



## HUNTINGTON'S DISEASE SOCIETY OF AMERICA CENTERS OF EXCELLENCE 2018 Program Description

### DATES AND DEADLINES

Online submission of Letter of Interest	<i>due by</i>	September 15, 2017
Invitation to submit application	<i>no later than</i>	September 29, 2017
Completed application for funding	<i>due by</i>	December 1, 2017
Letters of Designation	<i>by</i>	Early February 2018*

### 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 providing 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.

A Level 1 or 2 HDSA Center of Excellence will offer comprehensive diagnostic and therapeutic services with identified staff responsible for most services in each of the following disciplines:

- Neurology
- Psychiatry or neuropsychiatry
- Psychology or neuropsychology
- Genetic counseling and testing utilizing the 2016 HDSA protocol  
For protocol, visit: <http://hdsa.org/wp-content/uploads/2015/02/HDSA-Gen-Testing-Protocol-for-HD.pdf>
- Social services
- Physical therapy
- Occupational therapy
- Speech-Language services
- Nutritional/Dietary
- Directly participate in HD clinical trials

Core personnel at a Level 3 HDSA Center of Excellence will include:

- Neurology
- Psychiatry or psychology
- Social services
- Genetic counseling and testing utilizing the 2016 HDSA protocol (see link to protocol above)
- Serve as a conduit to assist recruitment for existing HD clinical trials.

A Level 3 HDSA Center of Excellence may also offer access to ancillary services such as physical therapy, occupational therapy and speech-language services.

In addition, COEs will have expertise and involvement in the care of institutionalized patients, support groups and opportunities to participate in clinical research. All Level 1 and 2 COEs must be *active* ENROLL-HD sites (see definition of “active” on page 3) and members of the Huntington Study Group.

#### ACCESS TO SERVICES

- For Level 1 and 2 funding, multidisciplinary HD specific clinic held at least one full day per month. For Level 3 funding, a minimum of a half day per month.
- Genetic testing and counseling available by appointment outside of clinic hours to improve access.
- Offer complementary scheduling on campus or in the HD clinic for ancillary services, such as physical therapy, occupational therapy and speech-language services. If not available in clinic or on-campus then services must be referred to therapists with expertise in HD.

- Service triage through a “help line,” social worker, clinic coordinator, nurse, or other identified staff person to ensure timely access to needed services.
- Procedure 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.

#### *EDUCATIONAL MISSION*

- In-service training in care of persons with HD for acute and long-term care units.
- Consults/trains/presents/supervises education in HD for area health/science professionals.
- HD advocacy for general public, public officials and agencies, potential donors, etc.
- Educational services in support of HDSA chapter/regional activities.
- For Levels 1 and 2, the Center Director must attend and actively participate in at least two HDSA sponsored events annually (with at least one being educational). Center staff are encouraged to participate in a minimum of one event (educational) annually.

#### *GENETIC COUNSELING/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 vital service either during clinic, on a separate day or by patient needs. HDSA Centers of Excellence must follow the HDSA guidelines 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.

#### *RESEARCH MISSION*

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 must be *active* ENROLL-HD sites. *Active* is defined as having a signed/executed contract with CHDI Management, Inc. by the application deadline of December 1, 2017.
- All Level 1 and 2 Centers of Excellence must be a credentialed research site of the Huntington Study Group (HSG) by the application deadline of December 1, 2017.
- 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.

#### *ADMINISTRATION*

*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;
- Oversees Center operations; and
- Is responsible for timely and proper reporting.

While it is 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.

*Center Advisory Board:* members include representatives from local HDSA chapter(s) or affiliates and/or community, local business leaders, and the Center director as a non-voting member.

- 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.

*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.

## **ELIGIBILITY CRITERIA FOR AN HDSA CENTER OF EXCELLENCE**

There are **three** granting levels under the HDSA Center of Excellence designation.

1. **Level 3:** Centers that receive Level 3 funding (one year grant of **up to** \$20,000) are clinics that provide a core set of services and support to persons with HD and their families, however these services do not need to be available at the time of application (see below).

Level 3 sites *must*:

- Have a minimum of 25 patients at the time of application.
- Offer HD clinic at least one half day per month.
- Provide their HD patients and families a connection to HDSA support groups.
- Provide in-services to LTC facilities and assist in identifying placement for HD patients/families.
- Provide all of the services as outlined in chart of services below.

2. **Level 2:** Centers that receive Level 2 funding (annual grants of **up to** \$50,000) are institutions that offer comprehensive HD diagnostic and therapeutic services as outlined on pages 2/3 within a specific catchment area as delineated in their application and award.

Level 2 sites must offer all of the services listed for Level 3 *plus*:

- Be a credentialed research site of the Huntington Study Group (HSG) by the application deadline of December 1, 2017.
- Possess an executed contract to become an Enroll-HD site.
- Have a minimum of 75 patients at the time of application
- Offer HD clinic at least one full day per month.
- Provide lay and professional education

3. **Level 1:** Centers that receive Level 1 funding (annual grants of **up to** \$75,000) offer comprehensive HD diagnostic and therapeutic services as outlined on pages 2/3 **and** have established a formal partnership(s) with other HD clinics within a specific region as delineated in their application and award.

Level 1 sites must offer all of the services listed for Level 2 and 3 *plus*:

- Have a partnership with another HD clinic or institution to expand access to HD care
- Have a minimum of 150 patients (not including patients at partner site(s)) at the time of application.

**CENTER OF EXCELLENCE CHART OF SERVICES**

Service	Level 1		Level 2		Level 3		Community Referral
	Clinic	Campus	Clinic	Campus	Clinic	Campus	
<i>Clinic director (HD experience)</i>	x		x		x		
<i>Neurologist(s) (HD experience)</i>	x		x		x		
<i>Psychiatrist (HD experience)</i>	x	x	x	x		x	x
<i>Genetic Counselor/Testing</i>	x		x	x	x	x	
<i>Social Worker</i>	x		x		x	x	
<i>Psychology</i>		x		x		x	x
<i>Neuropsychology</i>		x		x		x	x
<i>PT - initial evaluation</i>	x	x	x	x		x	x
<i>OT - initial evaluation</i>	x	x	x	x		x	x
<i>SLP - initial evaluation</i>	x	x	x	x		x	x
<i>Nutrition/Diet - initial evaluation</i>	x	x	x	x		x	x
<i>HD clinical research</i>	x	x	x	x			x
<i>Nurse</i>	x		x		n/a		
<i>Clinic Coordinator</i>	OPT		OPT		OPT		
<i>Helpline/Triage</i>	x	x	x	x	x	x	
<i>Collaborate w other HD clinics</i>	x	x	x	x	n/a		
<i>Indigent Care</i>	x		x		x		

*Please note:* If you indicated “clinic” for any of the items above, this implies those HD services are available on the same day and located in the same building as the HD clinic. If you indicated “campus”, those HD services are within walking distance or a short drive to the office. Neither clinic nor campus located services should require a separate appointment. “Community referral” suggests that the HD clinic will have to refer the patient to an expert within the local community for a separate appointment. Finally, be prepared to provide information about how the multidisciplinary providers collaborate with one another to ensure optimal continuity of care for patients and caregivers. OPT = optional; n/a = not applicable.

## EXPECTATIONS

### *Level 1 and 2 Centers*

While there is no set formula for how a Level 1 or 2 HDSA Center of Excellence should do its work, there are certain expectations that include:

- An active relationship with the local and national HDSA community.
- An organized multidisciplinary HD clinic held at least one full day per month (or equivalent).
- Clinic medical director or co-director either a Neurologist or Psychiatrist well qualified in the movement disorder field with expertise in HD.
- Minimum patient base (excluding trial/study participants and patients at partner site) of 150 for Level 1 and 75 for Level 2 at time of application with proven record of new patients seeking care annually. Reported patient numbers can include tele-neurology patients (not visits).
- Substantial track record of institutional support for HD or movement disorder clinic prior to award.
- Active involvement in HD specific research. It is mandatory that all Level 1 and 2 HDSA Centers of Excellence be: Active ENROLL-HD site and a credentialed research site of the Huntington Study Group (HSG).
- Collaboration with other HDSA Centers of Excellence.
- Full multidisciplinary team (on site and with ancillary professionals available on HD specific clinic days) including but not limited to:
  - HD knowledgeable neurologist or psychiatrist
  - Ability to provide in clinic or refer to mental health professional
  - Nursing professional
  - Genetic counselor
  - Social Worker
  - Speech-language pathologist
  - Occupational therapist
  - Physical therapist
  - Mental Health Professional:
    - Ability to refer a patient for follow-up mental health needs.
    - If absent from clinic, another team member (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.
  - PT, OT and SLP
    - Desired to have licensed professionals available in clinic or on campus for evaluations and assessments. However, COE may refer to HD experienced therapist outside of Center.
  - Social Worker, Minimum MSW, licensed and HIPAA compliant, available in clinic and with adequate hours after clinic or additional days to follow up on issues raised during HD clinic.
    - Social worker is highly encouraged to attend HDSA Professional Training Day held annually the Thursday prior to the HDSA Annual Convention. 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 (Friday/Saturday).

- Genetic Counselor
  - May be available during clinic or on alternate day(s) that facilitate the counseling/testing process.
  - Follows HDSA genetic testing protocol.

*Level 3 Centers*

For Level 3 funding, there are certain expectations that include:

1. Active relationship with and support from the local and national HDSA community.
2. Organized HD specific clinic at least one half day per month.
3. Clinic medical director or co-director either a Neurologist or Psychiatrist well qualified in the movement disorder field with expertise in HD.
4. Existing HD specific clinic with a minimum of 25 patients (excluding clinical study and trial participants) with a proven record of attracting new patients annually. When designated, the goal of the clinic would be to build a multidisciplinary team as described below.
5. Multidisciplinary team consisting of the following:
  - Neurologist or movement disorder specialist\*
  - Social worker – MSW \*
  - Genetic Counselor
  - Speech language pathologist
  - Occupational therapist
  - Physical therapist
  - Mental health professional

\* Required in clinic.

Other disciplines may be offered on campus or by referral. See chart of services on page 5. Note genetic counseling may be available during clinic or on alternate day(s) that facilitate the counseling/testing process.

**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.

## **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 December 1, 2017. 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.

## GRANT PROCESS

Based upon the qualifications of the online Letter of Interest process, 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/18COELOI](http://www.hdsa.org/18COELOI).

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.

To prepare your site for the application process, the following information is 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, space, frequency, personnel and their roles, 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 section should include information on the partnering entities as well. 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.
- 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 and Center Advisory Board. Provide specific information about your proposed committee and Center Advisory Board, including names and proposed roles where possible.
- G. 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.
- H. 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.
- I. 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?

- J. **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.
- K. **Supporting Material:** Include the following supporting materials – curriculum vitae of core Center personnel, and letters of support from local HDSA Chapters and/or Affiliates. Letter of support from Center Advisory Board is required at renewal only.

## 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 2018. 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. At that point, a letter indicating institutional support will be required. The clinic director will be responsible for ensuring the services listed are available to patients and families. Considering that responsibility, the most appropriate representative from the institution can provide a letter. Examples may include, department chairperson, Dean, etc.

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, 2018. 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](mailto:gyohrling@hdsa.org) or by calling 212-242-1968 x211.