-risk individuals elect to self-

pay for predictive testing, all HDSA Centers of Excellence *must offer a sliding scale* for those who cannot afford the out of pocket expense.

Mental Health

HDSA Centers of Excellence must be able at all times to refer a patient for follow-up mental health needs.

- If the primary mental health provider (psychiatrist) is absent from clinic, another team member (psychologist, Master's degree nurse, or social worker) must be capable of performing required consultations, evaluations, recommendations and referrals.
- If a known psychological or psychiatric need exists, there must be a timely plan for a psychologist/psychiatrist to meet with the person(s) and/or family to address issues.

Research

Although the primary mission of an HDSA Center of Excellence is to provide clinical service, Centers are also expected to participate, as much as possible, in research benefiting the entire HD community.

- All Level 1 and 2 Centers of Excellence are encouraged to be *active* ENROLL-HD sites. Active is defined as having a signed/executed contract with CHDI Management, Inc. by the application deadline of November 30, 2018.
- All Level 1 and 2 Centers of Excellence must be credentialed research sites of the Huntington Study Group (HSG) by the application deadline of November 30, 2018.
- A Level 3 HDSA Center of Excellence is not required to provide or participate in HD research opportunities, but is strongly encouraged to do so. All Level 3 sites are expected to provide their patients with updated information about clinical studies and trials in their area.
- Level 1 Partner site(s) are not required to provide or participate in HD research opportunities, but it is strongly encouraged that they do so. Partner site(s) must also provide their patients with updated information about clinical studies and trials in their area.

Educational Mission and Requirements

The Educational Mission of the HDSA Centers of Excellence involves the following:

- In-service training in care of persons with HD for acute and long-term care units/facilities.
- Consultation, training, presentation, and supervision of education in HD for area health and science professionals.
- HD advocacy for general public, public officials and agencies, potential donors, etc.
- Educational services in support of HDSA chapter/regional activities.

Educational requirements for onsite personnel include the following:

Center Director

The HDSA Center of Excellence Director must attend and actively participate in at least two HDSA sponsored events annually (with at least one being educational).

Social Worker

HDSA Center of Excellence social workers are highly encouraged to attend HDSA Professional Training Day held annually the Thursday prior to the HDSA Annual Convention (June 27th, 2019 in Boston, Massachusetts). Sufficient funds should be set aside from any grant provided by HDSA to allow for travel and hotel accommodations.

At the discretion of the HDSA Center of Excellence director and based on availability of the social worker, it is strongly urged that the social worker also attend the two-day HDSA Annual Convention (June 28th-29th, 2019 in Boston, Massachusetts).

All Center Staff

Center staff are encouraged to participate in a minimum of one event (educational) annually.

Long Term Care

HDSA Centers of Excellence must provide in-service training to all appropriate staff at local long-term care (LTC) facilities and assist in identifying placement in LTC facilities for HD patients and families.

Social Support

HDSA Centers of Excellence must provide HD patients and families a connection to HDSA support groups.

The Social Worker is expected to provide education, referrals and assistance to HD families both inside and outside clinic hours.

Indigent Care

Procedures must be in place for providing care to those without insurance or the ability to pay. All sites are required to provide clinical care to persons with HD who may lack health insurance or the ability to pay by either creating a sliding scale that will allow a person to pay some portion of the fee or by setting aside a % of their annual grant from HDSA that does not exceed 5%. If funds are utilized for indigent care, then a detailed report of the number of persons served and their care costs will be required at the time of renewal/re-application.

Collaboration with local HDSA Community

There are many ways in which Centers of Excellence and HDSA chapters, affiliates and regions can support each other. Consistent with the HDSA mission, close relations between Centers and HDSA chapters/affiliates are highly desired.

Some ways that Centers and chapters/affiliates may assist each other include:

- Educational programs for people with HD and their families;
- In-services for local Long Term Care facilities;
- Public dissemination of information about HD and HDSA; and
- Involvement/connection to HDSA support groups.

Other Support and Institutional Commitment

If you receive additional funding for your HDSA Center of Excellence in the form of grants, donations that cover salaries, administrative support and/or space, please provide details in Part 10 of your application.

Funding Plan

Historically, HDSA awards 50% - 90% of the grant requested at time of application. A detailed plan as to how you will support the services outlined in your application should be included in Part 10 of your application.

Partner Site(s)

Those seeking Level 1 designation must provide information in Part 11 about their proposed partner site(s) including clinic personnel, services, frequency, and funding allocation.

TERMS AND CONDITIONS

1. Confidentiality

In connection with an application to be designated as an HDSA Center of Excellence, prospective Centers and HDSA may each provide the other party with financial and other information regarding the disclosing party, including regarding the application and evaluation process. All such information (whether written or oral) provided by either party or any of its affiliated entities or representatives shall be considered "Confidential Information," unless such information is publicly available prior to such disclosure. In consideration of the application process, each of the prospective Centers and HDSA hereby agrees to keep the Confidential Information confidential and use it solely for the purpose of evaluating the application to become a Center of Excellence and

acceptance of such designation (including any related grant), and each party will not disclose any Confidential Information of the other party without the prior written consent of such other party, unless otherwise required by applicable law.

2. Non-Disparagement

Each of the prospective Centers and HDSA (including their respective directors, employees and other representatives) agree not to make any negative comments or otherwise disparage the other party or any of its directors, employees, or other representatives, except with respect to any truthful statements made in response to legal proceedings.

3. Agreement to Terms and Process

Each prospective Center shall be deemed to have agreed to the confidentiality and non-disparagement terms and provisions set forth above automatically in connection with its submission of an application to be designated as an HDSA Center of Excellence. Each prospective Center agrees that HDSA and its directors, advisors and representatives (i) reserve the right, in their sole discretion, to approve or reject any applications; and (ii) shall be free to conduct the application and evaluation process as they in their sole discretion shall determine. Except with respect to a violation of the mutual confidentiality and non-disparagement provisions set forth above, each prospective Center agrees that it shall have no claims whatsoever against HDSA or any of its directors, advisors or representatives arising out of or relating to the application and evaluation process.

4. Right to Revoke Status

In addition to all other remedies available at law or equity, HDSA hereby expressly reserves the right to revoke the status of an HDSA Center of Excellence and/or require repayment of any awards, in each case as determined by HDSA in its sole discretion, in connection with any violation of the confidentiality and non-disparagement provisions set forth above, or in connection with any misuse of award funds or fraud.

The Terms and Conditions document must be signed by an official authorized to sign on behalf of the institution. The prospective Center of Excellence director or co-director are not acceptable signers. Please submit the Terms and Conditions document to your institution upon receipt of the Application Package so there is adequate time to process and return it to HDSA prior to the deadline for submission of your application.