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, multi-disciplinary care and facilitate PPGL research. The Clinical and Research Center of Excellence (CRCE) designation recognizes centers that provide cutting-edge, high-quality, multi-disciplinary care and have a comprehensive PPGL research program.

The Clinical & Research Center of Excellence program provides an environment where patients receive the best possible PPGL care through a geographically diverse network of clinical centers. 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 pheochromocytoma or paraganglioma, 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 can be found 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 health care 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 to those who are 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 providing outstanding and 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 Center of Excellence directory.
- ✓ Joint press release announcing approval of designation.
- ✓ Mass email and social media post 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 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 names of collaborative departments and senior specialist's information on the application. These specialists should also be available for tumor board meetings, when necessary.

The following outlines the criteria that need to be met for the CCE and CRCE designations.

Clinical Center of Excellence (CCE) Qualifying Criteria

Evaluation Category	Qualifying Criteria ***all* criteria listed below should be met.**	Additional Information Requested in Application
Caseload	• >25 new cases per year (including mutation carriers) • >50 cases in follow-up per year (including mutation carriers) • >20 surgical procedures per year	Surgical procedures include: • 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)	• 24-hour urine and/or plasma metanephrines • genetic testing • MRI, CT • functional imaging: FDG PET/CT or 68Ga-DOTATATE /DOTATOC or 64Cu-DOTATATE	Optional: ^{18}F-DOPA
Therapeutic Modalities:	Surgical capability for: • open adrenalectomy • minimally invasive adrenalectomy • partial laparoscopic (cortical sparing) adrenalectomy • resection of abdominal/pelvic paraganglioma • resection of head/neck paraganglioma Non-surgical: • chemotherapy • PRRT • external beam radiation	Optional: • radiofrequency ablation • re-operative partial adrenalectomy • emerging off-label treatments

	• stereotactic radiosurgery • referral to institution able to provide treatments not available at applicant institution	
Specialists	The following specialists need to present on site: • Endocrinologist • Endocrine and other surgeons • Radiologist • Nuclear Medicine specialist • Geneticist • Genetic Counselor • Head and Neck Surgeon • Radiation Oncologist • Pediatric Endocrinologist	The following questions need to be answered in the application form, (approximations are acceptable, some of this information may be most easily obtained through pathology): • 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	• 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.	In the application form: • Trials need to be specified. • Publications over the last 3 years listed. • Detail regarding participation in clinical research meetings.
Wellness	Patients must: • Receive educational information & seminars. • Are informed about potential support from social worker. • Have opportunities to participate in survival clinics and support groups.	Optional: patients receive information about nutrition, financial resources and other support services.

Multi-Disciplinary Review Board (MDRB)	MDRB meetings must be held every 4 weeks in-person or virtually and attended by: ● 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 treated on-site.	Allowed alternative if patients are referred to an off-site collaborating center: ● 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: ● 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 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: ● Diagnosis (biochemical testing, imaging, genetics) ● Presurgical preparation ● Short/long-term follow-up and surveillance	
Center Coordination/ Administration	● 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	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 Category	**Qualifying Criteria** ***all criteria listed below should be met***	**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.	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). List the field of clinical studies: • Natural history • Biochemical diagnosis • Imaging diagnosis • Drug treatment (trials) • Non-drug treatment • Genetics • Outcome • Translational research • Surgical intervention and approach

		• Others/(specify)
Basic Studies	≥ 2 ongoing or approved basic studies	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). List the field of basic studies: • Molecular biology • Immunology: mechanism/treatment • Metabolomics • Preclinical imaging • Experimental animal models • Experimental cell models • Experimental therapies • Others/ (specify)
Funding	≥ 2 official grants for clinical or basic studies obtained in the last 5 years or appropriate funding from other resources.	List funding organizations.
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.	

Scientific Output	5+ papers over the last 3 years with JIF >5 and/or within Q1 of the Scimago JR or a cumulative IF > 25 over the last 3 years. Impactful papers include: research papers, editorials, reviews, commentaries, case reports (in peer-reviewed journals) and book chapters.	As 1e, 2e, penultimate last or last author.
Scientific Conditions /Environment	Training of persons for: ● Masters degree ● Predoctoral degree ● Postdoctoral degree ● Clinical fellow At least three of four categories required.	List the laboratory where basic studies are performed, platform for small animal imaging and any additional facilities used for research.

Virtual Site Visit

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 that are an integral part of 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.

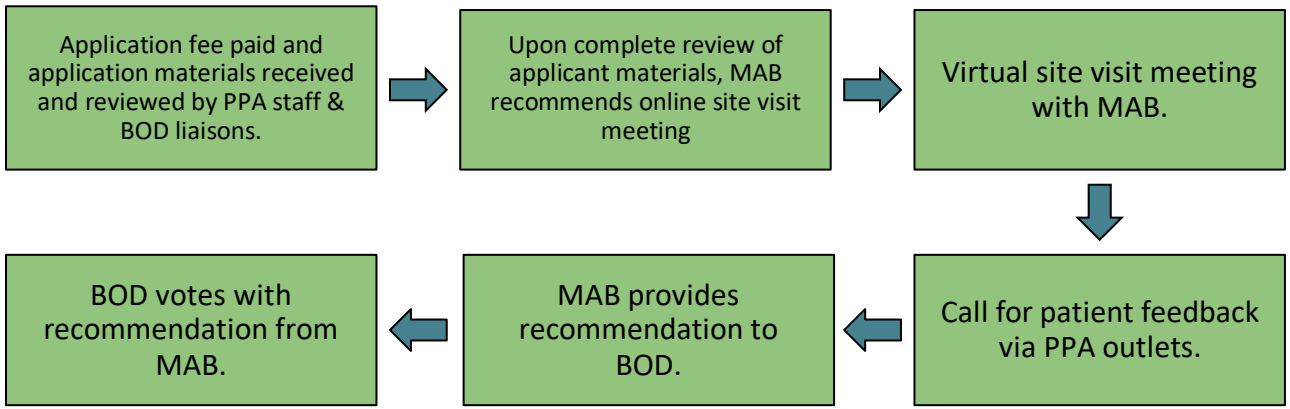
Application & Reapplication Process

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 application for CCE or CRCE designation every three years.

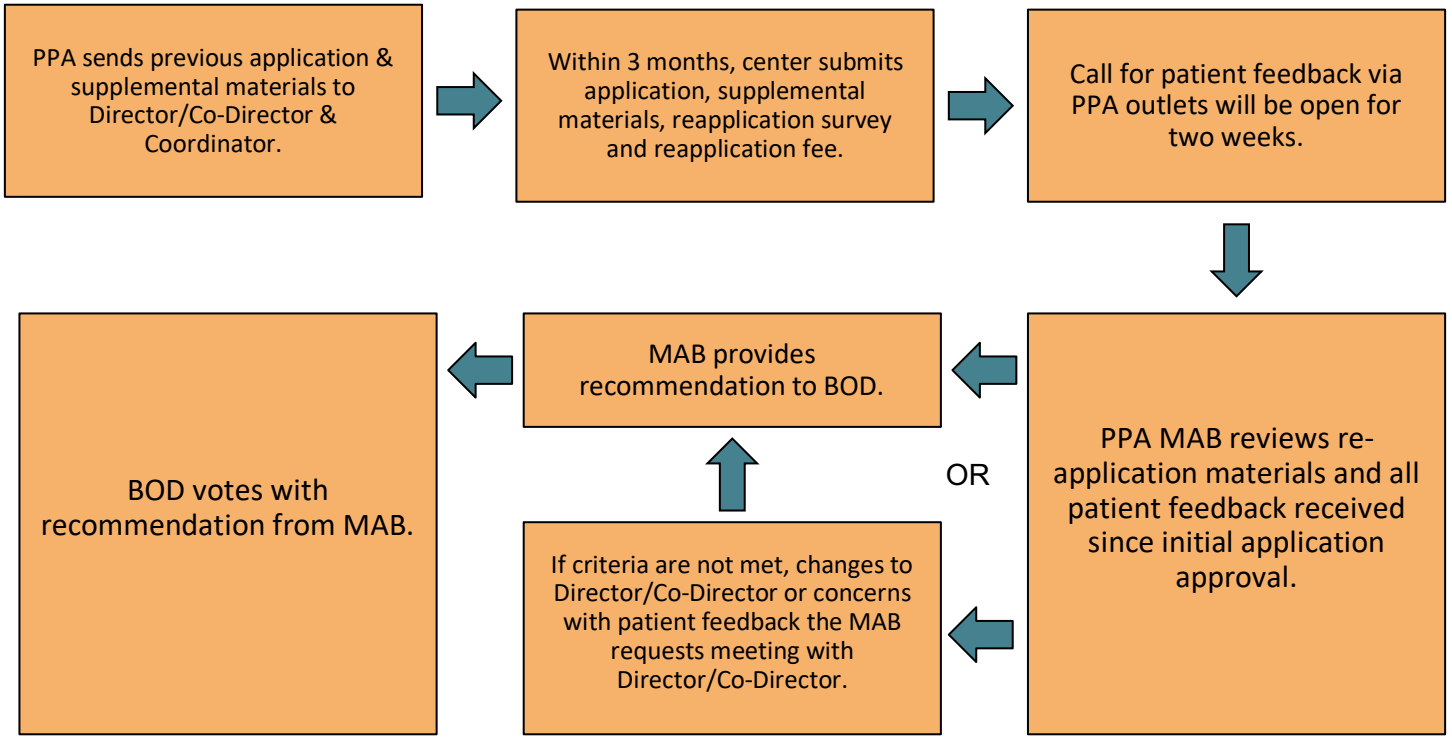
In any year in which an unsatisfactory reapplication is submitted, the Center fails to submit a reapplication within three months after the three-year anniversary of the date of designation, or upon failure to deliver the services or adhere to the requirements of the program, Pheo Para Alliance reserves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

First-Time Application Process*



*includes previously denied applicants.

Reapplication Process*



*for centers that currently have a COE designation.

Roles and Responsibilities

Director/Co-Director

- 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.
- 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.

- 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

- 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

- 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.

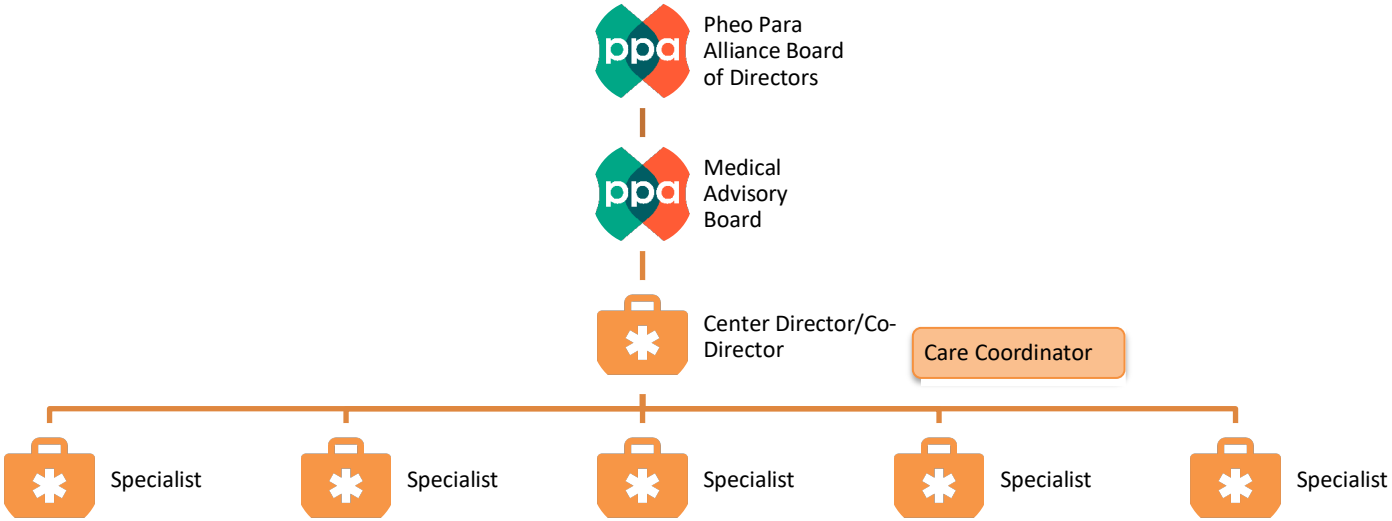
Patient Ambassador (optional)

- Patient/caregiver that serves as local contact for patients at your center.
- Provides peer support and connects patients with other local patients, if requested.
- Provides Pheo Para Alliance and relevant resources to patients, as needed.
- Provides patient testimonials to educate healthcare providers at your center about PPGL.
- Shares feedback received from patients with center to improve patient experience.

If a Director leaves the institution, the outgoing Director can name an internal replacement, or the incoming staff replacement can serve as the new Director of the Center. Ideally, the specialist with the most PPGL experience should be named as Director. If a Co-Director leaves the institution, the other 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 is required with a Pheo Para Alliance representative within 30 days of appointment as Director/Co-Director of the program to ensure the new appointee complies with the program requirements. In addition, changes in Coordinator and Specialists must be communicated with Pheo Para Alliance within 30 days.

Governance Chart



Link to Application