January 2022

THE RESEARCH SPECTATOR

DHR Health Institute for Research and Development

To Discover | To Innovate | To Excel

DHR Health Institute for Research & Development is the largest and most comprehensive clinical research entity in South Texas. A nonprofit organization, the DHR Health Institute for Research & Development is committed to bringing the most innovative and advanced clinical care to over 2 million people who live in the eight counties in the border region.

To continue to facilitate patients' engagement in cutting-edge clinical research and advanced clinical care, DHR Health Institute for Research and Development has established a satellite in Brownsville. This expansion will bring over 160 clinical trials in the areas of liver and infectious diseases, cardiovascular disorders, diabetes, obesity, stroke, dementia, cancer, trauma, etc., to benefit the community in Cameron County.

The Research Liver team hosted a Fibroscan® event in Brownsville on Wednesday, December 29, 2021 at the DHR Health Specialty Clinic. Fibroscan® is a non-invasive, diagnostic-ultrasound-based device used to measure liver scarring (fibrosis), caused by different liver diseases. Similar to a conventional ultrasound exam, outpatient Fibroscan® testing is quick, painless, and easy and provides a non-surgical alternative to the traditional liver biopsy to assess liver damage.

During this event, the team scanned patients and provided them with information about non-alcoholic fatty liver disease (NAFLD). NAFLD is a spectrum of disease that starts with non-alcoholic fatty liver (NAFL), which is an overabundance of fat storage in the liver cell that may progress to non-alcoholic steatohepatitis (NASH). NASH involves liver inflammation along with a fatty liver state, and progresses scarring (fibrosis) from mild to severe. In the severe stage of scarring, or cirrhosis, serious complications arise. Overall, patients do not exhibit any symptoms with NAFLD. Thus, this silent disease may go unnoticed until it is too late. By providing this Fibroscan event, we are able to increase awareness and start the conversation with patients about their liver health status.

The Research Liver team will be hosting the next Fibroscan® event on Thursday, January 27, 2022 from 9 a.m. to 3 p.m. at the DHR Health Specialty Clinic. To register for this free event please call (956) 362-3715.

To learn more about the DHR Health Institute for Research & Development, visit: www.dhrresearch.org.

Master Research Affiliation Agreement

DHR HEALTH INSTITUTE FOR RESEARCH & DEVELOPMENT SIGNS A MASTER RESEARCH AFFILIATION AGREEMENT WITH THE UNIVERSITY OF TEXAS RIO GRANDE VALLEY

To continue to enhance its ongoing academic affiliation with the University of Texas Rio Grande Valley (UTRGV), the DHR Health Institute for Research & Development (DHR-IRD) has signed a Master Research Affiliation Agreement. Articulation of this agreement would allow the two institutions to continue to work together to augment basic, translational, and clinical research collaborations in areas such as cancer, liver diseases, infectious diseases, cardiovascular disorders, diabetes, stroke, trauma, etc. Students, residents, fellows, and faculty at UTRGV will work closely with physician investigators in the Research Academy, DHR-IRD to initiate innovative research studies that would benefit our community. This comprehensive agreement is a summation of five (5) independent agreements:

- Mutual Confidentiality and Nondisclosure Agreement
- Master Material Transfer Agreement
- Business Associate Agreement
- Agreement for Institutional Review Board Authorization for Reliance and Cooperation for the Protection of Human Subjects in Research
- Mutual Trademark Licensing Agreement

To learn more about this Master Research Affiliation Agreement, please contact the following site coordinators:

DHR-IRD

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UTRGV:

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Cont. on pg. 3

Pathways for IRB Submission

Who will be the Principal Investigator for research conducted at DHR Health facilitates?

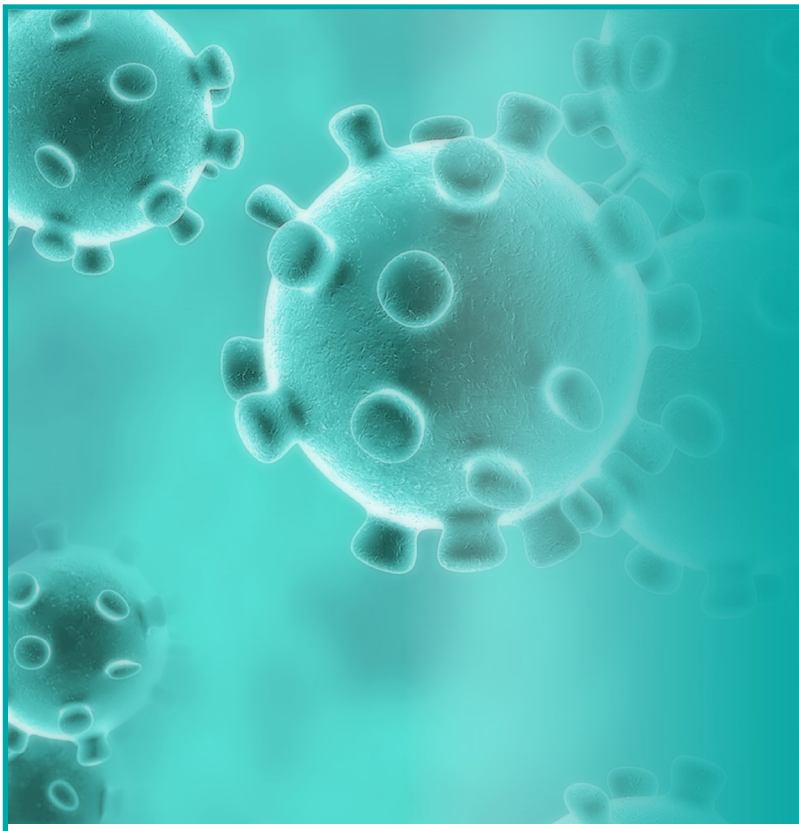
UTRGV Student, Resident, Fellow or Faculty	DHR Physician
• Will follow Pathway #1 • Submit to UTRGV and Smart IRB (contact UTRGV IRB for additional information) • UTRGV will be the reviewing IRB • DHR-IRD will be the relying IRB • Students and Residents will require faculty advisor	• Will follow Pathway #2 • Submit to DHR-IRD and Smart IRB • DHR-IRD will be the reviewing IRB • UTRGV will be the relying IRB

Pathway #1

Initiate Request to SMART IRB	DHR-IRD IRBNet	DHR-IRD Acknowledgment
Attach UTRGV approval, Protocols, ICF, and all other relevant documents. UTRGV Reviewing IRB DHR-IRD Relying IRB	DHR-IRD IRB Coordinator will pull documents from Smart IRB and submit to IRBNet for Administrative Review. PI and staff will be required to have an IRBNet account.	DHR-IRD will issue acknowledgement letter via IRBNet and finalize Smart IRB Reliance Agreement. Research project may begin.

Pathway #2

Submit to IRBNet	Contact UTRGV	Initiate Request to SMART IRB	DHR-IRD Indicates Approval
Attach Application, Protocols, ICF, and all other relevant documents.	Contact the UTRGV IRB to determine their requirements when relying on DHR-IRD IRB.	Attach Protocols, ICF, and all other relevant documents. DHR-IRD Reviewing IRB UTRGV Relying IRB	Once DHR-IRD IRB has reviewed proposed research, approval letter will be issued via IRBNet and SMART IRB agreement finalized. Research may begin once UTRGV requirements are met.



DHR Health
Institute for Research and Development

Newly Detected:

COVID-19 Omicron Variant With Multiple Mutations

Implications for Transmission, Diagnostics, Therapeutics, and Immune Evasion

The global and regional impact of SARS-CoV-2 pandemic continues to be a source of grave concern. While the availability of vaccines against the SARS-CoV-2 virus may have partially assuaged this anxiety in certain parts of the world, it remains a prevailing and unpretentious global public health crisis. The latter outcome is fueled by the convergence of several factors which include (but not limited to) the lack of availability of adequate number of vaccines; poor socio-economic conditions; vaccine hesitancy; and rampant proliferation of misinformation on the social media.

To date, SARS-CoV-2 pandemic has infected over 48 million people in the United States resulting in the death of over 777 thousand (1). It is noteworthy that to a large extent, refusal by hominoid to get vaccinated in the United States continues to be a source of much consternation. Not only do unvaccinated people have a much higher rate of infection and hospitalization, but they are also a very fertile source for generation of SARS-CoV-2 variants. Since the identification of the first infected case of COVID-19 in Wuhan, China in December 2019, the world has witnessed multiple peaks of resurgence of COVID-19 pandemic largely as a consequence of mutations in the SARS-CoV-2 with enhanced transmissibility and infectivity.

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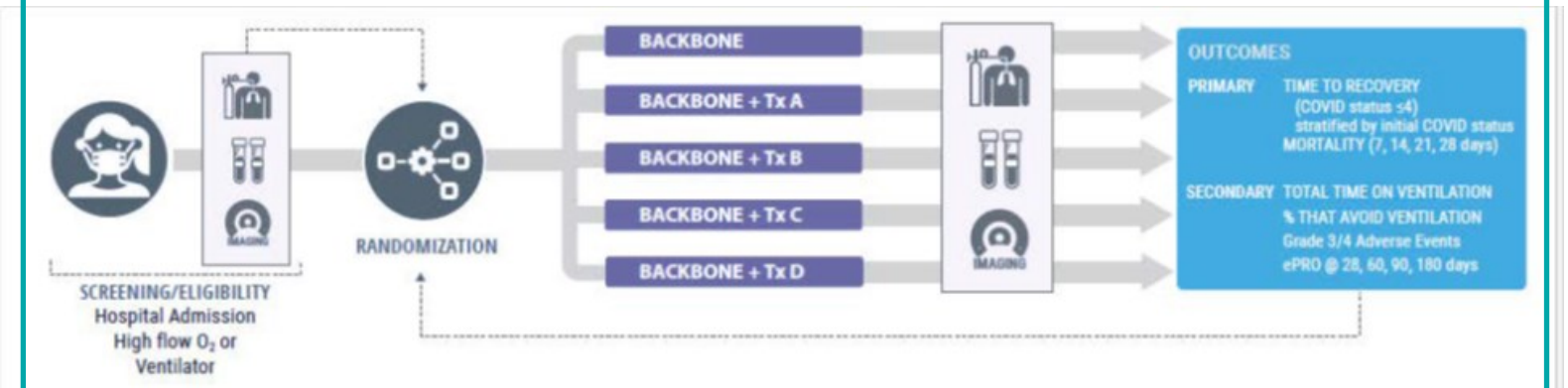
In conclusion, the identification of a new potentially more dangerous variant is a somber reminder that the world is still living under the umbrella of a pandemic and remains highly vulnerable to another wave of SARS-CoV-2 infection. Despite these travel restrictions, it is only a matter of time that the B.1.1.529 variant will be identified in patients in the US. **In fact, we predict that the B.1.1.529 variant has already penetrated the US eco-system.** While it must be confirmed unequivocally, given some similarities of observed mutations in B.1.1.529 to that to the Delta variant, we envisage that the immune responses raised by the currently available vaccines will be effective in protecting against this variant. It is the degree of protection afforded by these vaccines against Omicron which is the focus of studies currently underway. Hence the need for universal vaccination all around the world otherwise, the threat of evolving new and more dangerous SARS-CoV-2 variants will always be lurking in the background. Recent affirmative news about the gradual decline in the rate of infection and hospitalization in some states has perhaps bestowed false reassurance prompting many to abandon US Centers for Disease Control & Prevention guidelines for limiting the spread of COVID-19. It **is, therefore, imperative that we continue to exercise extreme caution in our social congregations and all those who are eligible must get vaccinated including the third and/or the booster doses**.

Read the Full Article at DHR Proceedings: https://www.dhrproceedings.org/index.php/DHRP/article/

Upcoming Study

I-SPY Covid-19 Trial

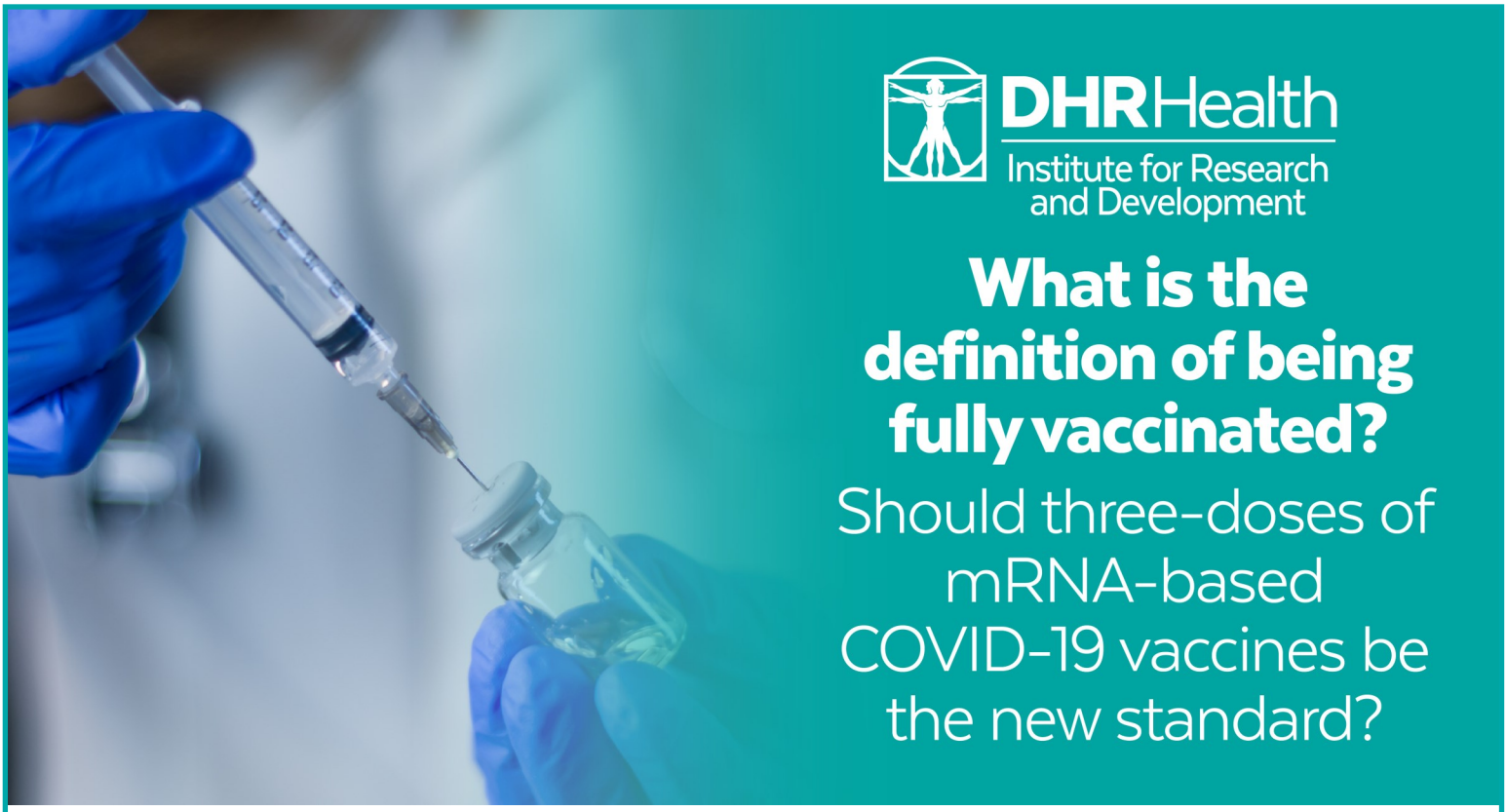
Approximately 10-15% of those infected with the highly contagious SARS-CoV2 virus develop an acute respiratory illness, with a death rate in the 2-10% range. Of patients who present with respiratory distress, 40-60% requires ventilation for a mean of 10-14 days. The unprecedented rate of infection, with greater than 10 million cases world-wide and over 2.5 million of which are in the United States, has already led to more than 500,000 deaths, of which over 125,000 are in the US. **The goal of this research project is to rapidly screen promising agents, in the setting of an adaptive platform trial, for treatment of critically ill COVID-19 patients.** In this phase 2 platform design, we will be able to identify agents with a signal suggesting a big impact on reducing mortality and the need for, as well as duration, of mechanical ventilation.



The platform trial design is shown above. Patients that enter the hospital and that are placed on high flow oxygen or are intubated will be screened for trial eligibility. Enrolled patients must have had a positive COVID-19 test by PCR or rapid antigen testing for SARS-CoV-2 infection. Eligible PCR-positive patients or their designated surrogates will be asked if they want to enroll on the therapeutic portion of the trial. All enrolled patients will receive backbone therapy with or without an additional investigational agent. The approach that we will take in this trial is to focus on finding agents with a big impact on reducing both mortality and time on ventilators for those critically ill as a result of COVID 19.

An observational component, separate from the platform trial, will follow ICU patients via medical records. The ICU patients may or may not be enrolled in the platform trial, must have a positive COVID- 19 test by PCR or rapid antigen testing for SARS-CoV-2 infection and must be on high flow oxygen or intubated

For addition information regarding this and other COVID-19 trials, please contact Luis Cantu Jr., Clinical Research Coordinator-Infectious Disease at lu.cantu@dhr-rgv.com or (956) 362-2396.



Despite the availability of numerous clinically effective COVID-19 vaccines which have been approved and/or authorized for use in humans, mitigating morbidity and mortality associated with the exposure to or infection with SARS-CoV-2 virus remains an elusive global challenge. It is quite alarming that worldwide, over 5.2 million people have already died as a result of SARS-CoV-2 infection and over 8,000 continue to meet this tragic fate every day (1). In the US, over 790,000 have died as a result of COVID-19 and over 1,000 people are dying every day as a consequence of infection with SARS-CoV-2 (2).

In the US, three COVID-19 vaccines have been approved and/or authorized by the FDA and the CDC (Table 1). Using the currently recommended criteria, as of December 10, 2021, 60.5% (>200,000) of the U.S. population has been fully vaccinated (Table 1) and 71.5% have received at least one dose of the COVID-19 vaccine (2). It is perturbing that multiple clinical studies have demonstrated the decline in vaccine protection against SARS-CoV-2 infection (3, 4). A large cohort study by Chemaitelly, *et.al.,* using subjects who received Pfizer vaccine showed that in the first two weeks after the first dose of the vaccine, vaccine effectiveness against the wild-type and any SARS-CoV-2 variant was undetectable (3). However, seven days later, it increased to 36.8%, peaking at 77.5% in the four weeks after the second dose. Interestingly, regardless of the age group, vaccine effectiveness against the wild-type SARS-CoV-2 and all its variants (including Delta) gradually decreased after one month, with the decline accelerating after month four, to only about 20% after five to six months following the second dose (3).

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From the foregoing scientific evidence, we conclude that to afford effective protection against various variants of the SARS-CoV-2, at a minimum three doses of Pfizer or Moderna and two doses of Jansen vaccine would be required. In fact, we had previously argued that the Pfizer/BioNTech or Moderna COVID-19 vaccines should have been authorized by the FDA as a three dose primary vaccination series. Likewise, we had also previously suggested that Jansen COVID-19 vaccine should have been a two dose primary vaccination series. **Considering the available data, we are also recommending that booster dose should be authorized for children 5-15 years of age ensuring that they are also protected against the SARS-CoV-2 variants. Lastly, we are also recommending that the definition of FULLY VACCINATED be revised to include three doses of Pfizer/BioNTech or Moderna and two doses of Jansen COVID-19 vaccines.** ***It is not entirely inconceivable that in the very near future, we may require additional doses of COVID-19 vaccine that has been tailored to neutralize evolving SARS-CoV-2 variants.***

Read the Full Article at DHR Proceedings: https://www.dhrproceedings.org/index.php/DHRP/article/view/37/28

Hearing hoofbeats? Think head and neck trauma: a10-year NTDB analysis of equestrian related trauma in the USA

Data from the US Centers for Disease Control and Prevention show that more than 30 million people participate in equestrian leisure and sporting activities every year in the USA. But relatively little is known about the prevalence and consequences of injuries sustained while horse riding.

To plug this knowledge gap, the Level 1 Trauma team at DHR Health and researchers from the DHR Health Institute for Research and Development drew on data supplied from level I and II trauma centers to the US National Trauma Data Bank (NTDB) between 2007 and 2016, on injuries sustained by adults while horse riding.

The study finds that the risk of an injury, requiring hospital admission, is higher for horse riding than for other potentially risky sporting activities, such as football, motor racing, or skiing. The manuscript is published online in the journal Trauma Surgery & Acute Care Open.

While the most common site of injury was the chest, head and neck injuries were the most lethal, the findings show. Between 2007 and 2016, details of 45,671 patients with equestrian injuries were retrieved from the NTDB. But data were incomplete for 20,880, leaving 24,791 for inclusion in the analysis. Their average age was 47, with almost equal proportions of men and women. The most common site of injuries recorded was the chest: 9,189 (37%). Injuries to the hands and feet occurred in 6560 (26.5%), while 5689 (23%) sustained head injuries. Abdominal injuries were the least common: 3,353 (13.5%).

Severe neurological damage, classified as a Glasgow Coma Scale (GCS) score of 3–8, was observed in 888 (3.5%) patients. The GCS is a clinical scale used to reliably measure a person's level of consciousness after a brain injury. It ranges from 3 to 15. Within this group, head and neck injuries were the most likely cause, occurring in 706 patients. Moderate impairment (score 9–12) occurred in only 258 (1%). Some 21,917 (88.5%) patients had a GCS between 13 and 15. But 4,508 (20.5%) of these patients nevertheless had a head and neck injury.

While injuries were mainly categorized as mild (33%) to moderate (43.5%) in severity, most (88%) of these patients required admission to hospital, with more than a quarter (28%) sent to intensive care. Around 1 in 10 required surgery. Average length of stay in hospital was 4.5 days, with an average of 4 days spent in intensive care and 6 days on a ventilator. Those aged 50–59 were most likely to present to trauma centres, accounting for more than 1 in 4 of all those injured: 5,939 (26.5%). Those aged 60+ accounted for 4,883 (22%) of the injured. Those aged 30–39 were the least likely to feature among the injured, accounting for just 2,946 (13%) patients. Some 14,096 (57%) patients were discharged home without requiring additional services, while 1,747 (7%) were transferred to rehab or a skilled nursing facility. Some 320 people died of their injuries during the study period, with head and neck injuries the leading cause of death in three out of four (237; 75%). Just 7 (2%) of those who died had sustained injuries to their hands or feet. Riders with head and neck injuries were 44 times as likely to die as those with hand/foot injuries, while those with chest and abdominal injuries were around 6 times as likely to do so. If patients arrived at the emergency care department with a systolic blood pressure of less than 90 mm Hg, they were 23 times more likely to die than were patients with a higher reading.

This is an observational study, and included only those patients treated at US trauma centers reporting data to the NTDB. In the manuscript, the DHR Health researchers noted: “When taken together, these data suggest that the dangers of equestrian activities have been severely underappreciated. When controlled for hours of activity, horseback riding resulted in a higher proportion of hospital admission than other higher risk activities like skiing.” “Studies have shown that a large fraction of riders involved in equestrian injuries were not wearing helmets at the time of their accident. It stands to reason that raising awareness of the possible injuries and increasing preventive measures to protect against head injuries would significantly reduce mortality.”

The DHR Health researchers also stated: “Interestingly, hospital admission risk from horseback riding is higher than football, auto and motorcycle racing, and skiing. Recently, some attention has been paid by equestrian sporting agencies to the use of protective equipment to prevent injuries, especially as it relates to concussion and brain injuries; however, very few public health campaigns have focused on preventing injuries in riders using horses for leisure and work.”

Research Team Spotlight: Luis Cantu, Jr.

Meet Luis Cantu Jr. He serves as the Clinical Research Coordinator for studies involving Infectious Diseases at DHR Health Institute for Research and Development.

He has obtained a B.S. in Biology from the University of Texas Rio Grande Valley and a M.S. in Biochemistry and Molecular Biology from the University of Texas Rio Grande Valley. His previous experience involves being a Graduate Research Assistant and a Graduate Teaching Assistant at the University of Texas Rio Grande Valley.

Luis is bilingual and enjoys reading and volunteering at the UTRGV Research labs in his free time.

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New Additions to the DHR Health Institute for Research and Development Team

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Investigator Spotlight: Dr. Dynio Honrubia

Dr. Dynio Honrubia studied at the University of California, Los Angeles, where he received his undergraduate and medical degrees. He then completed an internship and residency program in pediatrics at UCLA-Cedars Sinai Medical Center in Los Angeles, California. Dr. Honrubia continued his training with a neonatology fellowship at Children's Hospital Boston, Harvard Medical School and a postdoctoral fellowship at Harvard Medical School Morton Molecular Hearing Laboratory.

During his career Dr. Honrubia has held many academic and professional positions at Boston Children's Hospital, Harvard Medical School, UCLA Cedars-Sinai Medical Center, UCLA School of Medicine, the University of Texas Medical Branch and the Doctors Hospital at Renaissance Health System. He is currently the principal investigator in multiple neonatal research studies.

Dr. Honrubia is the director of Neonatology for Partners for Pediatric Progress. Dr. Honrubia is board certified by the American Board of Pediatrics in the areas of pediatrics and neonatal-perinatal medicine.

DHR Proceedings

DHR Proceedings is one of the premier peer-reviewed health sciences journals in general and specialty medicine. It is the first such scientific journal to be published in the Rio Grande Valley. DHR Proceedings is sponsored by DHR Health Institute for Research & Development and invites submission from authors in the region and worldwide.

DHR Proceedings can be accessed at: https://dhrproceedings.org/index.php/DHRP/index

DHR Proceedings is currently welcoming submissions for a projected publication date in the spring of 2022.

DHR Health Institute for Research and Development
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