PEDIATRIC EYE DISEASE INVESTIGATOR GROUP (PEDIG)
ORGANIZATIONAL STRUCTURE
Version 8.1 - Effective Date: June 1, 2026

I. Introduction

The organizational structure of the Pediatric Eye Disease Investigator Group (PEDIG) includes the Coordinating Center, the office(s) of the Network Chair(s) and the following: Executive Committee, Operations Committee, Steering Committees, Disease-Area Working Groups, and the Data and Safety Monitoring Committee. Each major protocol is developed by a Protocol Planning Committee and is then administered by a Steering Committee. Investigators, coordinators, examiners, and other research personnel at institutional or private practice-based Clinical Sites participate in PEDIG studies.
Details of the specific role and function of each of these entities are included below.

A. Coordinating Center

The Coordinating Center (CC) for the Pediatric Eye Disease Investigator Group (PEDIG) is the Jaeb Center for Health Research (JCHR) in Tampa.

The CC is responsible for the development and maintenance of the organization of PEDIG and assuring that the policies and procedures defined in the PEDIG policies document and in this organizational structure document are followed.

For each study, staff in the CC have the responsibility for overseeing the development of the protocol, development of operational and analytical methodology, the conduct of each study according to the protocol, and analysis of all data.

The CC serves as an administrative resource for study investigators and coordinators. It is actively involved in facilitating IRB approval and yearly renewals.

Responsibilities of the Coordinating Center include the following:

- Solicit new study ideas from network members and manage non-network submissions.
- Solicit ideas for secondary analyses of PEDIG study data for potential abstracts, presentations, brief reports, or manuscripts.
- Assist Planning Committees with the development of study protocols.
  - Develop study documents such as protocols, informed consent forms, operating procedures manuals, and data collection forms.
- Obtain and maintain INDs and IDEs.
- Maintain version control of all protocols, study documents, publications, presentations, and the like.
- Develop and implement a data management system capable of supporting multiple protocols.
- Develop and maintain a multi-functional private website for use by the CC, clinical centers, reading centers when required, and committee members.
- Submit each protocol to clinicaltrials.gov and update for the duration of the study.
  - Submit final summary of study results upon completion of study.
- Develop and maintain a website for public use.
- Provide datasets of studies for public use as per the guidance on National Institutes of Health's (NIH) policy on the dissemination of NIH funded trials.

- Develop procedures for study participant enrollment and randomization.
- Develop and implement a system for adverse event reporting.
- Develop procedures and materials to implement a quality assurance program that includes training and certification of clinical centers and staff, monitoring of adherence to the protocol, reporting of quality control data, validation of collected data, assessments of imaging reading center(s), and assessment of drug packaging and labeling.
- Assist Steering Committees to coordinate and monitor the conduct of study protocols.
- Coordinate the selection process of new investigators and clinical centers in conjunction with the network Chair(s).
- Develop and maintain a web-based patient tracking system to assist the clinical centers in maintaining a high rate of study participant retention.
- Develop and maintain a system for drug/device distribution and accountability.
- Develop and maintain a system to facilitate communication between the central units, clinical centers, and committees.
- Coordinate site visits, prepare site visit agendas, and prepare site visit reports.
- Develop and maintain a system for collection, review, and reporting of financial disclosures as well as Financial Conflicts of Interests (FCOI) for investigators, coordinators, and other key personnel as defined in the Network's Financial Disclosure policy.
- Develop a system for integration of central laboratories into studies when necessary.
- Develop and oversee implementation of subaward contracts with clinical sites to participate in PEDIG studies.
- Develop contracts with industry collaborators following PEDIG's Industry Collaboration Guidelines.
- Develop materials for IRB submissions by the clinical centers.
- Track IRB approvals and expirations.
- Develop study close-out procedures and materials.
- Develop statistical analysis plans.
- Coordinate the preparation and publication of study manuscripts, including drafting the initial manuscript in conjunction with the lead author/s.
- Coordinate activities and data analyses for the Data and Safety Monitoring Committee.
- Conduct analyses for manuscripts, abstracts, presentations, and ancillary studies.
- Coordinate activities with the Operations Committee, Steering Committees, Executive Committee, Disease-Area Working Groups, and any other committees.
- Arrange meetings, including semi-annual Coordinator/Investigator meetings, semi-annual Executive Committee meetings, semi-annual Data and Safety Monitoring Committee meetings, and PEDIG meetings hosted at national conferences.
- Develop and disseminate agendas and summaries of committee conference calls and meetings.
- Assist with communication with NIH, regulatory agencies, the public, and with industry/foundations.
- Develop study specific budgets in conjunction with the Executive Committee and Steering Committees.
- Develop and maintain directory of study group personnel.

- Develop and coordinate grant submissions and progress reports.
- Develop and coordinate Press releases in conjunction with the National Eye Institute (NEI), Network Chair(s), and Protocol Chair(s).

B. Network Chair(s)

The Network Chair(s) works closely with the CC. Since its inception, PEDIG has been led by either a single Network Chair or two Network Co-chairs.

1. Selection Process

A single Network Chair or two Co-chairs may be appointed for each 5-year NIH grant cycle. In the instance of Co-chairs, ideally there would be one ophthalmologist and one optometrist, assuming strong candidates from each discipline.

Approximately 2 years before the end of the tenure of the Chair or Co-Chairs, a solicitation will be made to PEDIG investigators to nominate individuals for the position of network Chair or Co-chair (an individual may self-nominate). A formal application and review process will be followed and is summarized in a separate operational document. It is expected that the individual(s) will be selected and approved by the National Eye Institute (NEI) approximately 2 years before the end of the 5-year term of the preceding network Chair or Co-Chairs.

The incoming Network Chair(s) will join the Operations Committee (if not already a member) at this time, to serve on the Operations Committee prior to assuming the Network Chair or Network Co-Chair position.

2. Responsibilities of the Network Chair(s) include the following:

- Assume overall scientific responsibility for PEDIG.
- Attend the Weekly Chair call with the Director of the Coordinating Center.
- Chair or Co-Chair the Executive Committee.
- Serve on the Operations Committee as Chair(s) during the active grant cycle and as Vice Chairs in the cycle preceding, when possible.
- Lead investigator conference calls, as needed.
- Lead the semi-annual PEDIG Investigator meetings.
- Lead the PEDIG investigator meetings that may take place at the annual meetings of the American Academy of Optometry, the American Academy of Ophthalmology, and the American Association for Pediatric Ophthalmology and Strabismus.
- Supervise and provide daily support to protocol chairs across multiple simultaneous study protocols (one Co-Chair will be assigned primarily to each active protocol).
- Serve as members on each PEDIG Committee (Steering Committees, Disease-Area Working Group, Protocol Planning Committee, Writing Committee).
- Attend the DSMC meetings as non-voting members.
- Provide direction for future study protocols.
- Review ideas for future protocols and direct the prioritization of ideas for protocol development.
- Oversee the development of assigned study protocols which entails working closely with the Coordinating Center and with the Protocol planning chair(s).

- Work closely with the Coordinating Center and lead author(s) to provide input on all manuscripts, abstracts, and slide sets.
- Work closely with the Coordinating Center to oversee both site monitoring and protocol monitoring, and to develop and maintain quality assurance.
- Conduct site visits as needed.
- Review and approve new PEDIG sites and investigators.
- Communicate with site investigators as needed to resolve issues, encourage enrollment, and discuss other protocol or site-related issues.
- Serve as principal media contact(s) and primary public communicator(s) regarding the Network.
- Serve as principal industry contacts when PEDIG collaborates with industry.
- Lead grant writing and review.

C. Network Vice-chair(s)

The Vice-chair position has a 1-year term after which a Vice-chair may be invited by the Executive Committee to serve a second 1-year term. Vice-chair(s) serve on the Operations Committee (OC). Funding for each Vice-chair will be provided based upon the anticipated percentage effort, and the CC will provide administrative support.

The number and qualifications of the Vice-chair(s) will be determined by the Executive Committee (EC) based on the network's needs and available budget.

1. Selection Process

The OC will recommend to the EC the number and qualifications of Vice-chair(s). Approximately six months before the current Vice-chair(s) term ends, the CC will solicit applications from PEDIG investigators. A formal application and review process will be followed and is summarized in a separate operational document.

Responsibilities of Network Vice-chair(s) include the following:

- Serve as a Protocol Chair or Protocol Co-chair when possible.
- Serve as a member of the Operations Committee.
- Serve as a member of the Executive Committee.
- Lead Disease-Area Working Group, as necessary.
- Provide leadership at PEDIG investigator meetings (shared with Network Chair(s).
- Provide leadership at PEDIG coordinator meetings (shared with Network Chair(s).
- Lead the monthly investigator conference calls, as necessary.
- Lead quarterly New Investigator conference calls.

D. Leadership Development Fellows

The Leadership Development Fellowship position is a 1-year, unpaid term. The purpose of the program is to provide valuable experiences for future leaders in pediatric eye research by exposing them to Executive, Planning, Steering, and Writing Committees.

1. Selection Process

The Coordinating Center will solicit for applications for the Leadership Development Program in

late Summer. The Operations Committee will select from the applicants for the upcoming year. Two to four LDP Fellows will be selected, and if possible, will include at least one optometrist and one ophthalmologist. Preference will be given to investigators who have enrolled participants into PEDIG studies but have not yet held PEDIG leadership positions.

Responsibilities of Leadership Development Fellows may include the following:

- Attend monthly Executive Committee calls and at least one in-person meeting.
- Attend a DSMC meeting.
- Attend a Quality Control meeting.
- Attend the Meet & Greet between New Investigators & the Executive Committee the day prior to the Winter Study Group Meeting.
- May be given the opportunity to serve on a protocol Planning Committee, Steering Committee, Working Group, or Writing Committee.

E. Executive Committee

The Executive Committee consists of the following standing members: all members of the Operations Committee (see Section below), an expert in childhood vision assessment, a representative of the National Eye Institute, and rotating members from the network including investigators and at least one coordinator.

The Executive Committee is chaired by the Network Chair(s). The committee has regularly scheduled meetings and conference calls and convenes any time an issue requires its attention.

1. Membership

The rotating positions on the Executive Committee are filled by ophthalmologists, optometrists, and a site coordinator, all appointed for 24-month terms. Rotating members are selected by the Executive Committee. An investigator or coordinator from a site on probation is not eligible for nomination to the Executive Committee. If a site is put on probation, any investigators or coordinators serving on the Executive Committee may be asked to resign.

Responsibilities of the Executive Committee include the following:

- Primary responsibility for the scientific oversight of PEDIG.
- Oversight of the Network budget.
- Develop requirements for investigators to be members of PEDIG.
- Review and approve new PEDIG sites and investigators for applications not meeting established PEDIG requirements for which the Network Chair(s) believes that special consideration should be given.
- Review site performance issues brought by the Operations Committee, including sites and/or site personnel for which probation or dismissal from the network is being considered.
- Select Network Chair(s) and Vice-Chairs.
- Prioritize studies for protocol development.
- Define Disease Area Working Groups as needed for each future study cycle.
- Approve Protocol Chairs as recommended by the Operations Committee.
- Review and approve all protocols, including protocol budgets, and any budgetary

increases of $25,000 or more, or greater than 20% of the study budget, after initial approval.
  - Any budgetary increases of $25,000 or less, or of less than 20% of the study budget, are reviewed and approved by the Operations Committee.
  - After initial approval of a protocol by the Executive Committee, the Steering Committee reviews and approves any subsequent changes to a protocol.
  - At the discretion of the Network Chair(s), any changes to a protocol can be re-reviewed for approval by the Executive Committee.
- Review and approve all ancillary studies that utilize network resources.
- Apply the PEDIG editorial policy as outlined in the Policies document.

2. Voting of the Executive Committee

A quorum of 2/3 of voting members must be in attendance to complete a vote. For example, if there are 16 voting members, 11 members must be present. Voting by email prior to the meeting is allowed as long as 2/3 of voting members are in attendance for the meeting.

A simple majority of voting members is required for a motion to pass. For example, if there are 16 voting members, 9 constitute the majority. If a majority is reached, no action is needed by the voting members who are not in attendance. If a majority is not reached, voting members who were not on the call will be asked to review the motion and supporting materials and submit their vote by email within 10 days.

If the submitter of a new protocol is an Executive Committee member, they may participate in the presentation, discussion, and vote.

F. Operations Committee

The Operations Committee oversees the day-to-day activities of the entire network. The Operations Committee will meet weekly via conference call, and face-to-face meetings will be scheduled as required.

1. Membership

Members of the Operations Committee include the Network Chair(s), the most recent past Network Chair(s), the Network Vice-chair(s), the Coordinating Center Director, Past Director, and Research Operations Manager.

Additional ad hoc members may be appointed by the Operations Committee as needed.

Responsibilities of the Operations Committee include the following:

- Select Protocol Planning Committee, if indicated, for each protocol to be developed.
- Propose a Protocol Chair for the protocol development phase, if indicated, to the Executive Committee.
- Oversee Active Protocols.
- Select Steering Committee members.
- Select Disease-Area Working Group members.
- Select Leadership Development Fellows.

- Manuscripts:
  - Prioritize manuscripts to be written, including review of manuscript ideas submitted by network members.
  - Select the writing committee for each manuscript.
  - Review and approve presentations/dissemination of study results
  - Determine professional meetings at which study results should be presented and develop general plans for publicizing PEDIG results.
- Serve as the PEDIG Quality Control Committee to develop and maintain a program of quality assurance across all studies.
  - Monitor the performance of participating sites.
  - Identify sites with excessive protocol deviations and/or quality issues to be reviewed by the Executive Committee.
- Review and approval of new sites and investigators
- Each member of the Operations Committee is a member of the Executive Committee.

G. Disease-Area Working Groups

The Executive Committee may create and define Disease-Area Working Groups based upon the type of future study ideas received each cycle. Each Working Group will be led by a Network Chair, a past Network Chair, or a Network Vice-chair.

1. Selection Process

Members will be invited from within the Study Group to serve a 1-year rotational term and will be selected by the Executive Committee from those who apply. Working Groups may also include outside experts nominated by the Executive Committee to provide specific expertise in a disease area.

Responsibilities of the Disease Area Working Groups include the following:

- Assist investigators with developing new study ideas that have been submitted, solicit new study ideas as needed, and/or combine study ideas when there is overlap.
- Review and coordinate which new study ideas need additional preparatory work or pilot studies prior to, or after, presentation to the Study Group at future meetings.
- Consider ways future study proposals can be combined if related.
- Make recommendations to the Executive Committee about which new study ideas will be presented at the annual Study Group meeting.

H. Protocol Chairs

Each protocol will have a designated Chair or co-Chairs. The Protocol Chair(s) will focus on the scientific aspects of a protocol. During protocol development, the Protocol Planning Chair will work with CC staff and Network Chair(s) to develop the protocol.

1. Selection Process

Each Protocol Chair will be proposed by the Operations Committee and approved by the Executive Committee. The Protocol Planning Chair(s) and the Protocol Chair(s) will often be the same people. The Executive Committee will appoint the Protocol Chair(s).

Responsibilities of Protocol Chairs include the following:

- Develop the protocol and other documents including procedures manual if needed, certification checklist, data collection forms, protocol cards, and IRB documents with CC staff and Network Chair(s)
- Present study updates at large-group meetings when needed
- Conduct protocol certification calls with the investigators at protocol initiation and at critical points during implementation (e.g., when a site conducts its first masked exam).
- Prompt recruitment by contacting sites for the duration of the study.
- Respond to queries from clinical sites regarding the protocol.
- Propose necessary modifications to the protocol, as needed. Quality control aspects will be the responsibility of the Operations Committee.
- Provide study updates at study group meetings.
- Chair the writing committee for the primary manuscript from the study and provide the initial public presentation of the main outcomes.

I. Protocol Planning Committee

A Protocol Planning Committee will be appointed for a protocol prioritized for development by the Executive Committee, as needed.

1. Selection Process

Members of the Protocol Planning Committee are selected by the Operations Committee. Each Planning Committee will be comprised of a Protocol Planning Chair or Chairs, the Network Chair(s), and one or more other investigators from the study group. One or more LDP Fellows, and, as needed, one or more coordinators may be added. The appointment of some committee members may require specific subcontracts (to be approved by the Operations Committee) for technical expertise, outcome measure development, and pilot testing of materials and methods.

Responsibilities of Protocol Planning Committee include the following:

- Development of the final protocol, informed consent form, data forms, study procedures, and other study materials.
- Development of requirements for coordinators, investigators, and any other required personnel to be certified for the protocol.
- Pilot testing of study forms and procedures prior to start of participant recruitment or use in the study.

J. Steering Committees

A Steering Committee oversees the day-to-day running of active protocols. One Steering Committee may oversee multiple protocols. A Steering Committee convenes by conference call monthly and additionally as needed. Whereas the Executive Committee is responsible for issues related to PEDIG in general, Steering Committees are responsible for issues specific to one or more particular protocols.

1. Selection Process

Members of each Steering Committee are appointed by the Operations Committee, and will include the Network Chair(s), members of the Executive Committee, Protocol Chairs, and other

investigators and site coordinators on a rotational basis (for an 18-month term). One or more LDP Fellows may be asked to join a Steering Committee.

In general, Protocol Chairs will serve on the appropriate Steering Committee while their respective protocol is active. Protocol Chairs will rotate off the Steering Committee after the study is complete unless their term is extended by vote of the Operations Committee.

Responsibilities of the Steering Committee include the following:

- Consider changes or modifications to the protocol as necessary or desirable.
- Advise and assist the Coordinating Center on operational matters pertaining to the protocol implementation and adherence.
- Review and approve abstracts and manuscripts for each protocol in collaboration with the Operations Committee.

K. Writing Committees

The Writing Committee for each abstract, presentation, or publication will be defined by the Operations Committee. The selection process is outlined in the separate PEDIG Policies document.

Responsibilities of the Writing Committee include the following:

- Draft an abstract, presentation, or a brief report/manuscript for submission to a meeting or journal as determined by the Operations Committee in a timely manner.
- Review and approval of any post submission modifications in a timely manner.

L. Data and Safety Monitoring Committee (DSMC)

The Data and Safety Monitoring Committee (DSMC) is responsible for reviewing the ethical conduct of a study and for monitoring data for evidence of adverse or beneficial treatment effects. Results are not available to participating investigators who are treating or examining patients until the DSMC recommends releasing this information. The DSMC is responsible for all randomized trials and is kept abreast of, but is not responsible for, unfunded data collections.

A separate Standard Operating Procedures document contains more details about DSMC functions.

1. Selection Process

The members of the DSMC will be selected by the National Eye Institute (NEI), which will also select one member to serve as the Chair. The Committee will include individuals with expertise in clinical trials, biostatistics, and pediatric eye conditions, as well as a layperson. The NEI Project Officer will be considered an ex officio non-voting member.

Responsibilities of the DSMC include the following:

- Prior to the initiation of recruitment for a study, the DSMC reviews and approves the study protocol, including the informed consent procedure and form.
- Periodically review study progress (at least twice each year, either at a meeting or a conference call). Both efficacy and safety are reviewed at these meetings.
- Decisions made by this Committee regarding the protection of participant rights and/or

resulting from data analysis are forwarded to the NEI and, if indicated, to the Steering Committee. The Committee determines specific plans for evaluating adverse effects and efficacy, including stopping rules for each protocol.

- Reviewing the ethical conduct of a study and monitoring of data for evidence of adverse or beneficial treatment effects.

M. Clinical Sites

Institutional or private practice-based entities may participate in PEDIG as a clinical site, provided the site has at least one individual who meets the criteria to be an investigator and a coordinator as defined in the Investigator Section below.

One investigator at the site must be designated as the principal investigator who will be responsible for PEDIG activities at the site as detailed in the Primary Investigator section below.

A participating site must also have at least one individual who meets criteria to be designated a primary site coordinator as defined in the coordinator section below.

1. Investigators

a. Full Investigator

Full Investigator status is open to all who meet the following qualifications:

- Pediatric ophthalmologists who have completed a pediatric ophthalmology fellowship or have comparable clinical experience (1-year of full-time pediatric eye care or 2 years at 50%) and whose practice is at least 40% pediatric eye care and/or strabismus.
- Pediatric optometrists who have completed a pediatric optometry residency or have comparable clinical experience (1-year of full-time pediatric eye care or 2 years at 50%) and whose practice is at least 40% pediatric eye care and/or strabismus.
- Other clinicians with the necessary expertise, as required by a particular protocol, as suggested by the Planning Committee to the Executive Committee.

Each Investigator will be reviewed and approved by a Network Co-Chair prior to joining PEDIG. Specific requirements may exist for an investigator to participate in a particular protocol. For all protocols, Investigators are required to have active medical licensure in the state where they see PEDIG protocol participants (see B4 below). A PEDIG Investigator can elect to participate in any or all studies for which they meet the certification requirements. Investigators may be required to participate in at least one study to maintain Active membership.

b. Associate Investigator

An individual who works with a PEDIG Investigator (with Full Investigator status) and who does not meet the criteria listed above for Full Investigator can apply to be an Associate Investigator.

An Associate Investigator can participate in protocols under the supervision of a Full Investigator. An Associate Investigator cannot independently enroll or randomize

participants, although they can screen patients, obtain informed consent as determined by the JCHR IRB, perform the examination that is used for enrollment or randomization, and perform follow-up exams. An Investigator with full Investigator status (i.e., not an Associate Investigator), must assume responsibility for verifying eligibility and ensure that the Associate Investigator follows the study protocol.

Associate Investigators may petition the PEDIG Executive Committee to enroll participants for one or more protocols or the Executive Committee may decide that any Associate Investigator may enroll for a particular protocol.

A PEDIG site cannot be active with only Associate Investigator(s) except in exceptional situations approved by the Executive Committee.

Specific requirements may exist for an Associate Investigator to participate in each protocol. An Associate Investigator can elect to participate in any or all studies for which they meet the certification requirements. Associate Investigators may be required to participate in at least one study to maintain Active membership.

An Associate Investigator can apply for a change in status if they should meet the criteria to become a full Investigator.

If an Associate Investigator does not meet the criteria to become a Full Investigator, they can apply for Full Investigator status after two years of participation in PEDIG after satisfying alternative criteria specified below.

- The Associate Investigator must submit to the Executive Committee a summary of involvement in PEDIG studies.
- They should also demonstrate a consistent and active role in at least one study.

c. Principal Investigator

Each clinical site that is approved to participate in the Pediatric Eye Disease Investigator Group (PEDIG) will have one individual designated as the Principal Investigator (PI) of the site. The PI has ultimate responsibility for PEDIG activities at that site.

Responsibilities of the Principal Investigator include the following:

- Have a thorough understanding of the PEDIG policies, protocol designs, and study methods.
- Ensure that local institutional requirements (if applicable) are satisfied, and that approvals and assurances are obtained annually.
- Ensure that the required PEDIG-certified staff, facilities, and equipment are available to meet PEDIG responsibilities.
- Provide adequate support and guidance to site investigators, coordinators, and other staff so that the PEDIG studies can be conducted according to protocol.
- Respond promptly to requests from the Coordinating Center, the Network or Protocol Chair’s Office or the National Eye Institute.

- Correspond and maintain accessibility via email and phone with a PEDIG protocol monitor.
- Oversee local PEDIG documentation and records.
- Conduct periodic meetings of PEDIG personnel at the site.
- Cooperate with PEDIG protocol monitors by working with the site coordinator to make available PEDIG personnel, PEDIG records and protocol binders, clinic charts for PEDIG study participants, and other necessary records needed for on-site clinic monitoring.
- Notify the Coordinating Center if any protocol adherence or data reporting problem is discovered or suspected.
- Attend scheduled PEDIG meetings and conference calls, including those for any PEDIG committees to which appointed.
- Review the site report card evaluating clinical site performance and to discuss with the local PEDIG personnel any areas identified to be deficient.

In addition to the above, the PI is obligated to notify JCHR in writing within 30 days of them becoming aware of any investigator or other personnel at their site who experiences any of the following:

- Loss of, suspension, or sanctions to their professional license.
- Debarment, suspension, exclusion, or otherwise declared ineligible to participate in research by any entity.
- Involuntary loss or suspension of any hospital / institutional privileges.

The Operations Committee, as the Quality Control Committee, will review any notifications and pertinent additional information to determine what action(s), if any, are necessary.

d. Coordinators

The study coordinator plays a critical role in the conduct of PEDIG-sponsored studies in ensuring the integrity of the research data. Together with the Principal Investigator, the coordinator ensures that participants receive appropriate consent, subjects meet all eligibility criteria, study protocols are followed correctly, study procedures are completed accurately, and data is entered accurately on the PEDIG website. These responsibilities require detailed and complete knowledge of each protocol and complete familiarity with the informed consent process and data collection procedures.

All sites must have a designated study coordinator responsible for the duties mentioned above as well as responsible for communications with the Coordinating Center. Orthoptists, technicians, health care personnel, and administrative support personnel may serve as study coordinators. There may be additional, institution-specific requirements to serve in this role. Coordinators will be responsible for some elements of testing consistent with their skills, completing forms, managing edits, obtain informed consent as determined by the JCHR IRB, and maintaining contact with participants and the Coordinating Center to facilitate their investigators' participation in studies. They are recognized in the published list of study center personnel as Coordinators in PEDIG

publications.

Ideally, a back-up coordinator should be available to fill in for the primary coordinator if the primary coordinator is unavailable. An investigator may act as a study coordinator with prior approval.

e. Clinical Testers

Any individual (e.g., orthoptists, technicians, optometrists, ophthalmologists, and administrative personnel) may serve as a clinical tester once certified by the Coordinating Center. There may be specific qualification requirements for specific tests (e.g., only an ophthalmologist, optometrist, certified orthoptist, or certified COMT may perform alignment testing). Such requirements are determined by the Protocol Development Committee and approved by the Executive Committee as part of the protocol approval process. Clinical testers are listed in the published PEDIG study center personnel list.