### Children’s Healthcare of Atlanta: Clinical Research Staff

*The Children’s Healthcare of Atlanta Clinical Research Staff Support Model* was developed more than 15 years ago to provide the research operational needs for Principal Investigators conducting research within Children’s. The core of highly qualified and trained clinical research coordinators, nurses, assistants, and interns are managed by 5 Clinical Research Managers located on each campus: Egleston, Scottish Rite/Hughes Spalding, Center for Advanced Pediatrics, Marcus Autism Center, and within our AFLAC Cancer Center’s CRO. These managers oversee a team of more than 100 clinical research professionals who partner with more than 150 Principal Investigators across our many subspecialties. While several have set study teams, there is also opportunity for Investigators to utilize the experienced pool of research coordinators on an as-needed basis. To facilitate acute access to research staff, Children’s implemented an expedited position approval process for extramurally funded positions in 2019. Research projects can be serviced immediately by clinical research campus managers while permanent staff is hired and onboarded, if needed. Research staff are specifically trained by the Children’s Clinical Research Department’s dedicated Research Educator in collaboration with their campus Manager to conduct all research activities according to federal regulations, institutional policies and procedures, and ICH/GCP guidelines. Study specific training is completed by sponsor resources or the Principal Investigator and documented accordingly in the study’s education log.

Clinical Research Support Training and Development: Children’s Clinical Research Department provides consistent, cross-campus onboarding, training, and on-going development to all our clinical research staff.  Research relevant training and career development activities include but not limited to:

·        For Emory-IRB approved studies:  Mandatory, live--“Introduction to Clinical Research at Emory for Coordinators and Nurses”.

·        Mandatory Children’s computer-based training--“Children’s Research Process Training” completed at hire and annually.

·        Completion of Children’s Research Department’s Orientation Checklist within 90 days of hire with Manager confirmation signature.

·        CITI Program human subject’s protection training every 3 years, including GCP.

·        Mandatory in-person Children’s Research Administration Orientation within first month of hire.  Presenters include representatives from the IRB, Research Compliance, and Research Finance.

·        Individualized coordinator/nurse training with the Research Educator on items such as informed consent training and review of internal audit findings identified by Children’s Compliance Department during routine reviews.

·        Children’s Research Mentorship Program with annual mentor/mentee pairings.

·        Quarterly clinical research department staff meetings where new policies, procedures, or regulation changes are reviewed.

·        Monthly research educational seminars offered on campus and on-line, such as:  Pediatric Research “K-Cub” Meeting Series, Research Resources 101, Coordinator Meetings, Emory Department of Pediatrics’ Grand Rounds and Pediatric Research Seminars.

·        Study-specific research conferences, SoCRA and/or ACRP Research Conferences, and the Southeastern Pediatric Research Conference held annually.

Clinical Research Support Resources: The clinical research support team has access to all Children’s and Emory subject matter experts in the following areas: IRB, Research Compliance, Research Education, OSP, ORA, Research Leadership, and any Children’s Clinical ancillary or professional partners for queries and on-going training needs.  All Children’s and Emory Institutional policies and procedures are readily accessible via Children’s and Emory intranets.  Additionally, helpful tools such as study start-up, close-out, and project transfer checklists, forms and templates for regulatory documents, and past research training sessions and webinars are also posted for easy access.