# Diego Aguilar

Miami FL, 33166 (786) 201-3099 Diego.aguilar003@gmail.com

**SUMMARY STATEMENT**

Experienced Research Engineer with expertise in clinical trial planning and development, study site management, multi-site coordination, IRB compliance and reporting, and HIPAA and GCP compliance. Highly proficient in device design, 3D modeling, rapid prototyping, and project management software. Strong leadership and mentorship skills with a proven track record of successfully training and supervising research personnel.

**EXPERIENCE**

Institute for Integrative and Innovative Research (I3R) Remote

**Clinical Trial Support Engineer** December 2021 to Present

- Designed and implemented the development plan of a longitudinal clinical study for a Class III medical device.
- Advised and supported Principal Investigators serving as point of contact for guidance and problem-solving in regard to Trial Master Records, Protocol, ICFs, CFRs, and SOPs.
- Reported study timelines, progress on deliverables, and clinical study management (CTM) data to study sponsor.
- Trained research personnel in regulatory affairs, CTM, data collection & participant management.
- Facilitated the successful submission of DOD & NIH Grant applications, securing funds for the expansion of research operations including additional research sites and increased capacity for study participants.
- Supervised the IRB approval & reporting of all research sites, including protocol amendments and site initiations.
- Authored SOPs, including IRB submissions, Trial Master Records management, recruiting, and data sharing between Sponsor and research sites, creating a reliable workflow.

Adaptive Neural Systems Laboratory Miami, FL

**Research Staff Engineer (Dual position, primary role)** August 2017 to December 2021

- Designed, manufactured, and tested Class I medical devices for a clinical study, aimed at assessing hand dexterity in upper limb prosthetic users. Produced, verified, and validated 4 devices which were successfully implemented to collect data from for over 75 experimental sessions.
- Created device assembly models and engineering drawings using Solidworks to document design history, run motion and mechanical simulations, and to ensure that design-for-manufacture requirements were met.
- Led project management during the prototyping and manufacture of 7 device designs, and supported numerous technology developments while training, mentoring, and supervising 8 research assistants during 4 engineering projects.
- Coordinated project goals, milestones, and timelines within a cross-functional team during technology development, data collection, data management, and reporting, promoting timely completion of milestones and successful outcomes.
- Balanced the roles of Research Engineer and Clinical Coordination, in a multidisciplinary team that relied on self-initiation and decision autonomy of its members.

Adaptive Neural Systems Laboratory Miami, FL

**Clinical Research Coordinator (Dual position, secondary role)** August 2017 to December 2021

- Conducted the clinical study under the FDA-IDE of a Class III medical device for the restoration of neurosensory function in a multi-disciplinary team. This study was featured on PBS/Netflix's "Human: the world within" (episode 6, min 37).
- Monitored the progress of a 2-year clinical trial while ensuring compliance with GCP and 21 CFR 812 Subparts E and G.
- Managed engagement with participants, external collaborators, and vendors to promote recruitment, ensure compliance to timelines, manage escalations, provide guidance, and advise decision-making from leadership.
- Authored templates & managed of over 100 types of clinical trial records including Trial Master Files, ICFs, logs, technical forms, HIPAA-covered material, data collection forms, data analysis reports, SOPs, manuals for procedures/devices.
- Tracked participant progress from first contact through study completion assessing risks, deviations, and adverse events.
- Authored and submitted reportable events, annual site reviews, and amendments to the IRB of record and other reviewers as established by IRB Authorization Agreements, with priority on thoroughness and timeliness.
- Lead the migration of data collection and trial mgt. from paper instruments to an Electronic Data Capture platform (CFR 21 Part 11 compliant), minimizing human error and enabling remote access to data collection for all research sites.

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## PROFICIENCIES

**Technical:**
- 3D Modeling & Sym.
- Rapid Prototyping
- Zoho & REDCap project management
- Technical document authoring

**Clinical:**
- Clinical Trial Planning & Development
- Study site management
- Multi-site coordination
- IRB compliance & reporting
- HIPAA & GCP compliance

**Communications:**
- English & Spanish fluent
- French, & Portuguese intermediate

## Leadership/Other Roles

**Professional Activities:** Presented research findings at 8 scientific events including academic research fairs, and the National Amputee Coalition Conferences and educational presentations to Hangar Clinic support groups.
**Mentorship:** Supervised 8 research interns in a pre-baccalaureate summer program. Taught over 100 undergraduate students in mathematics and science courses.

## EDUCATION

***Master of Science Biomedical Engineering*** Miami, FL
FLORIDA INTERNATIONAL UNIVERSITY Aug 2019 - May 2021

***Bachelor of Science Biomedical Engineering*** Miami, FL
FLORIDA INTERNATIONAL UNIVERSITY *Aug 2013* - May 2017

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