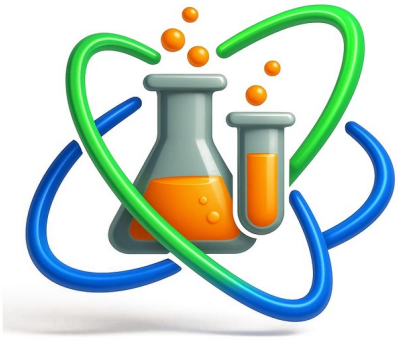

RHO RESEARCH CLINIC, LLC

CLINICAL TRIALS · RESEARCH · INNOVATION

SPONSOR SITE PROFILE

Hialeah, Florida · Miami-Dade County

Nephrology · Cardiometabolic · CNS and Psychiatry · Ophthalmology · Vaccines and Infectious Disease

Profile data period	Q3 2026, refreshed quarterly
Last validated	To be entered by site at release
Next scheduled review	To be entered by site at release
Version	v1.0, draft for site completion and internal review

3810 W 12th Avenue, Hialeah, FL 33012 · 786-637-6928 · info@rhorc.com · www.rhorc.com

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1. Site identification and routing	Who do I contact for what, and is this profile current
2. Positioning	In one paragraph, why should I read further
3. Investigator experience	Who will run my study, and what have they actually done
4. Key person risk closure	What happens to my study if one investigator becomes unavailable
5. Patient population and recruitment	Where do the participants come from, and how many are there
6. Therapeutic area depth	Do they understand my indication
7. Facility and operational capability	Can they execute my protocol without external dependencies
8. Cycle times and performance	How fast will they activate, and will they hit the plan
9. Diversity and representativeness	Can they help me meet my Diversity Action Plan targets
10. Regulatory, quality, technology	Are they ready for inspection and using modern tools
Appendix A. Completion checklist	What the site still needs to supply before release

SECTION 1

Site identification and routing

Legal entity	RHO Research Clinic, LLC
Site type	Independent, investigator led, single location clinical research site
Primary address	3810 W 12th Avenue, Hialeah, FL 33012, United States
Main telephone	786-637-6928
Facsimile	305-400-0445
General email	info@rhorc.com
Website	www.rhorc.com
Catchment	Miami-Dade County primary, Broward and Palm Beach Counties secondary
Operating languages	English and Spanish, fully bilingual across every study facing role

Role based routing

Sponsors and CROs should route by function rather than to a general inbox. Each function below has a named owner and a response commitment.

FUNCTION	NAMED CONTACT	EMAIL	RESPONSE COMMITMENT
Feasibility and confidentiality agreements	Olga Varona, Site Manager and Regulatory	ovarona@rhorc.com	48 to 72 hours for full feasibility response
Regulatory and IRB submissions	Olga Varona, Site Manager and Regulatory	ovarona@rhorc.com	5 business days from protocol finalization
Business, contracts and budget	Ray Roque, Chief Executive Officer	rroque@rhorc.com	2 to 4 weeks
Nephrology and infectious disease, PI/Sub-I	Pablo E. Puello Diaz, MD	ppuello@rhorc.com	24 to 72 hours
CNS, psychiatry and NeuroAIDS, PI/Sub-I	Hector Rodriguez, MD, MDiv	hrodriguez@rhorc.com	24 to 72 hours
Ophthalmology, PI/Sub-I	Abel Cabrera, MD	To be confirmed by site	24 to 72 hours
General enquiries	Site office	info@rhorc.com	Same business day acknowledgement

SITE TO COMPLETE

Supply the direct email address for Dr. Cabrera, and add any additional named contacts the site wants routed separately. Sponsors read a blank contact line as an unmanaged function.

Documents available at confidentiality agreement stage

The following are held in current form and are released on execution of a confidentiality agreement, with no preparation lag.

- Mutual confidentiality agreement template
- IRS Form W-9
- Certificate of insurance, including professional and general liability
- Investigator curriculum vitae in sponsor format or TransCelerate abbreviated format, with current medical licenses
- Good Clinical Practice training certificates for all delegated staff
- Site rate card and standard budget assumptions
- Financial disclosure workflow for each investigator, prepared under 21 CFR Part 54

SITE TO COMPLETE

Confirm which of the documents listed above are held in current form today, and note any that require preparation time. A sponsor who is told a document is ready and then waits two weeks for it discounts every other claim in this profile.

SECTION 2

Positioning

RHO Research Clinic reduces enrollment and retention risk in nephrology, cardiometabolic, central nervous system, ophthalmology, and vaccine studies through five credentialed investigators who bring documented Phase I to Phase IV protocol experience from prior research sites, a fully bilingual research team embedded in a Hialeah catchment that is 95.1 percent Hispanic or Latino and 20.3 percent aged 65 and over, and a quality framework aligned to ICH E6 with an internal Quality Assurance function, no FDA Form 483 observations, and no Warning Letters on record.

Three things follow from that statement, and each is evidenced in the sections below.

ONE · THE INVESTIGATOR BENCH IS THE ASSET

RHO Research is a young site with an experienced investigator bench. That distinction matters, and the profile does not blur it. The site itself is building its own performance record. The investigators are not. Between them they carry more than fifty industry protocols of documented Phase I to Phase IV experience as Principal Investigator or Sub-Investigator, spanning vaccines, respiratory, dermatology, gastroenterology, cardiometabolic disease, nephrology, rheumatology, ophthalmology, and central nervous system indications. A sponsor placing a first study at RHO is buying investigator experience that is already proven, supported by site infrastructure that is new but complete.

TWO · THE POPULATION IS THE DIFFERENTIATOR, NOT THE VOLUME

A patient database of approximately 3,000 active and archived records is a modest number in isolation. Segmented, it is not. The catchment is one of the most concentrated Hispanic and Latino populations in the United States, with an above average share of residents aged 65 and over. For sponsors carrying Diversity Action Plan commitments under the Food and Drug Omnibus Reform Act, this is operational capability rather than demographic reporting, because consent, study procedures, and retention contact all occur in the participant preferred language by default rather than by accommodation.

THREE · SPEED IS DOCUMENTED, NOT ASSERTED

Full activation is committed at under 30 days from protocol finalization, built from named component commitments rather than a single headline number. Section 8 states each component, and Appendix A asks the site to attach the evidence that supports it.

WHAT CHANGED IN THIS EDITION

Dr. Abel Cabrera, MD, joined RHO Research Clinic as Principal Investigator in June 2026. He is a fellowship trained cornea, refractive surgery, and external disease specialist, and his appointment opens ophthalmology as a fifth anchor therapeutic area for the site.

This edition also brings Dr. Lorely Mendez, Dr. Diana C. Limon, Dr. Pablo E. Puello Diaz, and Dr. Hector Rodriguez into a single investigator section with sourced protocol history, replaces unsegmented capability claims with segmented ones, and adds a key person risk closure section and a completion checklist.

SECTION 3

Investigator experience

For a site at this stage, investigator experience is the first asset a sponsor evaluates, not the second. This section is therefore written as an evidence stack rather than as a curriculum vitae summary. Each investigator entry states what they are credentialed to do, what they have actually done under protocol, and which of this site's therapeutic areas they anchor.

Investigator bench at a glance

INVESTIGATOR	SPECIALTY AND ANCHOR AREA	ROLE AT RHO	AT RHO SINCE
Abel Cabrera, MD	Ophthalmology. Cornea, refractive and external disease, retina and glaucoma protocols	Principal Investigator	June 2026
Pablo E. Puello Diaz, MD	Nephrology and internal medicine. CKD, AKI, hypertension, cardiometabolic	Principal Investigator	January 2026
Lorely Mendez, MD	Pediatrics and general practice. Vaccines, respiratory, dermatology, gastroenterology	Principal Investigator	August 2025
Diana C. Limon, MD	Family medicine. Cardiometabolic, dermatology, rheumatology, gastroenterology	Principal Investigator	July 2025
Hector Rodriguez, MD, MDiv	Psychiatry and neuroimaging. CNS, mood and anxiety disorders, NeuroAIDS	Principal Investigator and psychiatric consultant	June 2025

SITE TO COMPLETE

State the percentage of professional time each investigator commits to research at RHO Research, and the maximum number of concurrent studies each will accept. The capabilities page currently states 50 percent research effort for Dr. Puello and Dr. Rodriguez. Sponsors verify this figure at the prestudy site visit and treat an unstated commitment as an unmanaged one.

Abel Cabrera, MD · Ophthalmology

NEW APPOINTMENT, JUNE 2026

Fellowship trained cornea, refractive surgery, and external disease specialist. Dr. Cabrera brings anterior segment subspecialty depth together with protocol level experience across the four ophthalmic areas that carry the largest industry study volume: ocular surface and corneal disease, diabetic retinopathy and diabetic macular edema, glaucoma and intraocular pressure, and age related macular degeneration.

CREDENTIALS

Florida medical license	ME150663
National Provider Identifier	1780066670
Fellowship	Cornea, Refractive Surgery and External Disease, University of Florida, Gainesville, 2021 to 2022. AUPO and ACGME accredited
Residency	Ophthalmology, University of Puerto Rico School of Medicine, 2018 to 2021. ACGME accredited
Earlier training	Fellowship in Anterior Segment and Refractive Surgery, Institute of Ophthalmology of Havana, 2007 to 2008. Residency in Ophthalmology, Cuban Institute of Ophthalmology, 2003 to 2006. Residency in Family Medicine, Cuba, 2000 to 2003
Medical degree	Higher Institute of Medical Science of Havana, 1994 to 2000. Graduated with High Honors, Golden Seal
GCP training	CITI Program, Good Clinical Practice, compliant with ICH E6(R2)
Additional certification	Basic Life Support and Advanced Cardiac Life Support, active. IATA dangerous goods and biological specimen handling
Societies	American Academy of Ophthalmology. International Society of Refractive Surgery of the AAO. Cuban Society of Ophthalmology

PROTOCOL EXPERIENCE BY OPHTHALMIC AREA

All entries below are Sub-Investigator experience on Phase II to Phase IV industry protocols unless otherwise stated. Dr. Cabrera serves as Principal Investigator at RHO Research from June 2026.

AREA	PROTOCOL EXPERIENCE	PROTOCOL ASSESSMENTS PERFORMED
Cornea, external disease and ocular surface	Topical anti-inflammatory formulations, biologic therapies, and surgical interventions in corneal ectasia, dry eye disease, keratoconjunctivitis, and infectious keratitis	Slit lamp biomicroscopy, corneal topography and tomography, specular microscopy, pachymetry, fluorescein and lissamine green staining scoring
Diabetic retinopathy and diabetic macular edema	Anti-VEGF therapies, sustained release intravitreal implants, and combination protocols in NPDR, PDR and DME	Dilated fundus examination, ETDRS visual acuity, OCT and OCT angiography review, fluorescein angiography interpretation, retinal vascular change grading
Glaucoma and intraocular pressure	Phase II and Phase III multicenter studies of novel IOP lowering topical agents, sustained release delivery systems, and minimally invasive glaucoma surgery devices	Goldmann applanation tonometry diurnal curves, gonioscopy, optic nerve head evaluation, Humphrey visual field analysis, OCT retinal nerve fiber layer measurement

AREA	PROTOCOL EXPERIENCE	PROTOCOL ASSESSMENTS PERFORMED
Age related macular degeneration	Neovascular and geographic atrophy AMD, including next generation anti-VEGF agents and complement pathway inhibitors	ETDRS best corrected visual acuity, spectral domain OCT, fundus autofluorescence, structured adverse event reporting and follow up compliance

SURGICAL AND CLINICAL DEPTH RELEVANT TO PROTOCOL CONDUCT

- Penetrating keratoplasty, DSEK and DMEK partial corneal keratoplasty, and reconstructive ocular surface surgery
- Phakic intraocular lens placement, Ferrara intrastromal corneal ring implantation, and LASIK, LASEK and PRK corneal refractive surgery
- High volume cataract surgery experience, including a mission period performing 30 to 45 cataract procedures per week
- Instructor for residents in ocular surface disease and cataract technique, Cuban Institute of Ophthalmology, 2006 to 2010
- Current clinical practice in Hialeah and Miami as cornea, cataract and refractive surgeon since July 2022, including The Selem Center, Miami, from January 2024

WHY THIS APPOINTMENT CHANGES THE SITE'S MARKET POSITION

Ophthalmic studies are among the most equipment dependent and reader dependent in the industry. Sponsors do not place them with sites that lack a subspecialist who can perform and defend protocol specified assessments. Dr. Cabrera closes that gap on the investigator side.

The remaining question is imaging infrastructure, and it is addressed directly in Section 7 rather than left for a prestudy site visit to discover.

Pablo E. Puello Diaz, MD · Nephrology and internal medicine

Board certified internal medicine physician and fellowship trained nephrologist. Dr. Puello anchors the renal and cardiometabolic areas and holds the site's only currently enrolling study.

Florida medical license	ME143430, expires 31 January 2028
Board certification	Internal Medicine, American Board of Internal Medicine, certified 27 August 2018, certificate 388545
Fellowship	Nephrology, Cleveland Clinic Florida, Weston campus, 2018 to 2020
Residency	Internal Medicine, San Juan City Hospital, Puerto Rico, 2015 to 2018. Chief position during internship, Hospital Del Maestro, 2014 to 2015
Medical degree	University of Health Sciences Antigua School of Medicine, 2013. Bachelor of Science in General Biology, Universidad Metropolitana Ana G. Mendez, 2009
Subspecialty training	Peritoneal Dialysis University, USF Health and International Society for Peritoneal Dialysis, 2019. Columbia Renal Biopsy Course, Vagelos College of Physicians and Surgeons, 2019. CRRT Academy and Home Dialysis Academy, University of Alabama, 2018 and 2019

GCP training	Good Clinical Practice, NIDA Clinical Trials Network six hour certified course, completed 26 September 2025, valid to 26 September 2028
Societies	American Society of Nephrology, member 584292. American College of Physicians, member 03008027
Declared trial phases	Phase I, Phase II, Phase III and Phase IV, per TransCelerate abbreviated curriculum vitae dated 1 January 2026

CONCURRENT CLINICAL PRACTICE, AND WHY IT MATTERS FOR RECRUITMENT

Dr. Puello is President, Founder and Medical Director of South Florida Renal Care, LLC, which delivers nephrology and dialysis care in nursing homes and assisted living facilities across South and North Florida, and is a physician with Florida Kidney Care, covering Cleveland Clinic Indian River Hospital and Sebastian River Medical Center. He serves as Medical Director of Dialysis at Sebastian Fresenius Kidney Care and South Florida Dialysis Center.

For a renal study this is a recruitment channel rather than a biography line. It represents standing clinical access to dialysis and advanced chronic kidney disease populations that most competing sites reach only through referral.

SITE TO COMPLETE

Quantify the referral channel. Approximately how many patients with stage 3 to stage 5 chronic kidney disease, and how many patients on dialysis, are under Dr. Puello's care across South Florida Renal Care and Florida Kidney Care, and what proportion are within a reasonable travel distance of the Hialeah site. State the source of the figure and the date it was pulled. A segmented, sourced number here is worth more to a sponsor than any other sentence in this profile.

PROTOCOL AND RESEARCH HISTORY

THERAPEUTIC AREA	TYPE	PHASE	STATUS
Acute kidney injury related to vancomycin	Industry	III	Completed
Arthroplasty and risk for hemodialysis	Industry	III	Completed
Chronic kidney disease	Industry	IIa	Completed
Hypertension	Industry	II	Completed
Hypertension and cardiovascular disease	Industry	III	Completed
Diabetes and cardiomyopathy	Industry	II	Completed
Breast cancer hormonal therapy	Industry	II to IV	Completed

THERAPEUTIC AREA	TYPE	PHASE	STATUS
Vaccine development for Chagas disease, Trypanosoma cruzi	Industry	III	Completed

Investigator initiated and academic research includes acute kidney injury related to vancomycin spacer toxicity in arthroplasty and its risk for hemodialysis at Cleveland Clinic Florida, Weston, and biomedical research in Chagas disease vaccine development at the University of Texas at El Paso.

Lorely Mendez, MD · Pediatrics and general practice

Dr. Mendez holds the deepest documented industry protocol record on the RHO bench. Her curriculum vitae lists more than fifty industry protocols as Principal Investigator or Sub-Investigator across vaccines, respiratory disease, dermatology, gastroenterology, cardiometabolic disease, rheumatology, nephrology and central nervous system indications, in both pediatric and adult populations.

Residency	Pediatrics, San Juan City Hospital, Puerto Rico, 2007 to 2010. Internship, Ramon Ruiz Arnau Hospital, Puerto Rico, 2006 to 2007
Earlier training	Pediatric residency, Jose L. Miranda Hospital, Santa Clara, Cuba, 1990 to 1993
Medical degree	Institute of Medical Science of Villa Clara, Cuba, 1984 to 1990
Licensure examination	USMLE Steps 1, 2 and 3 complete
Clinical practice	Approximately fifteen years of primary care and pediatric practice in Hialeah and Miami-Dade, including Community Medical Group of Hialeah, La Colonia Medical Center, Sanitas Medical Center Doral, Conviva Medical Center, and Mendez J Medical Office. Civil Surgeon designation

PROTOCOL EXPERIENCE BY THERAPEUTIC AREA

AREA	REPRESENTATIVE PROTOCOL EXPERIENCE
Vaccines and immunization	Phase III adjuvanted quadrivalent subunit influenza vaccine versus non-adjuvanted comparator in children 6 to 72 months. Phase 2b meningococcal ABCWY vaccine schedules versus meningococcal group B vaccine in healthy adolescents
Respiratory	Pediatric and adult persistent asthma studies of fluticasone propionate, fluticasone and salmeterol combinations, and beclomethasone dipropionate by breath actuated and metered dose inhaler. Phase III benralizumab in moderate to very severe COPD, GALATHEA. Phase III astegolimab in COPD. Phase III brensocatib in non-cystic fibrosis bronchiectasis, ASPEN
Ear, nose and throat, pediatric	Principal Investigator on ciprofloxacin and dexamethasone otic suspension versus CIPRODEX in acute bacterial otitis media in children with tympanostomy tubes. Principal Investigator on antimicrobial efficacy in young children with acute otitis media. Phase III topical benzocaine for otitis media pain in children 5 to 12 years
Dermatology	Phase III povorcitinib in nonsegmental vitiligo. Phase 2b rezpegaldesleukin in moderate to severe atopic dermatitis. Serlopitant for pruritus in prurigo nodularis, NCT03677401. Plaque psoriasis, acne vulgaris, actinic keratosis, and adrenal suppression safety studies with topical corticosteroid sprays

AREA	REPRESENTATIVE PROTOCOL EXPERIENCE
Gastroenterology	Plecanatide in chronic idiopathic constipation and in IBS with constipation, including long term safety extensions. Linaclotide 290 microgram Phase III with randomized withdrawal in IBS-C. Lubiprostone bioequivalence versus AMITIZA. SYN-010 Phase 2b and 3 in IBS-C
Cardiometabolic and hepatology	Insulin and type 2 diabetes studies, hypercholesterolemia titration studies, abdominal obesity Phase II with open label extension. Phase III cenicriviroc for liver fibrosis in nonalcoholic steatohepatitis. First in human Phase I single and multiple ascending dose study in presumptive NAFLD
Nephrology and rheumatology	Event driven Phase III study of progression of kidney disease in type 2 diabetes with diabetic kidney disease. Phase II dose ranging BMS-986142 in moderate to severe rheumatoid arthritis. Phase II GS-5718 proof of concept in active rheumatoid arthritis
Central nervous system	Phase III digital therapeutic CT-155 as an adjunct to standard of care antipsychotic therapy in experiential negative symptoms of schizophrenia, in adult and late adolescent participants

SITE TO COMPLETE

Dr. Mendez's protocol list is the single strongest recruitment argument on this bench, and it is currently undated. For the ten most recent protocols, supply the sponsor or CRO, the year, the role held, the enrollment target at that site and the number actually randomized. A sponsor who can see a hit rate will treat the whole list as verified. A sponsor who cannot will discount it as a reading list.

Diana C. Limon, MD · Family medicine

Board certified family medicine physician with hospitalist and urgent care practice across Miami-Dade and the Florida Keys, and Sub-Investigator experience on industry protocols from six named sponsors.

Licensure	Florida medical license. Board certification in Family Medicine. DEA registration
Residency	Family Medicine, Larkin Community Hospital, Palm Springs Campus, 2020 to 2023. Chief Resident
Medical degree	Avalon University School of Medicine. Bachelor of Science in Medicine, University of St. Eustatius. Bachelor of Arts in Latin American Studies with a Biology minor, University of California, San Diego
Certification	ACLS, BLS and PALS provider. ALSO provider trained
Fellowship	Summer Fellowship in Hyperbaric Medicine, Sint Eustatius School of Medicine, 2008
Concurrent practice	Hospitalist, HHA, Miami, from July 2024. Family Medicine Physician and Chief Medical Officer, Islamorada Medical Center, from July 2023. Physician, Jackson Health System, 2024
Languages	English and Spanish fluent. French basic

EDC and EHR systems	Cerner, Medhost, NextGen, eClinicalWorks, Athenahealth, Practice Fusion

SUB-INVESTIGATOR PROTOCOL EXPERIENCE BY SPONSOR

SPONSOR	INDICATION
Eli Lilly and Company	Type 2 diabetes mellitus with obesity
Eli Lilly and Company	Individualized treatment approach in older patients with type 2 diabetes mellitus
AstraZeneca	Type 2 diabetes mellitus with inadequate glycemic control on basal insulin glargine
Ironwood Pharmaceuticals	Chronic idiopathic constipation
Novartis	Pimecrolimus cream 1 percent with topical corticosteroid in severe atopic dermatitis, patients aged 2 to 12 years
Boehringer Ingelheim	Moderately to severely active rheumatoid arthritis

A VERIFICATION ADVANTAGE WORTH NAMING

Six named sponsors across the bench means six independent verification paths. CROs cross-verify site claims through portal history, TransCelerate Shared Investigator Platform records, prior confidentiality agreement relationships, and reference calls. Named sponsors survive that check. Unnamed protocol counts do not.

Hector Rodriguez, MD, MDiv · Psychiatry and neuroimaging

Psychiatrist, published researcher, and neuroimaging specialist. Dr. Rodriguez anchors the central nervous system area and the site's NeuroAIDS and HIV neurology capability, which is an uncommon subspecialty combination in a community research setting and is directly relevant to a catchment with meaningful HIV prevalence.

Training	Resident Physician and Chief Resident, Larkin Community Hospital, July 2018 to June 2022
Clinical appointments	Founder and Psychiatrist, White Butterfly Clinic, from June 2025, directing psychiatric, neuroimaging and brain health services for a concierge wellness center focused on trauma and performance psychiatry. Psychiatrist, Amen Clinic, July 2022 to May 2025
Specialist capability	SPECT neuroimaging for diagnostic and research use in complex psychiatric and neurological presentations. Comprehensive psychiatric evaluation, treatment planning and management
Research focus	Neurobiological correlates of trauma, depression and anxiety disorders. HIV associated neurocognitive disorders
Additional qualification	Master of Divinity, with background in both medical and theological study

PEER REVIEWED PUBLICATION RECORD

PUBLICATION	VENUE AND YEAR	ROLE
NeuroAIDS, Comorbid Mood Disorders and Neuropsychiatric Effects of Antiretroviral Therapy	Global Virology IV, Springer, 2024	Principal Investigator and co-author
Gene Therapy Blueprints for NeuroAIDS	Global Virology II, HIV and NeuroAIDS, Springer, 2017	Co-author
Neuronal Apoptotic Pathways in HIV-Associated Dementia, Alzheimer's Disease, Parkinson's Disease and Huntington's Disease	Global Virology II, Springer, 2017	Co-author
HIV-1 Envelope Accessible Surface and Polarity Across Clade, Blood and Brain	Bioinformation, 2014. PMCID PMC3958261	Research contributor and co-author
Gene Expression for HIV-Associated Dementia and HIV Encephalitis in Microdissected Neurons	Neurobehavioral HIV Medicine, Taylor and Francis, 2011. DOI 10.2147/NBHIV.S13566	Research contributor and co-author
Gene Chromosomal Organization and Expression in Cultured Human Neurons Exposed to Cocaine and HIV-1 Proteins gp120 and tat	Frontiers in Bioscience, 2006. DOI 10.2741/1922. PMID 16368555	Research contributor and co-author

SITE TO COMPLETE

Confirm Dr. Rodriguez's Florida medical license number and expiration date, board certification status in psychiatry with the certifying board and date, ECFMG certification, and the provider and date of his current Good Clinical Practice training. These four items are checked on every CNS feasibility submission and a gap here will stop an otherwise strong package.

SITE TO COMPLETE

State whether the SPECT neuroimaging capability described above is available to RHO Research participants, and if so, under what arrangement, at which location, and on what turnaround. If it is available it is a genuine differentiator for CNS protocols with imaging substudies. If it is not, it should not appear in sponsor facing materials.

SECTION 4

Key person risk closure

Sponsors evaluating an investigator led site with a short site level track record ask a specific and reasonable question: what happens to my study if the investigator who won it becomes unavailable. Sites that leave this question unanswered are assessed as carrying unmanaged key person risk. This section answers it directly.

Structural coverage

RHO Research operates with five credentialed Principal Investigators rather than one, and the therapeutic areas overlap deliberately. No anchor area depends on a single individual for coverage of routine protocol conduct.

THERAPEUTIC AREA	PRIMARY INVESTIGATOR	SECONDARY COVERAGE	COVERAGE ASSESSMENT
Nephrology and renal	Puello	Limon, Mendez for general medical oversight	Subspecialty depth is single investigator. See risk note below
Cardiometabolic and diabetes	Puello	Limon, Mendez	Three investigators with documented protocol experience
CNS and psychiatry	Rodriguez	Mendez for schizophrenia adjunct protocol experience	Subspecialty depth is single investigator. See risk note below
Ophthalmology	Cabrera	None at present	Single investigator. See risk note below
Vaccines and infectious disease	Mendez	Puello, Limon	Three investigators, strongest coverage on the bench
Respiratory	Mendez	Limon	Two investigators
Dermatology	Mendez	Limon	Two investigators, both with sponsor named protocol history
Gastroenterology	Mendez	Limon	Two investigators, both with sponsor named protocol history

Where single investigator dependency exists, and how it is managed

Nephrology, central nervous system, and ophthalmology each currently depend on one subspecialist. RHO Research states this rather than obscuring it, and manages it through four mechanisms.

- **Delegation depth.** Two Foreign Medical Graduates provide physician level clinical oversight of participant management and a Florida licensed Registered Nurse covers protocol procedures, so routine visit conduct does not stop if a Principal Investigator is absent for a period.
- **Cross-coverage designation.** Every study delegation log names a Sub-Investigator authorized to conduct eligibility review, safety assessment and participant management in the Principal Investigator’s absence, from the bench above.
- **Documented handover standard.** Investigator transition, including notification to the sponsor and the IRB, updated Form FDA 1572, and re-delegation, is covered by standard operating procedure rather than improvised.

- **Institutional continuity.** Regulatory, source documentation, monitoring interface and study coordination sit with the site management function under Olga Varona and four research coordinators, independent of any single investigator.

SITE TO COMPLETE

Name the designated cross-covering Sub-Investigator for each of the three single dependency areas, and confirm whether the investigator transition standard operating procedure exists in current signed form. If it does not yet exist, this is the highest value single document the site can add before the next feasibility submission.

HOW TO USE THIS SECTION IN A FEASIBILITY RESPONSE

When a sponsor asks about site continuity, do not answer with reassurance. Answer with the coverage table, the four mechanisms, and the named cross-cover for the relevant area. A site that has already thought about its own failure modes reads as lower risk than one that has not been asked yet.

SECTION 5

Patient population and recruitment

The most common failure in a site profile is a large database number reported without segmentation, methodology, or eligibility forecasting. Sponsors discount an unsegmented number instantly, because it signals that the site does not understand its own population. This section reports what is currently sourced, and marks precisely what remains to be segmented.

Population at a glance

METRIC	FIGURE	SOURCE
Active and archived patient records	Approximately 3,000	Site electronic health record
Retention across completed studies	90 percent or higher	Site reported. Evidence to be attached, see Appendix A
Hialeah city population	230,968 as of 1 July 2025	U.S. Census Bureau QuickFacts, Hialeah city, Florida
Hialeah Hispanic or Latino share	95.1 percent	U.S. Census Bureau QuickFacts, Hialeah city, Florida
Hialeah residents aged 65 and over	20.3 percent	U.S. Census Bureau QuickFacts, Hialeah city, Florida
Regional catchment	Miami-Dade primary, Broward and Palm Beach secondary	Site reported

WHY THE CENSUS FIGURES BELONG IN THIS PROFILE

A sponsor carrying a Diversity Action Plan commitment for a cardiometabolic, renal or ophthalmic study is looking for sites that can deliver Hispanic and Latino enrollment without a targeted outreach budget. A catchment that is 95.1 percent Hispanic or Latino, with one in five residents aged 65 and over, delivers both that subgroup and the age band that carries the highest prevalence of chronic kidney disease, type 2 diabetes, glaucoma and age related macular degeneration.

This is a public, verifiable, independently sourced figure. It carries more weight in a feasibility review than any site reported claim, and it costs the site nothing to substantiate.

Documented condition concentrations

The following conditions are named on the site capabilities page as concentrated within the patient database. Counts are not yet segmented.

- Chronic kidney disease
- Type 2 diabetes mellitus
- Hypertension, including resistant hypertension
- Obesity
- HIV and AIDS

SITE TO COMPLETE

Segment the database. For each of the five conditions above, and for the ophthalmic conditions now in scope, state the number of patients in the electronic health record who meet the condition, the electronic health record query used, and the date the query was run. Then state a defensible eligibility forecast: of that number, approximately how many would be expected to meet typical inclusion criteria and consent. Approximate numbers with a stated method outperform exact numbers that read as invented.

SITE TO COMPLETE

Describe the recruitment channels in operation, and the volume each produces. Cover electronic health record pre-screening, referral relationships with named practices or physician groups, community outreach, database re-contact, and any advertising. Name the referring organizations where you have a genuine relationship. Named referral relationships in the therapeutic area are among the most persuasive items a profile can carry.

SITE TO COMPLETE

State the ophthalmic patient access route specifically. Dr. Cabrera maintains an independent practice in Hialeah at 1165 West 49th Street and works with The Selem Center in Miami. Confirm whether ophthalmic participants would be recruited from that practice population, from the RHO database, or both, and state the arrangement under which patients would be referred into RHO Research studies.

SECTION 6

Therapeutic area depth

Sponsors distinguish between areas a site can support and areas a site can anchor. Breadth without depth reads as a site that will take any study. This section separates the two.

Anchor areas

An anchor area has a named subspecialist investigator with documented protocol experience, a population route, and the on-site capability to execute the core assessments.

NEPHROLOGY AND RENAL

Chronic kidney disease stages 1 to 5, IgA nephropathy, glomerulonephritis, diabetic nephropathy, hypertensive nephrosclerosis, and vancomycin related acute kidney injury. Anchored by Dr. Puello, with concurrent dialysis and nephrology practice providing the population route. One Phase III vancomycin related acute kidney injury study is currently enrolling under his oversight.

CARDIOMETABOLIC DISEASE

Resistant hypertension, type 2 diabetes mellitus, dyslipidemia, obesity, and cardiovascular risk reduction. Three investigators carry documented protocol experience in this area, including studies for Eli Lilly and AstraZeneca in type 2 diabetes.

CENTRAL NERVOUS SYSTEM AND PSYCHIATRY

Major depressive disorder, treatment resistant depression, generalized anxiety disorder, adult attention deficit hyperactivity disorder, bipolar disorder, schizophrenia, and sleep wake disorders. Anchored by Dr. Rodriguez, with neuropsychological assessment instruments on site including the Mini-Mental State Examination, the Montreal Cognitive Assessment, and a full battery.

NEUROAIDS AND HIV NEUROLOGY

HIV associated neurocognitive disorders, central nervous system antiretroviral penetration, HIV encephalopathy, and neuroinflammation. This is a narrow area with few community sites able to claim published investigator depth. Dr. Rodriguez carries six peer reviewed contributions in it.

OPHTHALMOLOGY

New from June 2026. Cornea, external disease and ocular surface, diabetic retinopathy and diabetic macular edema, glaucoma and intraocular pressure, and age related macular degeneration including geographic atrophy. Anchored by Dr. Cabrera. Investigator readiness is complete. Imaging infrastructure is addressed in Section 7 and carries an open completion item.

VACCINES AND INFECTIOUS DISEASE

Influenza, respiratory syncytial virus, COVID-19, combination and booster studies, meningococcal vaccines, intravenous antibiotic therapy, drug induced nephrotoxicity, antibiotic pharmacokinetics in renal impairment, and HIV and AIDS comorbidities. Dr. Mendez carries Phase 2b and Phase III vaccine protocol experience in both pediatric and adolescent populations.

Supported areas

A supported area has documented investigator protocol experience and the operational capability to execute, but is not currently marketed as a primary focus.

AREA	INDICATIONS	INVESTIGATOR
Respiratory	Persistent asthma in pediatric and adult populations, COPD, non-cystic fibrosis bronchiectasis	Mendez, Limon
Dermatology	Plaque psoriasis, atopic dermatitis, acne vulgaris, actinic keratosis, prurigo nodularis, nonsegmental vitiligo, chronic idiopathic urticaria	Mendez, Limon
Gastroenterology	Chronic idiopathic constipation, irritable bowel syndrome with constipation	Mendez, Limon
Rheumatology	Moderate to severe rheumatoid arthritis	Mendez, Limon
Hepatology	Nonalcoholic fatty liver disease, nonalcoholic steatohepatitis	Mendez
Pediatrics	Acute otitis media, pediatric asthma, pediatric vaccines, functional constipation	Mendez
Pain and musculoskeletal	Osteoarthritis, chronic pain, functional rehabilitation	Mendez
Women’s health	Metabolic syndrome, hormonal health	Mendez, Limon
Internal medicine	General adult conditions and comorbidity management	Puello, Limon

A NOTE ON HOW TO USE THIS LIST

Do not send the full list into every feasibility response. Send the anchor area that matches the protocol, with the named investigator and their protocol history, and let the supported areas appear only in the general profile. A sponsor reading a nine area list in a nephrology feasibility response concludes the site is unfocused. The same sponsor reading two pages on Dr. Puello concludes the opposite.

SECTION 7

Facility and operational capability

The sponsor question is whether the site can execute the protocol without external dependencies, and where a dependency exists, whether the site will disclose it.

On-site clinical capability

CAPABILITY	DETAIL
Phlebotomy	On-site service with a trained phlebotomy specialist
Vital signs	Calibrated vital signs monitoring
Electrocardiography	12-lead digital ECG with transmission capability for central over-read
Specimen processing	On-site processing and centrifugation, with certified courier shipping
Investigational product storage	Secure, temperature monitored storage
Neuropsychological assessment	Mini-Mental State Examination, Montreal Cognitive Assessment, and full assessment battery

SITE TO COMPLETE

Name the equipment. Sponsors read "calibrated vital signs monitoring" as a category and "GE CARESCAPE V100, calibrated [date], next due [date]" as a fact. For each capability above, state the manufacturer and model, the calibration date and interval, and the responsible owner. Do the same for the centrifuge, the refrigerated and ambient investigational product storage units, the temperature monitoring platform with its alarm and escalation path, and the ECG unit.

SITE TO COMPLETE

State the specimen handling arrangement. Name the central laboratory or laboratories the site is set up with, the certified courier, the pickup schedule and cut-off times, whether the site holds a minus 20 or minus 70 degree Celsius freezer with continuous monitoring, and whether dry ice is held or sourced. Confirm which staff members hold current IATA or shipping certification, and their expiry dates.

Facility layout

SITE TO COMPLETE

Describe the facility room by room: total square footage, number of examination or study rooms, dedicated monitoring space with secure network access, secure regulatory document storage, investigational product room, laboratory processing space, participant waiting and comfort areas, accessibility provisions, and back-up power arrangements. Confirm whether the site can host two monitors concurrently. This section is materially stronger with three to five facility photographs, which sponsors and CROs use to reduce prestudy site visit uncertainty.

Ophthalmic capability, stated openly

The appointment of Dr. Cabrera makes ophthalmology an anchor area on the investigator side. Ophthalmic protocols are, however, among the most equipment dependent in the industry, and the site capabilities record does not currently list ophthalmic imaging. This profile states that openly rather than leaving a sponsor to discover it at the qualification visit, because scope disclosure is one of the strongest credibility moves a site profile can make.

The table below lists the equipment most commonly specified in the four ophthalmic areas Dr. Cabrera anchors. It is provided as a completion instrument, not as a claim.

ASSESSMENT	TYPICAL PROTOCOL REQUIREMENT	STATUS AT RHO
Best corrected visual acuity	ETDRS chart with standardized lighting and certified refractionist	To be confirmed by site
Slit lamp biomicroscopy	Slit lamp with imaging capability	To be confirmed by site

ASSESSMENT	TYPICAL PROTOCOL REQUIREMENT	STATUS AT RHO
Intraocular pressure	Goldmann applanation tonometry	To be confirmed by site
Optical coherence tomography	Spectral domain OCT, sponsor certified model, with reading centre certification	To be confirmed by site
OCT angiography	Sponsor specified platform	To be confirmed by site
Fundus photography and autofluorescence	Certified fundus camera with certified photographer	To be confirmed by site
Fluorescein angiography	Angiography capability with emergency response provision	To be confirmed by site
Visual fields	Humphrey visual field analyzer	To be confirmed by site
Corneal topography and tomography	Topographer or Scheimpflug tomographer	To be confirmed by site
Specular microscopy and pachymetry	Specular microscope, pachymeter	To be confirmed by site

SITE TO COMPLETE

For each row above, mark one of three answers: held on site with manufacturer and model, accessible through Dr. Cabrera's practice at 1165 West 49th Street, Hialeah, under a stated arrangement, or not currently available. Then state which staff members hold or can obtain reading centre certification as ophthalmic photographers and certified refractionists. A site that answers this table honestly will be selected for the studies it can run. A site that leaves it blank will be screened out of all of them.

RECOMMENDED POSITIONING WHILE THE TABLE IS INCOMPLETE

Until the equipment position is confirmed, position ophthalmology for protocols that are lower on imaging burden: ocular surface and dry eye disease studies, anterior segment and corneal studies, post-surgical outcome studies, and observational or registry work. These make full use of Dr. Cabrera's subspecialty depth without requiring reading centre certified retinal imaging on site.

Once the imaging position is confirmed, diabetic retinopathy, diabetic macular edema and age related macular degeneration studies become available, and they carry materially higher per-participant value.

SECTION 8

Cycle times and operational performance

Cycle time discipline is the single strongest operational signal available to a site without a long performance record, because it is a commitment the site controls entirely.

Start-up commitments

MILESTONE	COMMITMENT
Feasibility questionnaire response	48 to 72 hours
Site qualification visit readiness	5 business days
IRB submission after protocol finalization	5 business days
Site initiation visit to first participant screened	1 to 2 weeks
Full activation	Under 30 days

SITE TO COMPLETE

Add the two cycle times sponsors ask about most and that are missing above: confidentiality agreement turnaround, and clinical trial agreement and budget turnaround from first draft to full execution. Also state the query resolution commitment in days and the data entry commitment in days from visit. A start-up commitment without a data entry commitment reads as a site optimizing for the metrics that are easy to hit.

Availability and capacity

Coverage	24 hours a day, 7 days a week on-call support
Research coordinators	Four experienced research coordinators, bilingual across English and Spanish
Nursing	One Florida licensed Registered Nurse
Physician level support	Two Foreign Medical Graduates providing clinical oversight and participant management
Principal Investigators	Five, across five anchor therapeutic areas
Site management and regulatory	Olga Varona, Site Manager and Regulatory, holding a research coordinator credential

SITE TO COMPLETE

State current committed capacity and uncommitted capacity. How many studies are active today, how many participants are currently in follow-up, and how many additional studies can the site take without adding staff. Uncommitted capacity that is stated plainly is a competitive advantage over larger sites that are fully committed, and it is the question a CRO placing volume will ask first.

Performance evidence

One study is currently enrolling: a Phase III study in vancomycin related acute kidney injury, under Dr. Puello's oversight. Retention across completed studies is reported at 90 percent or higher.

SITE TO COMPLETE

For every study the site has conducted or is conducting, supply: sponsor or CRO, protocol number or short title, indication, phase, enrollment target at this site, number screened, number randomized, number completed, number of protocol deviations, and query rate per participant. Where a study is ongoing, state the figures to date. This table is the difference between a profile that argues from investigator history and a profile that argues from site performance, and it is the single most valuable item the site can add over the next twelve months.

SITE TO COMPLETE

Substantiate the 90 percent retention figure. State the number of studies it covers, the number of participants, the definition of retention used, and the date range. An unsupported retention figure is treated by feasibility reviewers as marketing. A supported one is treated as a reason to select the site.

SECTION 9

Diversity and representativeness

Sponsors are not asking whether the site is diverse. They are asking whether the site can help them deliver the enrollment commitments in their Diversity Action Plan. That is an operational question, and it is answered with operational capability rather than demographic reporting.

Population base

The site sits inside one of the most concentrated Hispanic and Latino populations in the United States. The figures below are public and independently verifiable, which is why they carry weight in a feasibility review.

MEASURE	HIALEAH CITY, FLORIDA
Total population, 1 July 2025 estimate	230,968
Hispanic or Latino, percent of population	95.1 percent
Persons aged 65 years and over, percent	20.3 percent

Source: U.S. Census Bureau QuickFacts, Hialeah city, Florida. Miami-Dade County, Broward County and Palm Beach County form the secondary catchment, with a combined population in excess of six million.

Language capability by use case

Language capability is reported by where it is used, because a sponsor needs to know that Spanish is available at the consent conversation, during study procedures, and in retention contact, not merely that someone in the building speaks it.

USE CASE	CAPABILITY
Informed consent conversation	Conducted in English or Spanish by the delegated investigator or coordinator, in the participant's preferred language
Day to day study procedures and assessments	All four research coordinators are bilingual. Physician level staff are bilingual
Retention contact and visit reminders	Conducted in the participant's preferred language
Source documentation and data entry	Conducted in English to sponsor standard, from bilingual source contact

SITE TO COMPLETE

Confirm the arrangement for translated study documents. State whether the site uses sponsor supplied certified Spanish translations of the informed consent form and participant materials, whether the site can obtain certified translation, and the turnaround if so. Also confirm whether any staff member holds a formal medical interpreter credential.

SITE TO COMPLETE

Name community partnerships with actual referral relationships: churches, community health organizations, senior centers, dialysis units, primary care groups, patient advocacy organizations. Name the organization and describe the relationship. Unnamed community outreach is discounted. A named partnership with a named contact is treated as a recruitment asset.

Subgroup monitoring during enrollment

When a Diversity Action Plan target applies to a study, RHO Research recommends the following monitoring approach and will operate it on sponsor request.

- Weekly subgroup pulls against the enrollment plan, reported to the sponsor or CRO in the agreed format
- A defined variance trigger, for example a subgroup running more than 15 percent below plan at any weekly checkpoint
- A tactical response menu agreed at study start-up: adjusted database re-contact, targeted referral outreach, extended clinic hours, and transport or scheduling accommodation
- Escalation to the sponsor with the site's proposed response rather than with the variance alone

RECOMMENDED ADDITIONS

Two credentials strengthen this section at no cost and are worth adding before the next feasibility submission. First, Cultural Competency certification for study facing staff, available free through Coordinare at coordinare.co. Second, team registration with Latinos in Clinical Research at latinosinclinicalresearch.com, a free professional community open to all backgrounds. Both are verifiable, both appear on the site profile, and both signal that diversity capability is managed rather than incidental.

SECTION 10

Regulatory, quality and technology

Quality function

RHO Research operates a dedicated in-house Quality Assurance function, which is uncommon at this site scale and is a genuine differentiator when it is described in operational terms.

- Continuous review of regulatory documentation, source documentation, study logs and essential documents
- Periodic internal audits
- Principal Investigator oversight verification and protocol adherence review
- Data integrity quality control and Good Clinical Practice compliance review
- Readiness preparation for site selection visits, site initiation visits, monitoring and quality visits, and sponsor or CRO audits

SITE TO COMPLETE

Describe how the Quality Assurance function operates: who holds the role, whether it is a dedicated or a shared position, the internal audit frequency and scope, how findings are documented, and how corrective and preventive actions are tracked to closure. Attach a redacted example internal audit report and a closed CAPA record if available. A quality function described in operational detail is a differentiator. One described in bullet points is a claim.

Regulatory standing

FDA inspection history	No FDA Form 483 observations and no Warning Letters on record
Standard operating procedures	SOP library covering informed consent, investigational product management, source documentation, safety reporting, delegation, training and quality, aligned to 21 CFR Parts 50, 54, 56 and 312
GCP training standard	ICH E6 aligned Good Clinical Practice training for delegated staff
Investigator site file	Maintained in audit ready condition
IRB experience	Central IRB experience with WCG and Advarra, and local IRB experience
Safety reporting	Structured adverse event and serious adverse event reporting with a corrective and preventive action framework
Privacy	HIPAA compliant

SITE TO COMPLETE

Confirm the Good Clinical Practice training provider, the version of ICH E6 the training reflects, the refresh interval, and the date each delegated staff member last completed it. If the site has not yet moved staff training to ICH E6(R3), note the planned date. Sponsors read E6(R3) fluency as a proxy for operational maturity. Also confirm whether a HIPAA security risk assessment has been completed within the last twelve months, and its date.

Technology

SYSTEM	STATUS AT RHO RESEARCH
Clinical trial management system	Fully implemented, with sponsor access provisioned
Electronic data capture	Medidata Rave, Veeva Vault, and sponsor mandated platforms
Electronic consent	Supported
Electronic trial master file	Active and audit ready
Remote monitoring and source data verification	Fully supported
EHR pre-screening	Active protocol eligibility matching
21 CFR Part 11 compliance	Yes, with complete electronic audit trail
HIPAA compliance	Yes

SITE TO COMPLETE

Name the platforms. State the clinical trial management system product name, the electronic regulatory and eTMF platform product name, the eConsent platform, and the temperature monitoring platform. Then state training status by team member for each electronic data capture platform listed, and name the sponsor portals the team is already provisioned on, including the TransCelerate Shared Investigator Platform. Named platforms with named trained users outperform capability categories in every feasibility review.

APPENDIX A

Completion checklist

What this appendix is for

This profile was drafted from the site capabilities record, the RHO company profile, and the curriculum vitae of each investigator. Wherever the draft reached the limit of what those sources could evidence, the text stops and a shaded orange box headed SITE TO COMPLETE appears in its place. Each box states the question a sponsor will ask and gives ruled lines for RHO to write the answer on.

This appendix is the index to those boxes. Rather than paging through the profile hunting for every shaded box, work down this list. When every row is answered and the answers have been written into the boxes in the body of the document, the profile is finished.

BEFORE THE PROFILE GOES TO A SPONSOR

This appendix is an internal working tool. It is written to RHO, not to a sponsor. Once the shaded boxes have been completed, delete this appendix, delete the orange box borders around the answers, and remove the Completion checklist line from the Contents page. What remains is the sponsor facing profile.

How to read the columns

COLUMN	WHAT IT MEANS
#	The item number. It is a reference only, so that items can be assigned and discussed by number. It has no meaning inside the profile itself
Item	The information the site needs to supply, written as the action to take
Sec.	Short for Section. The number is the section of this profile that contains the shaded box this item belongs to. Item 2 marked 7 means the shaded box in Section 7, Facility and operational capability. Turn to that section to find the box and write the answer into it
Owner	Left blank on purpose. Write the name of the person at RHO responsible for supplying that answer
Done	Left blank on purpose. Tick or date it once the answer has been written into the shaded box in the body of the profile

The three priority groups

The items are grouped by the value each one adds to a feasibility submission rather than by the order they appear in the document. Priority one items are the ones a sponsor checks first, so they carry the most weight for the least effort. Priority two and three items strengthen the profile but will not stop a submission.

PRIORITY ONE · CLOSE BEFORE THE NEXT FEASIBILITY SUBMISSION

#	ITEM	SEC.	OWNER	DONE
1	Segment the patient database by condition, with the EHR query and pull date, plus an eligibility forecast	5		
2	Complete the ophthalmic equipment table, marking each row held, accessible, or not available	7		

#	ITEM	SEC.	OWNER	DONE
3	Quantify Dr. Puello's dialysis and CKD referral channel with a sourced number	3		
4	Confirm Dr. Rodriguez's license, board certification, ECFMG and GCP training details	3		
5	Supply Dr. Cabrera's direct email address for the routing table	1		
6	State research time commitment and concurrent study capacity per investigator	3		
7	Substantiate the 90 percent retention figure with study count, participant count and definition	8		
8	Add CDA turnaround and CTA and budget turnaround to the cycle time table	8		

PRIORITY TWO · CLOSE WITHIN 30 DAYS

#	ITEM	SEC.	OWNER	DONE
9	Name all clinical equipment with manufacturer, model and calibration status	7		
10	Name the CTMS, eReg and eTMF, eConsent and temperature monitoring platforms	10		
11	State EDC training status by team member and list provisioned sponsor portals	10		
12	Name the central laboratory, courier, freezer capability and IATA certified staff	7		
13	Name the cross-covering Sub-Investigator for nephrology, CNS and ophthalmology	4		
14	Confirm the investigator transition SOP exists in signed form	4		
15	Describe recruitment channels with volume produced by each	5		
16	State the ophthalmic patient access route and referral arrangement	5		
17	Confirm GCP training provider, ICH E6 version, refresh interval and staff completion dates	10		
18	Confirm HIPAA security risk assessment completion date	10		

PRIORITY THREE · CLOSE WITHIN 90 DAYS

#	ITEM	SEC.	OWNER	DONE
19	Describe the facility room by room and add three to five facility photographs	7		

#	ITEM	SEC.	OWNER	DONE
20	Describe how the Quality Assurance function operates, with an example audit and CAPA record	10		
21	Name community partnerships with named contacts	9		
22	Confirm translated document arrangement and interpreter credentials	9		
23	State committed and uncommitted study capacity	8		
24	Build the study performance table with enrollment, screening and randomization figures	8		
25	Date the ten most recent protocols on Dr. Mendez's list with sponsor, role and enrollment achieved	3		
26	Confirm the SPECT neuroimaging arrangement, or remove it from sponsor facing materials	3		
27	Confirm which CDA stage documents are held in current form today	1		

THREE ADDITIONS THAT DO NOT APPEAR AS BOXES BUT CHANGE HOW THIS PROFILE READS

Team headshots for the five investigators and the site management team. Sponsors and CROs read faces as accountability.

A short site tour video, hosted and linked by QR code on the cover. It removes uncertainty ahead of a prestudy site visit and differentiates the profile from every text-only submission in the same review.

A quarterly refresh discipline. The profile states a data period and a next review date on the cover. Holding to it is what converts this document from a brochure into a business development asset.