



Helping to Light the Spark for Medical Breakthroughs



Photo by Robert A. Lisak

Members of the historic African Methodist Episcopal Zion Church partner with the Yale Center for Clinical Investigation to promote clinical research in communities of color.

As Cultural Ambassadors, members of our community have acted as vital partners to researchers at the Yale School of Medicine, and its strong tradition of developing promising new treatments and therapies. Yale doctors were the first in the U.S. to use chemotherapy to treat cancer. They developed the first artificial heart pump in the country, along with the first antiviral drug and the insulin pump used in treating diabetes. And recently, Yale researchers, including Dr. Onyema Ogbuagu, have been at the forefront of developing new vaccine technology that today can prevent Covid-19, but has the potential in the future to fight cancer.

The spark for these and other medical advances begins in the laboratory, but they wouldn't have been possible without the thousands of volunteers who agreed to participate in clinical trials. Our Cultural Ambassadors have helped ensure that our community has a seat at the table when it comes to developing therapies for medical conditions that so many people face, such as heart disease, diabetes, and asthma. Medicines like your blood pressure medicine, your child's asthma inhaler, and the antidepressant your friend relies on are all available as a result of clinical trials that show they are safe and effective.

We are so proud to be part of a community that believes it is our duty to contribute.

Thank you to all of our Cultural Ambassadors, and all of the volunteers they have inspired to participate in clinical research. We're grateful to you for helping us bring new treatments to the people who need them.

We have been volunteers in clinical research ourselves, and we are so proud to be part of a community that believes it is our duty to contribute to the good health of friends, family, and people everywhere through this act of service. When minority groups are not represented in research and the medical evidence it generates, this raises a serious social justice concern. We are so proud to be part of a community that believes so passionately about this.

With our help and input, Yale has become a national leader in health equity and community engagement in clinical research. The participation of the Cultural Ambassadors, both in the AME Zion Church and our sister organization, Junta, made a clear impact on the diversity of clinical research at Yale. Our experience has led us to become expert resources, advising Yale investigators on how to reach minority communities and ensure our voices are not only heard, but heard in a sensitive, respectful, and culturally aware manner.

And the result is clear: when the partnership was launched, only between 2 and 4 percent of total enrollment in clinical trials at Yale included people of color. In 2021, more than 31 percent of total enrollment was participants from communities of color and in the past 5 years, studies that engaged the Cultural Ambassadors can report approximately 61 percent of total enrollment from underrepresented communities.

Every day, there is a clinical trial happening at Yale that has the potential to change lives in the future. The spark of innovation is always lit, and the dedication and drive of our Cultural Ambassadors and volunteers goes on and on. We encourage you to learn more about participating in research, and the benefit it can provide not only to you, but to our community as a whole.

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The Snowball Effect: Cultural Ambassadors build on their participation in clinical trials to continue to bring new therapies to light.

Dr. Onyema Ogbuagu led a study at Yale that tested the efficacy of a new type of technology, the mRNA vaccine, in preventing the spread of Covid-19. As a result, millions of people worldwide gained access to a lifesaving vaccine. Now, Dr. Ogbuagu is leading a clinical trial to examine if mRNA technology can be used to build a better influenza vaccine. As he did with the Covid-19 study, he is calling on the Cultural Ambassadors for crucial assistance.

mRNA technology has an advantage over previous vaccine technologies, because they can be developed more quickly, and thus respond in real time to public health emergencies, such as Covid or influenza outbreaks, as they arise. The urgency of the Covid-19 pandemic provided the first real-world test for the new mRNA vaccines in human clinical trials. "Looking back, it's been amazing that a platform that was tested on a large scale with a changing virus has led to millions of people around the globe getting vaccinated," said Dr. Ogbuagu. "It's a tool we have learned how to use, and we will keep applying it to other infectious diseases."

Many trials have begun that test the technology in a variety of diseases, including Type 1 diabetes, Shingles, RSV, Lyme Disease, and even cancers such as melanoma. "We have very nimble vaccine technology and it is exciting to see where we go from here."

Influenza is a strong candidate for the next clinical trial, because each year, it makes so many ill, and causes so many deaths. A more effective vaccine could prevent many of the 700,000 flu hospitalizations and 52,000 deaths in the U.S. annually.

In developing the current flu vaccine, scientists must predict the strains of the flu that are most likely to circulate in the upcoming season, using data collected previously from parts of the world that experience an earlier flu season. Significant lead time is then needed to manufacture enough vaccines. If the vaccine turns out to be a poor match for the flu strains that develop, the opportunity to prevent widespread seasonal flu is lost.

"With this technology for the first time, we get a do-over where we can redesign a vaccine within the same season and hopefully deploy it on time," says Dr. Ogbuagu. In his research, he says, he can draw some inferences from our collective experience with the Covid pandemic. As with Covid, people get sick and well quickly, and in large numbers, as compared with a disease that moves more slowly, like HIV. This makes respiratory viruses easier to study.

Because we are all so susceptible to respiratory viruses, so many of us can help vaccine development by participating in clinical trials. Yet clinical trial participants don't always reflect the people the vaccines are trying to help. This is why Dr. Ogbuagu called on the Cultural Ambassadors to participate in his Covid trial, and now in his influenza



Photo by Anthony DeCarlo

Onyema Ogbuagu, MBBCh, FACP, FIDSA explained the development of the authorized COVID-19 vaccines.

trial. "The Cultural Ambassadors have been great for vaccine trials," he says. "Even globally the relative proportion of minorities was way below what we wanted, which was especially problematic for Covid, which disproportionately affected people of color."

The Cultural Ambassadors program can boost the representation of minority communities in clinical trials, making sure their health needs are addressed in the end result. By engaging these communities through trusted messengers, such as their pastors, researchers can build trust and relationships with patients and potential volunteers for clinical trials, who will then know what they are doing is not only safe, but helps their communities thrive. "Building that community engagement and partnership with the Cultural Ambassadors has been very fruitful," says Dr. Ogbuagu. As more people participate, and learn how clinical trials work, more people are encouraged to participate, growing the number of diverse volunteers for future studies. "There is a snowball effect. People come in and because they have a good experience, they then recruit their families and contacts, and the leaders lead by example."

"We are so proud of what we have achieved with the Cultural Ambassadors," says Dr. Ogbuagu. In the Pfizer Covid study, the Yale site achieved a 40 percent minority participation rate, which was much higher than other sites in the trial worldwide. Dr. Ogbuagu hopes for the same level of participation with the influenza trial.

"The beautiful thing is when you have the next study, you literally call up the same people," he says of his trusted community of Cultural Ambassadors. "When you participate, you understand the roles you play in advancing new therapies, so it is a much easier conversation. The trust you establish in that interaction is such great currency for future studies." So far, many of the same people who participated in the Covid study are participating in the influenza trial, and hopefully more will join.

Dr. Ogbuagu joined Rev. Perry and Rev. Clayton on the Tom Ficklin Show for a conversation on New Frontiers in Vaccines for Infectious Diseases. Scan the QR Code to view this show.



Breakthroughs in the Treatment of Depression

Depression is more than just mood swings and feelings of sadness. It is a serious mood disorder that affects 280 million people across the world, according to the World Health Organization. Yet for the past 50 years, there have been no major breakthroughs for this condition that affects the lives of so many.

In 2019, this changed, thanks to the pioneering research of a Yale physician. The Food and Drug Administration approved the use of a drug derived from ketamine, in the form of a nasal spray called Esketamine, or Spravato, that was discovered to be an effective treatment for depression. In one clinical trial, 70 percent of patients who did not respond to other treatments improved on Esketamine.

John Krystal, MD, now the chair of Psychiatry at Yale School of Medicine and co-director of YCCI, is one of the pioneers of the use of ketamine to treat depression. In the early 1990s, Dr. Krystal and his colleagues began studying ketamine and its influence on the neurotransmitter glutamate in symptoms of schizophrenia. He and his collaborator, Dennis Charney, MD, then began to contemplate glutamate's effect on depression as well. This was a new line of inquiry: previous research had focused almost exclusively on other neurotransmitters, serotonin and norepinephrine, and established antidepressant treatments worked to increase serotonin levels (SSRIs). Ketamine as a treatment was met with some skepticism as well, since at that time it was known as a street drug, Special K, with hallucinatory effects. Ketamine was also widely used as anesthesia during surgeries.

Since its initial discovery, Krystal and a team of Yale researchers have conducted clinical trials that gave patients intravenous doses of ketamine, less than what would be used in anesthesia, in controlled clinic settings. These were patients with severe depression who had not seen improvement with standard antidepressant treatments such as SSRIs. The results were dramatic: more than half of participants showed a significant decrease in depression symptoms after just 24 hours. These are patients who felt no meaningful improvement on other antidepressant medications.

The late Ronald Duman, MD, of the Yale Department of Psychiatry, also showed that ketamine produced its antidepressant effects by triggering the release of glutamate, which essentially creates new neural connections in the brain that persist long after the drug has left the body. Ultimately, this process can make the brain more adaptable and open to developing new positive thoughts and behavior patterns to combat depression. This had not been seen with previous antidepressant treatments. As a result, patients taking ketamine and Esketamine can take doses relatively infrequently, approximately every 2 to 3 weeks, with most patients being maintained on a dose every 2-3 weeks. Perhaps because of its novel effects, ketamine and Esketamine not only act more rapidly than prior antidepressants, but



Photo by Robert A. Lisak

John Krystal, MD is a leading expert in the areas of depression, alcoholism, schizophrenia, and post-traumatic stress disorder. He is best known for leading the discovery of ketamine's rapid antidepressant effects.

they are more effective for treatment-resistant depression symptoms, and better protect against depression relapse.

Dr. Krystal's findings were published in a now widely cited paper

and his work brought about a revolution in the understanding of depression. With FDA approval, the drug is beginning to reach a growing number of people with depression, who take ketamine in combination with other established treatments for depression.

Dr. Krystal and his colleagues continue to study ways to

optimize ketamine treatment through combining ketamine with psychotherapy or other medications. For example, at Yale, Ilan Harpaz-Rotem, PhD, found that reactivating trauma memories prior to ketamine administration produces long-lasting relief from those memories. Similarly, Dr. Krystal's team found that combining ketamine with another drug, rapamycin, extended the duration of ketamine benefits. A company called Freedom Biosciences is developing this new combination as a treatment.

The dedication of volunteers participating in clinical research means that researchers like Dr. Krystal and his collaborators can deliver a long-awaited improvement in depression treatment to millions of people. With the continued partnership of clinical research, the paradigms for treatment will continue to shift and improve until the effects of depression can finally decrease for people all over the world.

"The results were dramatic: more than half of participants showed a significant decrease in depression symptoms after just 24 hours."

Bridging the Gap Between Generations

The Cultural Ambassadors seek to educate and inform all segments of our community. This includes our young adults. In order to reach this demographic, the Cultural Ambassadors enlisted the help of young leaders who were already making an impact within their sphere of influence. The AME Zion Young Ambassadors program seeks to develop students of faith, science, intellect, and character who have skills and the desire to continue learning; who welcome the opportunity to serve as Cultural Ambassadors through the partnership with YCCI at Yale. To assist our Young Ambassadors, they have been assigned pastor mentors who will expedite their growth and development.



Jolly Black is a graduate of St. Augustine's University where he earned his Bachelor's Degree in Business Administration & Management. He's currently employed by New Opportunities Inc., where he serves as an Employment Specialist. In this role, Mr. Black helps adults and students transition into the working world by assisting them with finding employment, supporting them as they prepare for interviews, evaluating their work abilities, and building a case report that details how they can ensure future success.



Harmony Jones Duncan was born in Philadelphia, PA and moved to Middletown, CT at the age of 2. She is proud to be an alumna of the Middletown Public School District where she developed her love for business management. Ms. Jones graduated Class of 2019, with her Bachelor's Degree in Business Management. She currently works for the Ministerial Health Fellowship as a Covid-19 Counselor serving Middlesex County in CT.

Harmony holds a Community Health Worker certification with the state of CT.



Megan Perry is a member of St. Stephens AME Zion Church in Branford, CT. She graduated with a BA in English and a minor in Women and Gender Studies. She then earned her MA in Global Media and International Communications, and is currently pursuing an Ed.D in Educational Leadership.

Ms. Perry is also a proud member of Alpha Kappa Alpha Sorority, Inc. She is currently a Regional Resource & Data Specialist at The WorkPlace.



Shai Turner was born and raised in Middletown, CT. He attended Middletown High School where he developed his love for sports. It was through playing flag football with his friends that he was able to stay connected to his community while remaining active. Mr. Turner graduated from American International College with a BS in Public Health and currently works as a COVID-19 Crisis Counselor for the Ministerial Health Fellowship Advocacy Coalition for Middlesex County.

Shai holds a Community Health Worker certification with the state of CT.

Photos by Robert A. Lisak

Bringing Research to the Community: The 2023 YCCI Community Health Fair

On a sunny August day, more than 30 study teams set up in Scantlebury Park in New Haven, CT to tell residents about the cutting-edge research happening at Yale. There were studies on Alzheimer's Disease, autism, mental health, substance use, kidney disease, cancer, heart disease, COVID-19, and the *All of Us* program. Attendees had access to a health kiosk demo, blood donation information, health screenings, and information from Southern Connecticut State University College of Health and Human Services. The event was enhanced by free food, music, Zumba, face painting, a 360 Photo booth, and a special visit from Yale's mascot Handsome Dan and Heidi.



HELP US DISCOVER | Be Part of Clinical Research at Yale.

Yale has hundreds of clinical studies under way for a wide variety of conditions. None of them would be possible without volunteers who were willing to take part in clinical studies. Volunteers like you are the only way for medical breakthroughs to reach the public. Please consider participating in a clinical study and helping Yale continue its tradition of advancing medical knowledge.

Emotion Regulation in Children

Do you have a child between the ages of 5 and 15?



If you have a **child who is 5 to 15 years old** and has **disruptive behaviors** (such as anger, irritability, or aggression), they may be eligible to participate in a *free and confidential* study that examines your child's social and emotional skills. This research will lead to new ways of understanding how children processes and regulate their emotions. *Compensation up to \$100.*

If interested, contact us at (203) 785-7565 or email emotion@yale.edu

HIC #2000031303

Teen Binge Eating Study

Binge eating is a problem.

Teens 12 to 17 years old who are concerned about binge eating or their weight, may be eligible to participate in a *free and confidential* study that will test a new psychological treatment (talk therapy) that helps with healthy eating and nutrition. *Compensation of \$300.*

To learn more or see if you are eligible to participate, please call Yale Teen POWER at (203) 785-7210 or visit our website at m.yale.edu/teenpower

HIC #2000024926



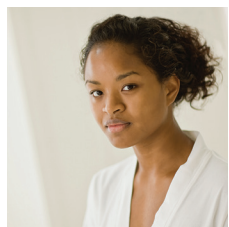
Sarcoidosis or Granuloma Annulare Study

Have you been diagnosed with Sarcoidosis or Granuloma Annulare?

If you are **18 years of age or older** and have been diagnosed with **cutaneous sarcoidosis or granuloma annulare (GA)**, you may be eligible to participate in a *free and confidential* study that may help the clearance of skin lesions and improve the way you feel. *Compensation up to \$500.*

To learn more or to see if you are eligible to participate, please contact Yvette Strong at (203) 737-2506 or email yvette.strong@yale.edu

HIC #2000023910



Mood Disorders Study

A Free Research Study on Talk Therapy

If you are **between the ages of 16 and 29 years, have symptoms or a diagnosis of bipolar disorder or depression**, you may be eligible to participate in a *free and confidential* research study on a talk therapy on improving mood symptoms and helping to reduce the risk of suicide. This study also looks at how the brain works with advanced MRI brain scanning techniques. *Compensation up to \$540*

To learn more or to see if you are eligible to participate, please contact Erin at (203) 737-2507 or Bernadette at (203) 737-2868.

HIC #2000032361



Child Development & Autism

Is your child on the autism spectrum?

The Autism Biomarkers Consortium for Clinical Trials (ABC-CT) is seeking families to participate in a study to improve diagnosis and treatment in Autism Spectrum Disorder (ASD). We are currently recruiting **both typically developing children and children with a diagnosis of ASD between the ages of 6 and 11 years old**. A diagnostic and cognitive evaluation is provided to all participants at no cost. *Participants will be compensated \$300.*

To learn more about the study, or to participate, please call us at (203) 785-6108, email our team at abc-ct@yale.edu

HIC #1509016477

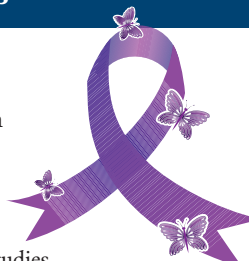


Lupus Studies

Do you have active Lupus?

If you are **18 years of age or older** and have been diagnosed with **Lupus**, you may be eligible to participate in a treatment study. There are very few treatment options available to patients with Lupus. Dr. Koumpouras at Yale University is currently conducting several clinical research studies that examine investigational new treatments for Lupus symptoms. *Compensation is offered, but varies by study.*

To learn more about our clinical trials program and see if you are eligible, please contact Julie Hefferman, Study Coordinator at (203) 785-6631 or email julie.hefferman@yale.edu



Menthol Smoking & Cigarette Study

Do you smoke menthol cigarettes regularly and are not looking to quit? Ever tried e-cigarettes/vapes?



If you are **at least 21 years old and identify as Black or African American, smoke menthol cigarettes regularly and have tried e-cigarettes/vapes**, you may be eligible for a confidential study. This study seeks to understand how menthol and nicotine affects the body. *Compensation up to \$530.*

African Americans are more likely than Whites to die from tobacco-related diseases. Therefore, it is important to understand tobacco use in African Americans.

To learn more or see if you are eligible to participate, call or text (475) 241-4904.

HIC #2000025687

All of Us Research Program

All of Us RESEARCH PROGRAM | The Future of Health Begins With You

The All of Us Research Program is inviting one million people across the U.S. to help build one of the most diverse health databases in history. We welcome participants from all backgrounds. Researchers will use the data to learn how our biology, lifestyle, and environment affect health. This may one day help them find ways to treat and prevent disease.



Scan the QR code for more information and to sign up.

HIC #2000034651

Sleep Study

Interested in learning more about your health and how drinking affects your body?

If you are **18 to 25 years old**, you may be eligible to participate in a *free and confidential* study conducted by Dr. Lisa Fucito. *Compensation up to \$279.*



To learn more or to see if you are eligible to participate, call (203) 430-4714, scan the QR code, or visit sleepstudy@yale.edu

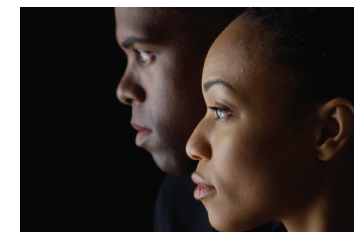


HIC #2000030417

Racial Stress Study

Have you ever experienced stress due to racism?

Do you identify as **Black, drink alcohol, and have you ever experienced stress due to racism?** If so, you may be eligible to participate in a *confidential* study. *Compensation is \$130*



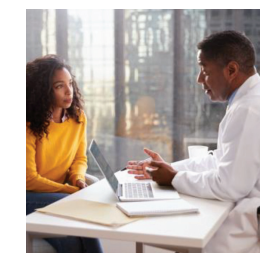
To learn more or to see if you are eligible to participate, please contact us at (203) 494-5250 or email: the.real@yale.edu

HIC #2000033162

Kidney Disease Study

Have you been diagnosed with kidney disease?

If you are **18 to 65 years old, diagnosed with kidney disease, and not diabetic**, you may be eligible for a clinical trial that is testing an investigational medication to treat **APOLI-Mediated Kidney Disease (AMKD)**. AMKD is caused by genetic variations, *which occur commonly in people with African ancestry*, and can increase your risk of reaching end-stage kidney disease. Interested participants will receive investigational genetic testing to see if they carry the disease-causing APOL1 genes.



Qualified participants will be compensated for study-related time and reimbursed for travel.

To learn more about the study or to see if you are eligible, please contact study coordinator Lawrence Ullman Jr. at (203) 737-1091 or email lawrence.ullmanjr@yale.edu

HIC #2000030942

Stop Smoking Study

Do you want to quit smoking?

If you are **18 to 60 years old** and would like to quit smoking, you may be eligible to participate in a *free and confidential* study that will look at how treatment can affect a person's ability to regulate cravings for cigarettes.



Participants will be compensated \$20 per hour, up to \$850.

To learn more or to see if you are eligible to participate, please call (203) 641-9417.

HIC #1210010970

To find out more about trials at Yale, visit our website, www.yalestudies.org. Or call 1-877-y-studies for more information.

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Yale

Why Should I Participate in Clinical Research?

Minorities Have Higher Rates of Certain Diseases

It is an unfortunate fact that minorities suffer disproportionately from such diseases as cancer, diabetes, cardiovascular disease, and HIV. The fastest and safest way to determine whether new treatments work for these and other diseases is through clinical research. Yet it's often difficult to find volunteers – especially minorities – willing to participate in clinical trials. There is a shortage of participants in clinical research – and minority participation is even lower than that of the general population.

It's Important to Include ALL Types of People in Clinical Studies

Human beings are very much alike. Only 0.01% of our genes varies from one person to the next. But even with these tiny differences, there are still people with different appearances and different health conditions. Illnesses affect each of us differently – as individuals, as families, as racial and ethnic groups, and as communities. Because of these differences, it's important to study different groups of people in order to understand which treatments work best for them. The best way to know that a particular medicine is right for someone is to test it in similar people.

Many diseases affect African Americans more often than people from other groups. For example:

- African Americans are more likely to have stomach cancer than other groups. Men have higher rates of lung and prostate cancer. Breast cancer is more common in African American women under 45, and they are more likely than other women to die from this disease.
- African Americans are twice as likely as non-Hispanic white adults to be diagnosed with diabetes. They are also more likely to have kidney disease, to be hospitalized, and to die from diabetes.
- African Americans have higher rates of high blood pressure. Men are more likely to die from heart disease. Women are more likely to be obese.
- African American infants are almost four times as likely to die from causes related to low birth weight compared to non-Hispanic white infants.
- African Americans are more likely than white adults to have a stroke. Men are 60% more likely to die from it. Survivors are more likely to become disabled and have difficulty with daily activities.

Courtesy of US Department of Health and Human Services Office of Minority Health.

Real People Who are Helping Us Discover



Photo Robert A. Lisak

Rev. Dr. Leroy O. Perry, St. Stephens AME Zion Church, Branford; Rev. Elvin Clayton, Walter's Memorial AME Zion Church, Bridgeport; Rev. Kelcy Steele, Varick Memorial Church, New Haven.

Three Ways to Sign Up for Clinical Research

Talk to a Cultural Ambassador – Contact your pastor, before or after service, to discuss your questions about participating in clinical research at Yale.

Email YCCI – Send an email to helpusdiscover@yale.edu indicating your interest in participating in clinical research.

Make a quick phone call – Call 1-877-978-8343 to inquire about opportunities for participation in clinical research.

