



# **Business Plan and Research Paper**

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# **gHIVe Business Plan**

## **Executive Summary**

The first known case of Human Immunodeficiency Virus (HIV) in the U.S. was recorded in 1981. Since then, the virus has escalated into an epidemic and is now the leading cause of death in men ages 25-44. HIV is transmitted through direct exchange of bodily fluids, and has caused the death of millions of people. HIV attacks and destroys immune cells, and without a strong immune system, the body is unable to recover from secondary infections. The last stage of HIV infection is called Acquired Immunodeficiency Syndrome (AIDS). People who have developed AIDS have an unusually low number of T-helper cells, and therefore are often victims of infections and cancers that rarely occur in healthy people.

Our organization, gHIVe, was founded by a group of high school students from the Engineering and Science University Magnet School in New Haven, Connecticut. gHIVe is a nonprofit organization that strives to educate, empower, and assist individuals who have contracted HIV by providing visual information about the virus and the resources available to combat it. Many people do not fully comprehend the need and development of HIV tests, and others do not know how or if they can receive treatment after a positive diagnosis. Through the use of 3D models and animations, gHIVe endeavors to removes the stigma and fear associated with HIV by effectively demonstrating the biological effects of the disease, treatments, and scientific developments.

gHIVe's talented team of high school digital media specialists and animators will be producing a variety of models, videos, and games exhibiting the functionality of the HIV virus on a molecular scale. Our products will have a significant impact on the HIV/AIDS community, while educating high school students who may participate in our initiative in the future.

Although we currently have limited financial resources, we expect to receive support and funding from local universities, research facilities, and pharmaceutical companies.



## **Marketing Opportunities & Analysis**

When HIV was first reported in the United States in 1981, scientists and researchers had no way to combat the deadly infection. Patients were only expected to live a few years past diagnosis, and HIV tests were either nonexistent or extremely ineffective. But now, a variety of HIV tests are available, often at a drugstore or for free at a local clinic. And, newly developed antiretroviral drug therapies can keep a person alive throughout their normal lifespan.

However, HIV is still a serious public health concern in the U.S, largely because of the lack of general knowledge regarding this topic. The prevalence of HIV in Connecticut has increased consistently since 2009 and is likely to continue increasing. This clearly supports the need for our organization, as we live in a community that has demonstrated susceptibility to HIV but, for the most part, is ignorant of the virus's molecular structure and function.

The size of our market is relatively large. 330 cases were diagnosed in 2013 in CT, and 156 deaths were reported with HIV/AIDS as the cause. Our target market will also include the families, friends, and coworkers of these individuals who are affected by the presence of HIV in their lives. In addition, we may later expand our efforts to apply to people across the nation, where an average of 50,000 new HIV cases are diagnosed each year.

Several initiatives are currently in place to educate the public about HIV that are run by the Center for Disease Control and the World Health Organization. However, these organizations typically focus on prevention. They do not explain the basic biology of the HIV virus or offer detailed visual information to individuals who have already tested positive. This information is equally relevant in our world today, and the demand for our media will increase as the public becomes aware of the unique information and resources offered by our organization.

## **SWOT Analysis**

### **Strengths:**

- Strong instructional leader – Mr. Tynes (sustainability)
- Unique multigenerational approach that educates students as they research and develop media
- Digital media and 3D modeling training is a part of students' curricula and not the responsibility of the organization
- Digital media for HIV/AIDS awareness and education is not currently being developed by students
- Not for profit organizations are usually tax exempt
- Low startup capital requirements (consumer server & website)
- Grass-roots organization possesses cultural and political knowledge and awareness of local economic condition
- NGOs often have a volunteer staff in many roles, resulting in fewer staff on payroll
- The board of directors must by law be composed of volunteers, which can be an advantage to the company
- Most of the money and materials that nonprofits use for their operational costs and charity work come from donations

### **Weaknesses:**

- Lack of community awareness or involvement with the HIV/AIDS issue
- Little money to cover their expenses with revenue
- Lower in-house salaries for employees than for-profit competitors.
- Finding grants and applying for them is a considerable task
- Not for profit organizations are not totally in control of since they cannot force companies or people to give them money
- Underdeveloped board of trustees
- Limited issue expertise and resources
- Lack of demonstrated results

### **Opportunities:**

- Potential school district and university support
- Pharmaceutical support and funding

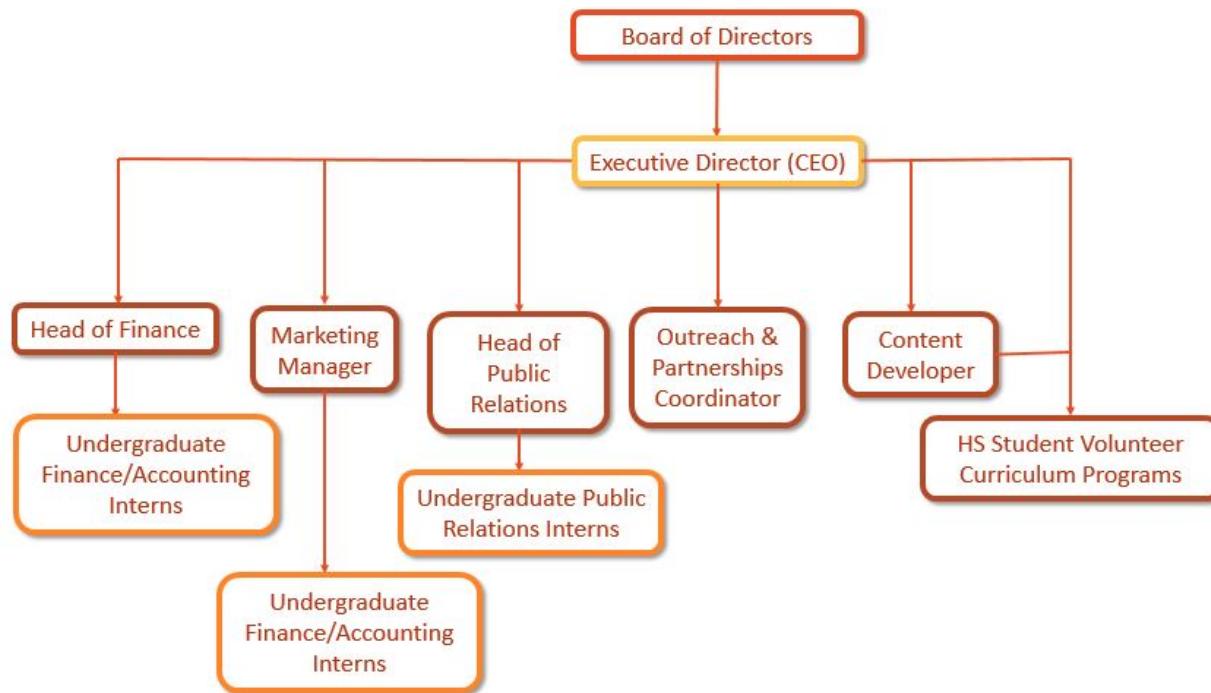
- HMO/PPO support and funding
- Little or no competition pertaining to student developed media
- Can overcome limited issue expertise and resources through university research partnerships
- Grant opportunities: government or private agency or group. There are many grants being offered even during a recession
- Alliances with other organizations & commercial business or other NGOs
- May be also eligible for many types of tax deductions and exemptions
- Cause marketing - a system in which a portion of a purchase price charged by a commercial business is donated to a specific charity

#### Threats:

- Vulnerability to economic crises and instability
- Digital media developed by research organizations or pharmaceutical companies (Kirschbaum, 2004)
- Lack of participation or encouragement by faculty and students at institutions of learning
- Increased scrutiny on accounting and booking practices avoid the perception of impropriety
- Weakened HIV/AIDS advocacy in the United States as patients on ARV treatment live longer
- Grass-roots organization may set up unsustainable initiatives without linking to wider trade development solutions
- Too much competition from many nonprofit organizations working for the same purpose of HIV/AIDS education and awareness
- The ability to organize substantive and meaningful fundraisers to help raise money and boost brand recognition

## Organization Description

gHIVe was founded in 2015 with the mission to create digital media to inform the public about the HIV virus. Our goal is to advocate for a better understanding of the necessity of HIV testing and drug adherence, as well as explain new scientific research regarding treatments, vaccinations, and potential cures. Our 3D models, animations, and videos will present crucial information about HIV virus that is not commonly known.



## Milestones

May 18th, 2015

Our first two-minute video will be unveiled on May 18th to commemorate HIV Vaccine Awareness Day. This project explores the viability of a vaccine and how it might combat the HIV virus inside the body. “This observance provides an opportunity to recognize and thank the many volunteers, community members, health professionals, and scientists who are working together to find a safe and effective preventive HIV vaccine. It is also a day to educate communities across the nation about the importance of preventive HIV vaccine research.”

(AIDS.gov)

June 6th, 2015

On June 6th, the gHIVe project will be showcased at the CT Student Innovation Exposition. It will be evaluated based on the project’s viability, creativity, development, and documentation. By this deadline, our website will be completed, and we will have created a wide variety of videos, 3D models, and animations.

Date TBD

We will expand our initiative to include other students in CT, engaging them in a unique, meaningful learning project that will have a significant impact on their communities.

Date TBD

gHIVe will approach local and national hospitals, research facilities, and pharmaceutical companies and develop partnerships with several different companies and institutions. These partnerships will provide gHIVe with financial resources and access to experts in the field of HIV/AIDS research.

## **Marketing Plan**

### **Target Customers**

The CDC reports the following demographic information: 1,201,100 persons aged 13 years and older are living with HIV infection. Gay, bisexual, and other men who have sex with men (MSM) of all races and ethnicities remain the population most profoundly affected by HIV. Blacks/African Americans continue to experience the most severe burden of HIV, compared with other races and ethnicities. HIV also disproportionately affects Hispanics/Latinos. According to the Centers for Disease Control and Prevention, 15 percent of new HIV/AIDS cases occur in people age 50 or older.

It is critical that we initially focus on fact-based informative videos to educate affected parties and supporters about the 5 focus areas on a molecular level. However, the secondary layer of videos will highlight issues that are specifically problematic for the aforementioned subgroups. This approach will allow gHIVe to build a comprehensive database that may be used in the medical, psychological, and sociological communities to inform patients and supporters pertaining to their demographic profile, which could increase comprehension and data retention within those immediate audiences.

The ancillary customer is the new generation (13-18 years old) and their peers. Students in this age group will be researching and developing the gHIVe media. They will also be learning about the HIV/AIDS pandemic as they construct their work product, and will be sharing their experiences through gHIVe's social media outlets.

## **Unique “Selling” Proposition (USP)**

Although gHIVe doesn’t plan to sell anything as a NGO, a unique market position exists. Currently, molecular HIV videos are developed to inform researchers and doctors. Our approach breaks down the medical and biological jargon using similar 3D structures to explain to patients and supporters how the viruses detected, its response to treatment and drug resistance, and illustrate the science behind a possible vaccine & cure.

## **Distribution Plan**

Our initial distribution model will be YouTube given its “free” status. The gHIVe website will feature embedded videos that link to the YouTube files, thus, creating an appearance that we are hosting and streaming the media on our own server. As we develop a body of digital media, we will work to host our own server and store/stream content. Our website will be retooled to feature “free” accounts to build a database of users.

## **Marketing Materials**

Our marketing materials will be the collateral you use to promote your organization to current and prospective users. We will work to stay in the digital realm in crafting our promotions, but some offline development will be necessary. Among others, they include our website, social media advertisements, business cards, pens and brochures. In markets largely affected by HIV/AIDS such as Atlanta, which was recently ranked the No. 1 city for new HIV/AIDS cases, traditional marketing in conjunction with our digital efforts are essential. Strategic placement of signage in clinics, social work agencies, etc. will be highly effective.

Giveaways such as branded hats and t-shirts distributed at events to HIV supporters and industry professionals will also help establish awareness of our brand and digital media.

## Promotions/Marketing Strategy

Our “free” membership and product offerings will be the primary message that will help us reach new users. We will employ promotional tactics such as related search engine ads, social media ads based on keyword searches, medical trade show marketing, press releases, online advertising, and HIV/AIDS event marketing.

The four key components to our online marketing strategy are as follows:

1. *Keyword Strategy*: we will start by brainstorming potential keywords, and see how competing HIV organizations look by using the Google AdWords Keyword Tool. If we observe that some keywords are redundant in our market, we will create long-tail keywords (between two and five words), which will be simpler to rank and develop phrase exclusivity in the search engines.
2. *Search Engine Optimization Strategy*: gHIVe will monitor our website metrics to fine-tune our page titles and descriptions to create relevant Meta tags for search engines. We will also build backlinks by submitting monthly or bi-monthly press releases on any innovative HIV NGO, and link to popular blogs in our market to develop a synergy and obtain a backlink from their website. We will focus on quality content development so people talking about the products we offer will link back. Furthermore, gHIVe will continuously develop graphics and newsworthy content that will influence bloggers and news websites to link that content. We will establish a strong social media presence on

sites like Facebook, Pinterest, Twitter, etc. as these sites send search engines signals of influence and authority.

3. *Paid Online Advertising Strategy:* gHIVe plans to work with major search engines to place ads based on searches for STI and HIV/AIDS information. However, these strategies will be limited given our NGO status and inherent restrictive revenue possibilities.
4. *Social Media Strategy:* Initially, we will use social media actively to document our emergence into the HIV/AIDS education and support market. We will then work to differentiate ourselves from other NGO's by highlighting our purpose of developing supportive scientific digital media designed with the layperson in mind. Once our purpose is established in the HIV/AIDS community, we will work to develop a consistent and clear message pertaining to our core values, mission statement, goals, deadlines, and brand image.

## Joint Ventures & Partnerships

Pharmaceutical Companies - Partnerships with pharmaceutical companies are essential to gHIVe's sustainability given their financial strength and prowess amongst the medical community. These companies have the ability to effortlessly fund gHIVe's initiatives and capital expenditures without jeopardizing their bottom line.

Universities - Synergies with universities are critical to success as they have the ability to advise the student developers about current and future developments regarding HIV/AIDS issues as they develop media. Also, much of the groundbreaking developments come from university research.

Other NGO's – These alliances are critical for organizational and product exposure. The participating organizations could include gHIVe in tradeshows and promotional events.

### **Retention Strategy:**

By using retention strategies such as a monthly newsletter or customer loyalty program, you can increase subscribers, partnerships and sponsorships by getting users to view content more frequently over time.

### **Financial Projections**

Financial sustainability can be gauged by an organization's net income (the surplus of revenues over expenses); liquidity (the cash available to pay bills); and solvency (the relationship of assets and debt or liabilities). The unique element of the gHIVe organization is that students will develop the media. As a result, the organization will have minimal staff on payroll, and more cash available for expenditures. In the early years, the company will be relatively liquid because it will not immediately require physical offices or technological hardware. The organization will use existing technological models to develop and distribute media for the first three years. In the meantime, the organization will develop financial partnerships with pharmaceutical companies, hospitals or universities to obtain a server to host the website and store/stream its content.

# gHIVe Research Paper

## The Virus

### What is it?

Human Immunodeficiency Virus (HIV) is classified under the retroviridae family, and the lentivirus subfamily. Retroviridae is a family of virus that is known for having a retroviral envelope that protects the RNA while allowing the virus to bind to the membrane of the targeted host cells. The subfamily lentivirus is characterized by its ability to lie dormant in an infected host cell for long periods of time (Francki 1991). The first known case of HIV in the U.S. was recorded in 1981. Since then, the virus has escalated into an epidemic and is now the leading cause of death in men ages 25-44 (Holland, 2013). HIV is transmitted through direct exchange of bodily fluids, and once contracted, it is usually fatal over time.

Despite its deadly effects, the HIV virus is surprisingly simplistic in structure. With only 9 genes producing 15 different proteins, it manages to inject its genetic material into the body's cells. After successfully entering a cell, the virus will quickly pass through the nuclear membrane and begin integrating its DNA into the host's genome. HIV does not destroy the host cell immediately, but manipulates the cell's own replicating machinery to make more copies of the virus, a characteristic unique to retroviruses. The virus specifically targets cells in the immune system, inhibiting their ability to fight off other diseases (Greene, 2006). CD4+ T-cells are particularly at risk, white blood cells whose role in the immune system is to activate other cells that secrete antibodies or kill infected cells (Albert 2002).

### How is it contracted?

HIV is spread through contact with the blood, semen, pre-seminal fluid, vaginal fluids, rectal fluids, or breast milk from a person infected with HIV. In the United States, HIV is most commonly spread through sexual intercourse or sharing drug injection equipment with someone who has HIV. Previously, there was a risk that a patient might become infected after receiving a blood transfusion or organ transplant from an HIV-infected donor. However, now that blood and organ donors are more carefully screened, this risk is significantly lower.

Hugging, kissing, or shaking hands with a person infected with HIV does not transmit HIV. Neither is the disease transmitted through contact with objects such as toilet seats, doorknobs, or dishes used by a person infected with HIV (AIDSinfo, 2015). Person to person contact with one of the above body fluids is the only way to contract the infection.

How can I avoid contracting it?

Anyone can get HIV, but there are certain measures a person can take to reduce the risk of infection.

- Get tested and know one's partner's HIV status. Individuals must talk to their partner about HIV testing and get tested before having sex.
- Have less risky sex. Oral sex is much less risky than anal or vaginal sex. Anal sex is the most likely type of sex to spread HIV.
- Use condoms. A person should use a condom every time they have vaginal, anal, or oral sex.
- Limit the number of sexual partners. If a person has more than one sexual partner, get tested for HIV regularly. Get tested and treated for sexually transmitted infections

(STIs), and insist that partners do too. Having an STI can increase the risk of becoming infected with HIV.

- Talk to a healthcare provider about pre-exposure prophylaxis (PrEP). PrEP is an HIV prevention method that involves taking an HIV medicine every day. PrEP is intended for people who don't have HIV, but who are at high risk of sexually transmitted HIV infection. PrEP should always be combined with other prevention methods, including condom use.
- Avoid IV drug use. Use only sterile drug injection equipment and never share equipment with others.

#### How is it treated?

Currently, there is no cure for HIV, but there are treatments that allow HIV-infected individuals to live with minimal or no symptoms. Certain medicines can slow the growth of the virus or stop it from replicating. These drugs do not eliminate the virus from the body, but they keep the amount of virus in the blood low. The amount of the virus in the blood is called the viral load, and it can be measured by a simple test.

### HIV Replication Cycle

After successfully entering a host cell, the virus envelope disassociates from the cell to release viral RNA and enzymes. Next, the reverse transcriptase begins translating the viral RNA into complementary DNA and uses these cDNA molecules to enter the nucleus of the host cell undetected. After entering the host nucleus, the integrase enzyme binds cDNA molecules to the host DNA, creating provirus DNA that can lie dormant for years. The virus can then begin to

replicate by transcribing viral DNA into mRNA, which subsequently enters the cytoplasm to be translated to TAT's and REV's. TAT's are proteins that help to catalyst viral production, and REV's bind to the viral mRNA, allowing unspliced RNA strands to leave the binding site (Biol 2012).

GAG and ENV proteins are also created from the translation of the full length RNA. The GAG proteins bind to the RNA to form the nucleocapsid of the new virus cell. The ENV proteins are transported to the Golgi apparatus of the infected host cell where they are cleaved off to form two new proteins: gp41 and gp120. The new proteins travel across the plasma membrane where they are attached to the unformed virion. Gp41 forms the membrane of the virion, and gp120 anchors itself to the inner membrane of the host cell. The virion is now completely formed and begins to bud from the infected host cell, but is still immature until the nucleocapsid, capsid, and the matrix of the virus are cleaved properly by the protease of the virus. When these organelles have been cleaved, the virion becomes a full HIV virus cell, destroying the original host cell in the process. After the HIV virus leaves the cell, it is now able to spread to other macrophages and T-cells, continuing its cycle.

## Testing

Over one million people are estimated to be living with HIV/AIDS in the United States as of 2011. Of those individuals, 14% had infections that were not been properly diagnosed. HIV tests are a relatively recent development in this field of study, but they are crucial to receiving proper treatment and care. Many different tests have emerged in the past few years, including antigen and RNA tests that detect HIV directly and antibody tests that detect the proteins produced by the body as a defense against the virus. Previously, HIV testing required a blood

sample, and while this is still the most reliable method, oral tests are now available as well. Some rapid tests are able to detect the virus's presence as soon as three weeks after exposure (CDC, 2015).

### Where can I get tested?

You can ask your healthcare provider for an HIV test. In addition, you can get free HIV tests at medical clinics, substance abuse treatment programs, community health centers, hospitals, Title X Family Planning Clinics, pharmacies, and many community-based organizations, AIDS services organizations, and even mobile testing vans.

### Antiretroviral Drugs

Highly active antiretroviral therapy (HAART) is a widely used treatment for HIV. Many classes of antiretroviral drugs are available, and multiple drugs are often necessary to slow the progression of the HIV infection. These drugs prevent HIV from growing and multiplying, thus lowering the viral load in the bloodstream, and reducing the likelihood that a patient will infect others. HIV antiretroviral drugs are not a cure, but they can extend a patient's life for many years.

Each antiretroviral treatment (ART) targets a different stage of HIV infection. For example, entry inhibitor drugs prevent HIV viruses from binding to a cell. Others prevent HIV from fusing with the cell membrane, copying its DNA, or assembling new viruses (NIH, 2013). Because HIV is always mutating and developing resistance to drugs, it is recommended that patients take three or more drugs in combination to minimize resistance.

## Adherence

While HIV medications can often keep a patient alive throughout their normal lifespan, it is crucial that they be taken consistently. Skipping a dose of medication or taking two doses at once can be detrimental to a patient's health. "HIV meds need to be maintained at high enough levels in the blood, 24 hours a day, every day" (AIDS Meds, 2014). If these levels are not maintained, the HIV virus will continue to mutate and replicate, which can lead to drug resistance. An estimated "77% of patients in the United States taking ART have suppressed viral loads" and "only 28% of all persons with HIV have virus levels that are fully suppressed" (Centers for Disease Control and Prevention, 2014). Although ART has proven to be successful in many patients, adherence to ART is the leading issue related to the successful suppression of the disease in the United States. In fact, a major study that evaluated whether Americans take their ART drugs every day recently reported failing statistics (McNeil, 2015). McNeil (2015) also reported that "only a quarter of all 1.1 million Americans with HIV are taking their drugs regularly enough to not be infectious."

Failure to take HIV medications consistently can lead to many issues. One significant public health problem arises when adaptations of HIV develop while a person is inconsistently taking HIV medicines, leading to new, drug-resistant strains of HIV (Department of Health and Human Services USA, 2015). Another adherence issue is that HIV attacks and kills white blood cells. An insufficient number of white blood cells can lead to a weak immune system, taking away the body's ability to fight off common bacteria and viruses.

Scientists have recently begun working to find a viable long-term solution to the issue of ART adherence and drug resistance by developing a device similar to a contraceptive implant. This device dispenses a consistent amount of the antiretroviral drug and "can be inserted into the

upper arm” (Carstensen, 2015). Dr. Mark Baum, founder of the Oak Crest Institute of Science, commented that this implant “will revolutionize how we treat or prevent HIV/AIDS as it delivers powerful HIV-stopping drugs and eliminates one of the key obstacles in HIV/AIDS prevention – adherence to proper dosing regimens” (Maskaly, 2015).

## The Search for a Vaccine

Several potential vaccines are currently being developed, but the process is slow. One of the largest setbacks is that HIV viruses are continuously evolving. HIV has such a high mutation rate so it quickly becomes immune to the drugs used to treat it (Taylor, 2006). HIV viruses are not uniform and react differently to treatment depending on the individual patient. A successful vaccine must take into account the diversity of the HIV virus.

Additionally, our understanding of the molecular biology of HIV is very limited. According to theoretical predictions, the virus should be swiftly eliminated by the immune system upon entering the body. But, it isn’t. Somehow, the virus manages to evade the body’s natural defenses and infect our cells anyway. Until this process is better understood, a vaccine may not be a viable option.

The latest vaccine development is centered on a 59-year-old man that is part of very rare group of HIV-positive patients who never develop HIV/AIDS because their immune systems are able to aggressively destroy the virus (Daily Mail, 2015). Researchers hypothesize that a chemical injection will strengthen the immune system with a 'kick and kill' strategy to chemically flush out dormant HIV viruses hiding in white blood cells, allowing a boosted immune system to identify and kill the cells (Lay, 2015). “The way [o]ur immune system [may] rapidly control HIV-1 tells us a lot about the types of immune responses we should target and

augment through vaccination,” said Nilu Goonetilleke, PhD and assistant professor at the University of North Carolina School of Medicine (Fitzpatrick, 2015).

## The Search for a Cure

HIV is treatable, but not curable. Medications can keep a patient alive throughout their normal lifespan, but they are unable to eliminate the virus entirely. According to the National Institute of Allergy and Infectious Diseases, HIV cure research is currently focusing on identifying latent HIV viruses throughout the body and understanding the ways that HIV survives current treatments (NIH, 2015).

One significant issue facing HIV cure researchers is the existence of the HIV reservoir, a small group of cells that contain HIV DNA hidden in their genomes. This reservoir poses a serious problem to researchers because it exists even in patients that appear to be cured of the infection. Antiretroviral drugs can keep the HIV cells dormant, but if a patient stops taking their medications, they will experience a relapse (Cohen, 2014).

In early 2015, a possible cure received FDA approval to begin clinical trials on humans. The cure is based off a rare white blood cell mutation that makes a small percentage of individuals immune to HIV infection. Researchers at Sangamo BioSciences Inc. have removed stem cells from HIV patients and genetically modified them, causing them to form white blood cells with the desired immune mutation. This treatment worked extremely well in a small test study conducted on 12 patients and will now be tested on a much larger scale (Dovey, 2015). If proven to be safe and effective, these researchers could be one step closer to a cure for HIV.

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