

Program Overview & Requirements

Clinical Center of Excellence (CCE) and Clinical & Research Center of Excellence (CRCE)

The program offers two designations. The Clinical Center of Excellence (CCE) designation recognizes centers that provide cutting-edge, high-quality, multidisciplinary care and conducts PPGL research. The Clinical and Research Center of Excellence (CRCE) designation recognizes centers that provide cutting-edge, high-quality, multidisciplinary care and have a comprehensive PPGL research program. A comprehensive PPGL research program is one that conducts research at the Center or Program level, is multidisciplinary and long-term, and integrates fundamental biomedical R&D with clinical, population-based, and/or community-oriented studies to achieve a specific major objective, such as disease prevention, diagnosis, and treatment. The CRCE program provides an environment in which patients receive the best possible PPGL care through a geographically diverse network of clinical centers led by directors or codirectors who are engaged in research and clinical care, while also mentoring the next generation of clinician-scientists. It is expected that directors and clinician-scientists at both COEs and CRCEs will lead robust research programs with both extramural and intramural funding, publish in prestigious peer-reviewed journals, present research findings at leading national and international conferences, mentor other clinician-scientists, and provide exceptional patient care. In addition to clinical and wellness services, the centers provide professional and lay education in the areas they serve, work with the Pheo Para Alliance in its efforts to empower patients with PPGL, their families, and medical professionals through advocacy, education, and a global community of support, while helping to advance research that accelerates treatments and cures.

Upon reviewing this document, the CCE and CRCE applications are available [here](#).

Program Objectives

1. Increase access to multi-disciplinary, coordinated clinical care for diagnosis, treatment, and follow-up of PPGL patients and their families.
2. Educate newly diagnosed patients and their families.
3. Educate healthcare professionals.
4. Support PPGL research.

Partnership Benefits



The Pheo Para Alliance is the premier organization dedicated to supporting those affected by PPGL. We strive to serve as a beacon of light for those searching for answers and the proper treatment they deserve. Overwhelmingly, patients and caregivers want to know where they can be seen by experts in their area. The Center of Excellence program connects patients with institutions that provide outstanding, up-to-date care.

Approved centers will be recognized in the following ways:

- ✓ Formal announcement released by Pheo Para Alliance.
- ✓ Name recognition and contact information on pheopara.org under the Center of Excellence directory.
- ✓ Joint press release announcing approval of designation.
- ✓ Mass email and social media posts on Twitter, Facebook, and Instagram to announce designation sent to 550+ healthcare providers and 5,000 + patient and caregiver constituents.
- ✓ Use of Pheo Para Alliance Center of Excellence designation seal on website and social media.

General Program Requirements

- Designate a Director/Co-Director & Patient Care Coordinator.
- The Center adheres to the [relevant clinical guidelines](#) as much as possible.
- Attend/Participate in Pheo Para Alliance patient education activities/conferences, as requested.
- Provide patients with Pheo Para Alliance educational material and peer support resources.
- Provide a tour of the center/lab to members of the Board of Directors and other Pheo Para Alliance constituents, as requested.
- Centers must reapply for CCE or CRCE designation every three years.
- Applicant centers may offer some services off-site, such as pediatrics, treatment of metastatic patients, etc. In this case, only the applicant center would receive the designation.
- The applicant center must include the names of collaborative departments and the senior specialist’s information on the application. These specialists should also be available for tumor board meetings, when necessary.

The following outlines the criteria for the CCE and CRCE designations.

Clinical Center of Excellence (CCE) Qualifying Criteria

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
Caseload	>25 new cases per year (including mutation carriers)	Surgical procedures include:

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
	>50 cases in follow-up per year (including mutation carriers) >20 surgical procedures per year	<ul style="list-style-type: none"> • pheo and para surgeries • head and neck para surgeries • Other adrenal surgeries are asked for in the application form.
Diagnosis and Surveillance Procedures (on-site)	<ul style="list-style-type: none"> • 24-hour urine and/or plasma metanephrines • genetic testing • MRI, CT • functional imaging: 18F-FDG PET/CT or 68Ga-DOTATATE /DOTATOC or 64Cu-DOTATATE 	Optional: F-FDOPA
Therapeutic Modalities:	Surgical capability for: <ul style="list-style-type: none"> • open adrenalectomy • minimally invasive adrenalectomy • partial laparoscopic (cortical sparing) adrenalectomy • resection of abdominal/pelvic paraganglioma • resection of head/neck paraganglioma Non-surgical: <ul style="list-style-type: none"> • chemotherapy • PRRT • external beam radiation • stereotactic radiosurgery • referral to institution able to provide treatments not available at applicant institution 	Therapeutic Modalities: Optional <ul style="list-style-type: none"> • radiofrequency ablation • re-operative partial adrenalectomy • emerging off-label treatments
Specialists	The following specialists need to present on site:	The following questions need to be answered

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
	<ul style="list-style-type: none"> • Endocrinologist • Endocrine and other surgeons • Radiologist • Nuclear Medicine specialist • Geneticist • Genetic Counselor • Head and Neck Surgeon • Radiation Oncologist • Pediatric Endocrinologist 	<p>in the application form, (approximations are acceptable, some of this information may be most easily obtained through pathology):</p> <ul style="list-style-type: none"> • How many surgeons are available for pheo surgery? • Who is responsible for para surgery? • How many head/neck surgeons are available? • Who is responsible for presurgical preparation? • Are the following specialists present on site: Vascular Surgeon, Anesthesiologist, Intensive Care Specialist, Oncologist, Cardiologist, Psychology/ Psychiatry, Hypertension Specialist, Nephrologist, Neurosurgeon, Interventional Radiologist, Pathologist, Maternal/ Fetal High-Risk Obstetrics, Palliative Care, Cardiothoracic Surgeon
Clinical Trials	<ul style="list-style-type: none"> • Patients are actively recruited for participation in collaborative diagnostic or therapeutic clinical trials, registries, or translational studies. • Patients are encouraged to take part in patient registries. • The center banks tissue. 	<p>In the application form:</p> <ul style="list-style-type: none"> • Trials need to be specified. • Publications over the last 3 years listed. • Detail regarding participation in clinical research meetings.
Wellness	<p>Patients must:</p> <ul style="list-style-type: none"> • Receive educational information & seminars. 	<p>Optional: patients receive information about nutrition, financial resources and other support services.</p>

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
	<ul style="list-style-type: none"> • Are informed about potential support from social worker. • Have opportunities to participate in survival clinics and support groups. 	
Multi-Disciplinary Review Board (MDRB)	MDRB meetings must be held every 4 weeks in-person or virtually and attended by: <ul style="list-style-type: none"> • Endocrinologist • Endocrine and other surgeons • Radiologist • Nuclear medicine physician 	Optional or ad hoc available: Pathologist, Oncologist, Geneticist, Anesthesiologist, Vascular surgeon, Psychiatrist /Psychologist, Obstetrician
Metastatic Disease	Patients with metastatic disease are treated on-site.	Allowed alternative if patients are referred to an off-site collaborating center: <ul style="list-style-type: none"> • Provide names of collaborating center and specialists who are responsible and indicate how the communication with the center is organized. • The off-site specialist should take part in the MDRB.
Pediatrics	Pediatric patients treated on-site.	Allowed alternative if patients are referred to an off-site collaborating center: <ul style="list-style-type: none"> • Provide names of collaborating center and specialists who are responsible. • Indicate how the communication with the genetics department is organized: the off-site specialist should take part in the MDRB.
Standard Operating Procedures (SOPs)	SOPs available for all health care workers in the	

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
	<p>center which include the names of specialists and/or patient coordinator primarily responsible. All members of team are expected to adhere to SOPs. The required SOPs are:</p> <ul style="list-style-type: none"> • Diagnosis (biochemical testing, imaging, genetics) • Presurgical preparation • Short/long-term follow-up and surveillance 	
Center Coordination/ Administration	<ul style="list-style-type: none"> • Patient Coordinator available and responsible for coordinating patient pathway • Center scheduling and appointment coordination • Protocol available describing the flow, timing and responsibilities for efficient and patient-friendly patient routing through different departments • Timely communication with primary healthcare provider 	
Patient Feedback	<ul style="list-style-type: none"> • The Pheo Para Alliance will seek patient feedback through an online survey shared via PPA communication channels. Patient survey results must be positive overall. 	

Clinical and Research Center of Excellence (CRCE) Qualifying Criteria

CRCE applicants with a comprehensive pheo para research program must meet all criteria outlined for CCE designation in addition to the criteria below.

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
Clinical Studies	≥2 ongoing clinical /translational IRB-approved studies or studies whereby a waiver is issued from the local Ethics Committee.	<p>List the names of studies in which the center is involved and indicate initiating or (co)leading roles for each study (at the time of application).</p> <p>List the field of clinical studies:</p> <ul style="list-style-type: none"> • Natural history • Biochemical diagnosis • Imaging diagnosis • Drug treatment (trials) • Non-drug treatment • Genetics • Outcome • Translational research • Surgical intervention and approach • Other (please specify)
Basic Studies	≥ 2 ongoing or approved basic studies	<p>List the names of studies in which the center is involved and indicate initiating or (co)leading roles for each study (at the time of application).</p> <p>List the field of basic studies:</p> <ul style="list-style-type: none"> • Molecular biology • Immunology: mechanism/treatment • Metabolomics • Preclinical imaging • Experimental animal models • Experimental cell models • Experimental therapies • Others (please specify)
Funding	≥ 2 official grants for clinical or basic studies obtained in the last 5 years or appropriate funding	List funding organizations.

Evaluation Criteria	Qualifying Criteria	Additional Information Requested in Application
	from other resources	
National or International Research Network	Participation in national or international research networks or collaborative studies.	List names of networks or collaborative studies
National or International Registries	Participation in national or international registries.	List names of registries.
Tumor Tissue Bank	Center has a tumor tissue and blood bank that is used for research purposes.	List the names of the tumor tissue bank.
Research Meetings	Regular research meetings in place for basic, translational and Clinical projects.	

Virtual Site Visits

After the application is received and upon recommendation by the Pheo Para Medical Advisory Board, an hour-long discussion with the applicant center will be scheduled via Zoom (may not be relevant for reapplicants who are a current COE, see reapplicant process below). Ideally, the meeting should be attended by the following members of your team: the Director/Co-Director, Care Coordinator, endocrinologist, endocrine surgeon, head and neck surgeon, oncologist, genetic counselor or geneticist, and/or other specialists who are integral to your MDT. Applicant centers are requested to provide a 10-15-minute presentation about their center, which should include specifics about how your team works together, research highlights, surveillance of genetic mutation carriers, the pathway for metastatic patients, coordination with pediatrics, and anything else that is specific to your center that may be worth noting. Pheo Para Alliance attendees will include members of our Medical Advisory Board and patient representatives.

Patient Feedback

Patient Feedback is an important part of the application and reapplication process. Pheo Para Alliance will solicit patient and caregiver feedback via email and social media about care received at the institution. Centers are encouraged to share the survey with patients, but it is not required. For first-time applicants, the MAB requires a certain number of responses to continue the application process, so sharing the survey with your patients can expedite this process. De-identified feedback is shared with the Medical Advisory Board, Board of Directors, and Directors/Co-Directors of the applicant center. Overall, the Medical Advisory Board seeks to identify patterns of deficiencies associated with negative feedback.

Application & Reapplication Process

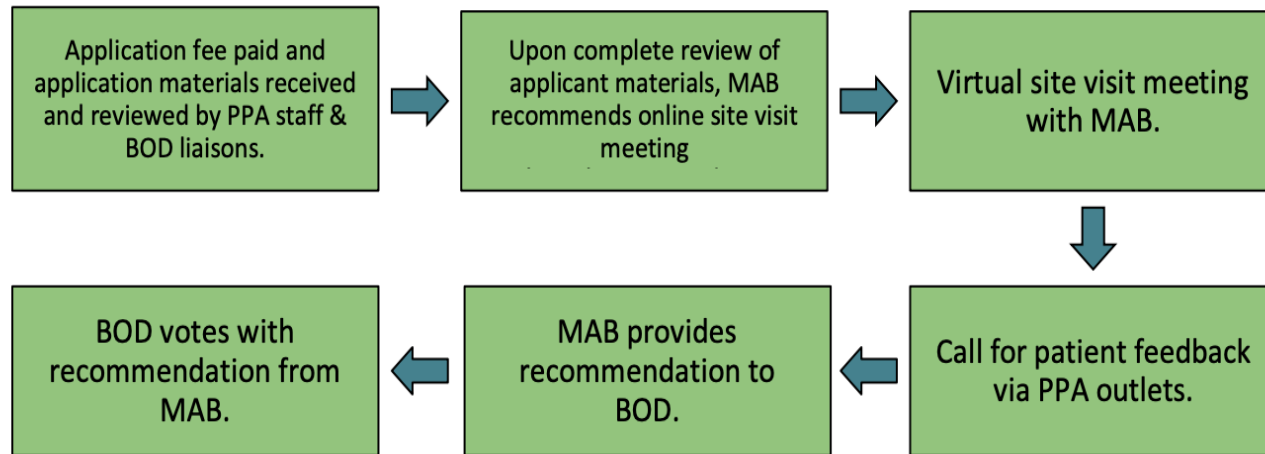
Below is a diagram of the application and reapplication process. Applications are reviewed, and upon recommendation by the Pheo Para Alliance MAB, a site visit via online meeting is scheduled with members of the MAB and the Center Director/Co-Director, Care Coordinator, Patient Ambassador, and Specialists, as identified by the applicant (may not be relevant for reapplicants who currently have a COE designation, see reapplicant process below).

After the online meeting, Pheo Para Alliance will solicit patient and caregiver feedback via email and social media about care received at the institution. The MAB will provide the PPA Board of Directors with a recommendation to approve/deny the designation. In both cases, feedback will be provided to the applicant

institution. Centers must complete a reapplication for CCE or CRCE designation every three years.

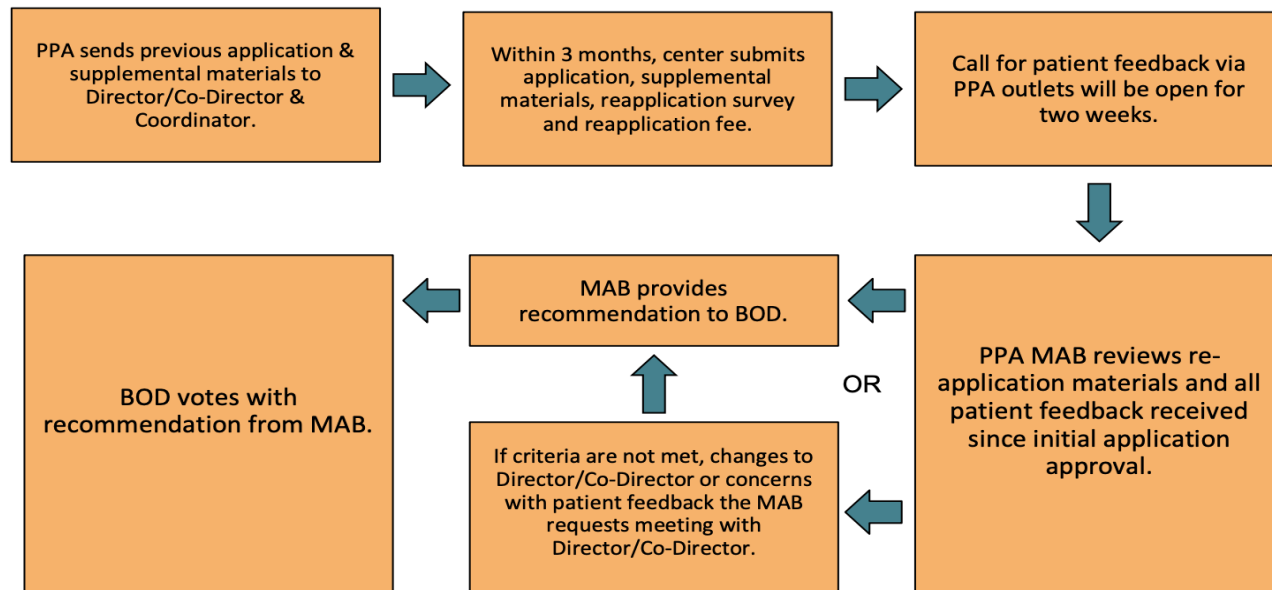
In any year in which an unsatisfactory reapplication is submitted, the Center fails to submit a reapplication within three months after the three-year anniversary of the date of designation, or upon failure to deliver the services or adhere to the requirements of the program, Pheo Para Alliance reserves the right to suspend the designation until identified deficiencies are resolved. If deficiencies are not resolved within 90 days, the designation will be revoked.

First Time Application Process



*includes previously denied applicants.

Reapplication Process



*for centers that currently have a COE designation.

Suggested Roles and Responsibilities

Role	Responsibilities
Director/Co-Director	<ul style="list-style-type: none"> Serves as the sponsoring physician(s) of the program and ensures requirements of the program are met (2 Co-Directors are recommended; one must be a physician). Serves as the point of contact for Pheo Para Alliance staff and MAB. Identifies PPGL team and serves as lead supporting the team in conducting research, clinical care, and scholarly activities. Facilitates communication with a patient care coordinator and specialists to ensure best patient experience and best clinical outcome. Attends the International Pheo Para Conference (in-person or virtual), as requested. PPA sends previous application & supplemental materials to Director/Co-Director & Coordinator. Within 3 months, center submits the application, supplemental materials, reapplication survey and reapplication fee. Call for patient feedback via PPA outlets will

Role	Responsibilities
	<p>be open for two weeks. PPA MAB reviews reapplication materials and all patient feedback received since initial application approval. MAB provides recommendation to BOD. BOD votes with recommendation from MAB. If criteria are not met, changes to Director/Co-Director or concerns with patient feedback the MAB requests meeting with Director/Co-Director. OR pheopara.org / info@pheopara.org / @pheopara</p> <ul style="list-style-type: none"> • Encourages educational opportunities for physicians to learn about the illness. A patient representative can be requested through Pheo Para Alliance. • Presents on pheo/para at physician and/or patient meetings, as requested by Pheo Para Alliance. • Ensures SOPs are available to all healthcare providers and updated as necessary.
Patient Care Coordinator	<ul style="list-style-type: none"> • Serves as the initial point of contact for patients (contact information is listed on pheopara.org and outreach materials). • Serves as a member of the lead team for the program. • Understands the basics of PPGL (does not provide medical advice). • Shares Intro to Pheo Para and Pheo Para Genetics brochures provided by Pheo Para Alliance with newly diagnosed patients and genetic mutation carriers. • Directs patients and families to Pheo Para Alliance resources, as needed. • Ensures diagnostic and specialist appointments are scheduled, and appointments are coordinated for best patient experience. • Monitors patient’s psychosocial needs and assists in finding support close to home. • Ensures patient’s primary care physician receives timely visit reports and diagnostics results. • Provides direction to wellness resources.
Specialist	<ul style="list-style-type: none"> • Serves as department expert on PPGL. • Monitors patient’s psychosocial needs and communicates them to Patient Care Coordinator. • Understands and adheres in general to all Clinical Center of Excellence SOPs. • Participates in multi-disciplinary tumor board meetings, as needed. • Supports the coordination of multiple appointments for best patient experience. • Encourages educational opportunities for physicians to learn about the illness. A patient representative can be requested through Pheo Para Alliance. • Present on pheochromocytoma paraganglioma at physician and/or patient meetings, as

Role	Responsibilities
Patient Ambassador	<p>requested by Pheo Para Alliance.</p> <ul style="list-style-type: none"> • Serves as department expert on PPGL. • Monitors patient’s psychosocial needs and communicates them to Patient Care Coordinator. • Understands and adheres in general to all Clinical Center of Excellence SOPs. • Participates in multi-disciplinary tumor board meetings, as needed. • Supports the coordination of multiple appointments for best patient experience. • Encourages educational opportunities for physicians to learn about the illness. A patient representative can be requested through Pheo Para Alliance. • Present on pheochromocytoma paraganglioma at physician and/or patient meetings, as requested by Pheo Para Alliance.

Should the Director leave the institution, the outgoing Director may designate an internal replacement, or the incoming staff member may serve as the new Director of the Center. Ideally, the specialist with the most PPGL experience should be named Director. If a Co-Director leaves the institution, the remaining Co-Director of the Center will appoint a new Co-Director or serve as the sole Director of the program. Co-Directors are encouraged to ensure the program provides continuity of care and consistently meets program expectations.

If a new staff member is appointed as Director/Co-Director, an introductory call with a Pheo Para Alliance representative is required within 30 days of the appointment to ensure the new appointee complies with the program requirements. In addition, any changes to the Coordinator and Specialists must be communicated to Pheo Para Alliance within 30 days.

Governance Chart

