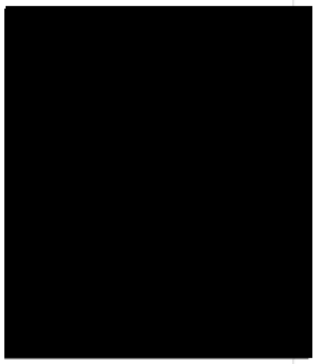

Neurological diseases field, the last four (4) of which [redacted] spent tirelessly working in [redacted] Infections of the [redacted].

I. [redacted] QUALIFICATIONS FOR PERMANENT RESIDENCE

[redacted] qualifies for permanent residence as a foreign national who is an advanced degree professional. [redacted] holds a Master of Science with a specialization in [redacted] from [redacted], located in [redacted]. Please see Exhibit XXX: Diploma confirming award in [redacted]. [redacted] also earned a [redacted] in [redacted] from [redacted], located in [redacted]. See Exhibit XXX: Diploma confirming award of degree in [redacted]. In addition, [redacted] earned a [redacted] in [redacted] from [redacted], located in [redacted]. See Exhibit XXX: Diploma confirming award in [redacted]. Currently, [redacted] is pursuing Certificate Course in [redacted] from [redacted], National Institute of Health in [redacted]. See Exhibit XXX: Diploma continuing letter. Based on [redacted] exceptional and path-breaking research in the field of Neurological diseases, [redacted] was presented with "[redacted] Award" for the performance at [redacted] for two years in a row [redacted]. See Exhibit XXX: Certification of Excellence.

Moreover, [redacted] is currently engaged in full-time employment as a [redacted] and is focusing [redacted] research on studying the [redacted] of [redacted] and the involvement of [redacted] in [redacted]. [redacted] is also taking part in multi organization international research program on [redacted].

The specific responsibilities of this position are detailed further herein. As detailed below, [redacted] exceptional research in the [redacted] will not only substantially benefit the national interest of the [redacted] but people living with the disabling and degenerative disease in the entire world. For a summary of [redacted] qualifications, please see Exhibit XXX: Copy of [redacted] Curriculum Vitae.

II. [redacted] QUALIFICATIONS FOR A NATIONAL INTEREST WAIVER

[redacted]

Through [redacted] exceptional work with [redacted] projects, [redacted] plays a crucial role in leading the research against the fatal and degenerative neurological diseases and providing a productive and health lives to millions of peoples around the world including the [redacted].

[redacted] qualifications and distinction in the field merit a waiver of the Labor Certification requirement.

A. [redacted] Seeks Employment In An Area Of Substantial Intrinsic Merit.

[redacted] seeks to continue to tirelessly work in [redacted] field of expertise, [redacted]. In particular, [redacted] aim is to help millions of people suffering from various neurological diseases including Motor Neuron disease such as [redacted], etc. causing economic burden to [redacted] and emotional problems to their family members through [redacted] path-breaking research contributions.

[redacted], sometimes called [redacted] disease, is a rapidly progressive, invariably fatal neurological disease that attacks the nerve cells (*neurons*) responsible for controlling voluntary muscles (muscle action we are able to control, such as those in the arms, legs, and face). The disease belongs to a group of disorders known as *motor neuron diseases*, which are characterized by the gradual degeneration and death of motor neurons.

More than [redacted] people in the [redacted] have a definite diagnosis of [redacted] for a prevalence of [redacted] cases per [redacted] persons in the [redacted]. general population, according to a report on data from the [redacted]. [redacted] is one of the most common [redacted] diseases worldwide, and people of all races and ethnic backgrounds are affected. [redacted] is more common among [redacted], [redacted]s, and persons aged [redacted] years, but younger and older people also can develop the disease. Men are affected more often than women.
Link: [redacted]

Scientists at the [redacted] **(with whom [redacted] is currently working)** discovered that reactivation of ancient viral genes embedded in the human genome may cause the destruction of neurons in some forms of [redacted]. The results, published in [redacted], suggest a link between [redacted] The findings also raise the question of whether antiretroviral drugs, similar to those used for suppressing [redacted], may help some [redacted] patients.

For generations, humans have been passing on genetic remnants of [redacted] infections that may have happened millions of years ago. Although nearly eight percent of the normal human genome is made up of these genes, very little is known about their role in health and disease. "[redacted]," said [redacted], M.D., [redacted] at the [redacted] and a senior author of the study (**one of [redacted] Recommender**). "Ultimately we hope the results will lead to effective treatments for a heartbreaking disorder." Currently, there is no effective treatment for the more than [redacted]. This fatal disorder destroys neurons that control movements, including speaking, walking, breathing and swallowing. On rare occasions, HIV-infected, AIDS patients develop [redacted]-like symptoms. In many of these

patients, the symptoms can be reversed by treatment with antiretroviral drugs. Previous studies found reverse transcriptase, a protein encoded by retroviral genes, in the blood of some [redacted] patients but its role in the disorder is unknown.

Notably, as noted, [redacted] research is vital in furthering the knowledge of [redacted]. [redacted] is a young and dynamic researcher who has contributed vital information during [redacted] time in the NIH. [redacted] has contributed immensely in the understanding the role of Tat in HIV-1 infection, disease pathology of [redacted], and [redacted]. [redacted] path-breaking works has been published in internationally renowned journals such as [redacted] The publication of the articles in these renowned journals speaks volumes of [redacted] contribution and experience. Articles presented in these journals are evaluated by eminent researchers and scientists. Based on [redacted] significant contributions in [redacted] in such a short span, [redacted] works in an area that clearly has substantial, intrinsic merit.

B. The Benefits of [redacted] Work Are National in Scope.

As noted, [redacted] works with the [redacted]. [redacted] is a part of the [redacted] and [redacted] agency. Its primary focus is making important discoveries that improve health and save lives. Remarkably, [redacted] has the distinction of providing support to around [redacted], whose studies led to the development of MRI, understanding of how viruses can cause cancer, insights into cholesterol control, and knowledge of how our brain processes visual information, among dozens of other advances.

[redacted] work is national in scope, as [redacted] research focus on neurological diseases that has affected a good number of citizens in [redacted]. One of [redacted] projects focuses on understanding how [redacted] causes persistent injury to the [redacted]. Although highly active antiretroviral drugs can successfully suppress the active replication and spread of [redacted] in [redacted] patients, some viral proteins are still produced and cause continuous neurodegeneration and neuroinflammation.

[redacted] infection causes neurocognitive impairment in nearly one third of individuals despite adequate antiretroviral therapy ([redacted] et al. 2011). Considering the fact that over [redacted] people are infected with the virus worldwide, the impact of this neurodegenerative process has important socioeconomic consequences [redacted]. However, despite a huge investment of resources in trying to understand the pathophysiology of HIV-associated neurocognitive disorders (HAND) and despite several clinical trials using neuroprotective drugs, there is no neuroprotective treatment available to date. Pathological studies have demonstrated that the virus infects glial cells while the neurons are not infected. Nevertheless, the neurons undergo synaptic pruning, neurite and

axonal retraction, and eventually apoptosis ([redacted] et al[redacted]. Pathophysiological studies suggest that neuronal injury is mediated via viral proteins, cytokines, and other mediators released from HIV-infected and activated glial cells ([redacted]). Based on these studies, clinical trials have been conducted using drugs that target excitotoxicity, oxidative stress, and neuroinflammatory pathways, all of which have failed ([redacted] et al. [redacted]. Unfortunately, such neuroprotective strategies have failed in most neurodegenerative diseases where they have been tried ([redacted] et al. [redacted]). Current approaches are now focused on neuroregeneration. However, the delivery of stem cells and viral vectors will be limited to select patient populations hence other strategies are necessary for the population at large. (**Taken from** [redacted])

[redacted] estimates that [redacted] persons aged [redacted] years and older are living with HIV infection, Including [redacted] ([redacted]) who are unaware of their infection. Over the past decade, the number of people living with HIV has increased, while the annual number of new HIV infections has remained relatively stable. In [redacted], an estimated [redacted] people were diagnosed with HIV infection in the [redacted]. In that same year, an estimated [redacted] people were diagnosed with AIDS. Overall, an estimated [redacted] people in the [redacted] have been diagnosed with AIDS. An estimated [redacted] people with an AIDS diagnosis died in [redacted], and approximately [redacted] people in the [redacted] with an AIDS diagnosis have died overall. (link: [redacted]).

The areas in which [redacted] scientific contributions have created an impact are areas of research and development that have the potential to benefit the [redacted] as a whole, rather than producing benefits that are limited to one particular region or socioeconomic demographic. For instance, [redacted] work specifically contributed to the finding that one of the [redacted] called [redacted] can evade the [redacted] drug treatment and lead to [redacted]. This research is hailed as one of the most significant discoveries in the recent times. As this discovery has paved a new way for treating [redacted] patients and enhancing the quality of life of the victims of this dreadful disease.

Additionally, as part of [redacted] rare disease program, [redacted] is also working on a collaboration project with [redacted] and the [redacted] to identify the cause of [redacted]. [redacted] is a neurological disorder of unknown etiology and pathogenesis characterized by atonic seizures that affects children between [redacted] of age. The reason we are interested in a mysterious syndrome seen in this region of the world is because any disease that spreads rapidly is a global threat and studying rare diseases like [redacted] syndrome can lead to profound insights into common diseases. For example, in the [redacted]. alone, several [redacted] people suffer from seizures. Studying [redacted] syndrome could provide us with new insights about what causes seizures and new approaches to treating them.

[redacted]

The total indirect and direct cost of [redacted] in the [redacted] is estimated to be [redacted] yearly. This estimate is based on a reported cost of [redacted] in [redacted] converted to [redacted] value using [redacted] data. (Link: [redacted]).

Based on [redacted] ongoing research contributions on important national health programs, [redacted] work is national in scope. [redacted] contribution in the identification of [redacted] envelop protein is just one example of how greater was achieved and could pave way for further discoveries based on [redacted] research. Granting [redacted] lawful permanent residence so that [redacted] may continue [redacted] research at [redacted] will expedite the process of developing innovative techniques and medicines in the area of neurological diseases and advancement of understanding them, ensuring that the [redacted] does not lose a valuable asset to its scientific community, and supporting [redacted] continue contribution toward the [redacted] national interest.

C. The Significant Benefit Derived From [redacted] Participation In This National Interest Field Of Endeavor Considerably Outweighs The Inherent National Interest In Protecting [redacted] Workers Through The [redacted]s.

[redacted] qualifications and experience enable [redacted] to perform in this position better than a [redacted] worker who has the same minimum qualifications. [redacted] possesses exceptional knowledge, unique abilities and skills, and has made significant contribution in this field. Specifically, [redacted] should be granted a waiver of the labor certification requirement due to [redacted] documented standing and reputation in the field, as well as [redacted] considerable education and experience, which is required to perform the services in question.

As we seek to demonstrate herein, and by specifically describing [redacted] outstanding experience, qualifications and benefit to the [redacted] national interest, we submit that [redacted] national interest benefit substantially outweighs the interest in protecting [redacted] workers through the labor certification process.

[redacted]

Specifically, as [redacted] experience, accomplishments and supporting documents demonstrate, [redacted] is already serving the national interest to a substantially greater degree than would an available [redacted] worker having similar minimum qualifications would. The attached supporting testimonial letters, provided by eminent researchers, all suggest that no [redacted] worker would be able to benefit the [redacted] national interest in a way [redacted] would. Additionally, [redacted] track record in the field, evidenced by [redacted] employment and significant contribution to the ongoing research, letters of support and recommendation and published articles all clearly indicate a proven track record of success in the field. [redacted] over eight years of highly inspiring and path-breaking researches, as described below, make [redacted] an invaluable and proven asset to the [redacted].

[redacted] innovative accomplishments, training, and exceptional abilities prove [redacted] capacity to perform well beyond the majority of [redacted] peers. [redacted] has already made substantial contributions to [redacted] research field, and as is evident from the enclosed letters of recommendation, and [redacted] has acquired great respect from other expert scientists. Please see Exhibit XXX. Although [redacted] only recently received [redacted] degree in [redacted], [redacted] has been actively involved in [redacted] field of research since [redacted], and possesses over [redacted] years of research experience and has [redacted] articles published in various leading scientific journals.

Finally, in support of our assertion that [redacted] benefits to the [redacted] national interest outweighs the interest in protecting [redacted] workers, we seek to highlight in relevant detail [redacted] experience and accomplishments over the past eight (8) years of experience in the [redacted] field.

[redacted] Research Experience

i. [redacted], [redacted]. ([redacted] – Present)

Currently, [redacted] is employed as a [redacted], Section of Infections of the Nervous System and works with the [redacted] through [redacted] employment in H-1B status with [redacted], Inc. See Exhibit XXX: Offer Letter from [redacted] Inc., name of [redacted] in bibliography of various published articles.

Presently, [redacted] is working on the project which is studying the disease pathology of [redacted] and the involvement of Human endogenous retrovirus in [redacted]. [redacted] are footprints of ancient retroviral infection and integration into our genome. Most [redacted] have been inactivated by millions of years of human evolution, while a very small portion has preserved the ability to make viral particles and viral proteins. Most importantly, these active endogenous retroviruses may cause neurodegenerative and neuroinflammatory disease under certain conditions, meaning that they could be emerging infectious agents from within our body. [redacted] and [redacted] group is the first to discover that the activation of one member of this virus family, human endogenous retrovirus subtype [redacted] can lead to a motor neuron neuropathology that is very similar to [redacted]. This is a very important step towards furthering their understanding of this fatal disease. [redacted] is a rapidly progressive, invariably fatal neurological disease characterized by progressive degeneration of motor neurons, leading to muscular atrophy, paralysis and death in 3–5 years from the first appearance of symptoms. [redacted] occurs throughout the world with no racial, ethnic or socioeconomic boundaries and can affect anyone. Because of its severity, [redacted] causes significant morbidity and mortality, imposing a major burden on the patient, their family and society, with respect to heath care use, loss of work capabilities and caregiving. No

[redacted]

intervention is currently possible that reduces the severity of the disease and its associated mortality.

The goal of [redacted] research is to find the cause or causes of [redacted], understand the mechanisms involved in the progression of the disease, and develop effective treatments. To this end, [redacted] group is investigating potential treatments for [redacted] patients. As one of the potential strategies to treat [redacted] patients with high [redacted] expression, [redacted] studied the effects of HIV-1 antiretroviral drugs on [redacted], since HIV-1 and [redacted] share many viral characteristics. [redacted] found that HIV-1 drugs are largely effective on [redacted], and can prevent [redacted] replication and infection in a cell culture system. [redacted] work led to the design of a clinical trial using HIV-1 antiretroviral drugs to treat [redacted] patients with high [redacted] activation. This clinical trial is currently ongoing in the clinical center of the [redacted].

[redacted] work specifically contributed to the identification of [redacted] as a [redacted]. [redacted] also participated in the generation of a transgenic mouse model using [redacted]. [redacted] group animal model recapitulates most of the [redacted] symptoms including neuropathological changes in the cortical and spinal motor neurons, muscle atrophy, and movement disorders; thus it is superior to other [redacted] based on mutation of [redacted] associated genes. Researchers could use it to investigate the pathological mechanisms of [redacted] and to test potential drugs for [redacted] treatment. [redacted] group has deposited this animal strain to the [redacted], which will distribute it to researchers worldwide who are interested in the study of [redacted].

As stated above, [redacted] is also participating in the multi organizations international research on [redacted].

Specifically, [redacted] duties include the following:

Potential role of [redacted] [redacted] [redacted] [redacted] in [redacted].

This project focuses on understanding the pathophysiology of endogenous retroviral infection in neurodegenerative diseases specifically [redacted] research involves studying the mechanism of activation of [redacted] in [redacted] and identifying how this activation leads to neurotoxicity in patients. As part of this project and in order to establish clinical significance of our invitro results, [redacted] has also developed different assays such as PERT, LIPS to screen serum, plasma and brain tissues from ALS patients.

Currently, [redacted] is working on establishing an invitro model of [redacted] in [redacted] derived neurons using CRISPR/TALEN techniques. [redacted] responsibilities also include designing

and executing in vitro experiments to identify and validate therapeutic candidates to treat [redacted]

Identify potential therapeutic strategies for eliminating latent HIV infection.

Developing novel invitro strategies to target HIV-1 latent infection which includes

- Suicide gene therapy for selective killing of HIV-1 infected cells.
- Using Antisense Oligonucleotides to target HIV-Tat Protein.
- Establish Stable cell line to screen and validate novel therapeutic candidates that functionally inhibit HIV-1 Tat.

Pathophysiology of [redacted] and role of [redacted]

To determine if an autoimmune process is contributing to the pathogenesis of NS, [redacted] and [redacted] group profiled autoantibodies in sera from patients with NS using an unbiased approach. After identifying a potential autoantigen we utilized quantitative PCR, Western blotting and immunohistochemical analyses to confirm the expression of the protein within the CNS.

Notably, for [redacted] inspiring research performance, [redacted] has presented [redacted] with "[redacted]."

ii. [redacted], [redacted]. ([redacted])

Prior to joining [redacted], [redacted] worked with another prestigious medical facility, [redacted] in the [redacted]. Here [redacted] made important discovery on the role of [redacted]. While working at [redacted] University, [redacted] projects focuses on understanding how HIV-1 infection causes persistent injury to the nervous system. Although highly active antiretroviral drugs can successfully suppress the active replication and spread of HIV-1 in HIV/AIDS patients, some viral proteins are still produced and cause continuous neurodegeneration and neuroinflammation [redacted] work specifically contributed to the finding that one of the HIV-1 proteins called Tat can evade the antiretroviral drug treatment and lead to persistent neurotocixity.

In addition, it may activate lymphocytes and trigger Immune Reconstitution Inflammatory Syndrome (IRIS), a severe condition that can accompany initiation or change to active antiretroviral therapy is considered to be a path-breaking discovery. Because this finding has paved the new insights in HIV-1 treatment, that is, to inhibit viral protein production and its toxic effects. Indeed, [redacted] and [redacted] group are designing a high throughput screening system to identify compounds that counteract HIV-1 viral proteins. Additionally, they are

currently testing antisense DNA molecules that directly block Tat protein production. Since Tat is both a master regulator of HIV replication and a driving force in HIV-associated neurocognitive impairment, reducing Tat levels can significantly reduce viral load and slow the progression of neurological complications. Therefore, development of broadly-acting anti-Tat drugs will significantly enhance quality of life for the HIV+ population.

[redacted] was involved in the following duties on regular basis:

- Conducted a study on the role of HIV-Tat on Neurodegeneration; identified the role of HIV-Tat on degeneration of neurons. Assessed the interaction of NMDA-Receptor with HIV-Tat by crystallography.
- Involved in various invitro and invivo studies to analyze the specific effects and the level of degeneration.
- Handled cloning of different genes and purified the protein for crystallography.

<u>Other Research Experiences (2007 – 2009)</u>

Before joining [redacted], [redacted] was involved in the research of [redacted] area of expertise, which included the following:

iii. **Intern, Office of Technology Transfer, [redacted] University ([redacted]), [redacted]. ([redacted])**

iv. **Research Assistance, [redacted] University, [redacted] [redacted] (2[redacted])**

v. **Research Analyst, Smart Analyst Inc., [redacted] ([redacted])**

vi. **Intern, [redacted] University, [redacted] ([redacted])**

[redacted] started [redacted] research career as an intern shortly after receiving [redacted] degree in [redacted].

III. CONCLUSION

[redacted] clearly meets the regulatory standards for the Employment-Based Second Preference Category, with a request for a National Interest Waiver. [redacted] has already made significant and lasting contributions to the field of [redacted] through [redacted] exceptional research to the [redacted] in both the [redacted] and other countries. [redacted] ongoing

research will result in developing medicines and ways in fight against several Neurological diseases and thus eventually make [redacted] the leader in this area. To complete next phase of [redacted] ongoing research [redacted] requires better atmosphere and advance research facilities that United States has. If [redacted] has to leave the [redacted] [redacted] research has to be stopped which could lead to delay in developing medicines for various neurological diseases causing physical and mental agony to millions of victims of these degenerative and disabling diseases. The recognized experts who have submitted letters on [redacted] behalf agree that [redacted] continued presence is critical to the success of [redacted] past and current research at [redacted]. Given the unique, interdisciplinary background that [redacted] brings to [redacted] research, it is clear that [redacted] absence would detrimentally affect the important projects in which [redacted] is currently involved. While there may be other [redacted] citizen in [redacted] research field with a similar education or experiential pedigree, [redacted] clearly rises above to a substantially greater degree, such that [redacted] contributions and knowledge merit a waiver of the [redacted]. The inherent national interest of protecting the [redacted] workforce is far exceeded by [redacted] outstanding and continuous contributions to the [redacted] citizens health and welfare and the field of Health Sciences.

On the basis of this clear, independent and persuasive evidence of [redacted] work in the national interest of the [redacted], and on behalf of [redacted], we request favorable adjudication of this I-140 EB-2 NIW Petition.

Please do not hesitate to contact me with any questions or concerns in connection with the Petition.

Respectfully submitted,

[redacted]
Counsel for [redacted]

Enclosures: as noted
cc: [redacted] (via electronic mail, with enclosures)

[redacted]

Exhibit List

Exhibit 1: Passport Biographic Page and I-94 Card

Exhibit 2: [redacted] Degree in [redacted] from [redacted] University

Exhibit 3: [redacted] in [redacted] from [redacted] University

Exhibit 4: [redacted] Degree in [redacted] from [redacted]

Exhibit 5: Certificate Course in [redacted] from [redacted] from [redacted]

Exhibit 6: "[redacted]" for the performance at [redacted]

Exhibit 7: Curriculum Vitae

Exhibit 8: Offer Letter from [redacted].

Exhibit 9: List of Publications

Exhibit 10: Letter of Support – [redacted], MD, [redacted]

Exhibit 11: Letter of Support – [redacted]

Exhibit 12: Letter of Support – [redacted]

Exhibit 13: Letter of Support – [redacted]

Exhibit 14: Letter of Support – [redacted]

Exhibit 15: Letter of Support – [redacted]

[redacted]