



NEW CLINICAL TRIALS AIM TO ADDRESS CHALLENGES OF THE IMMUNE SYSTEM

“It is an exciting time in diabetes research because we will have five clinical trials progressing in parallel at the DRI, which is unprecedented in our history.”

Overcoming the significant challenges of the immune system is absolutely critical for developing a biological cure, which is why it is now the subject of increasingly intense focus at the Diabetes Research Institute. While islet transplantation has already changed the lives of those with type 1 diabetes (T1D), only a small percentage of people can benefit from this cell-replacement therapy due to various hurdles, including the need for lifelong immunosuppression. These harsh drugs cause unwanted side effects and, while effective at preventing the body from rejecting the transplant, do not address the underlying disease process that triggers the attack on the insulin-producing cells.

“The widespread application of islet transplantation for type 1 diabetes will be a limited approach we can offer until there are less toxic immunosuppressive regimens, more robust ways of inducing immune tolerance to the transplanted islets, and, ultimately, the development of strategies to block autoimmunity,” explains Camillo Ricordi, M.D., director of the DRI. “If we can ensure that new islets will not be destroyed by autoimmune disease, then we can even

think about regenerating insulin-producing cells from the patient’s own tissues.”

Scientists have learned a great deal about the immune system thanks to decades of experience in clinical islet transplantation and other diabetes research trials. Now, they are developing novel approaches that are designed to be safer and more effective in tackling the immune system head on.

The idea behind these new immunotherapies is to use naturally occurring molecules and low-dose agents to correct autoimmunity and halt the attack on the insulin-producing cells. Some of the DRI’s most innovative strategies aim to better regulate the immune system and target the multiple immune pathways that are implicated in T1D.

At the DRI, many promising initiatives are ready to be tested in patients. Recently, DRI scientists received approval from the Food and Drug Administration (FDA) to proceed with several new clinical trials, while others are pending approval and funding.

Continued on page 3

WAYS TO GIVE

IN MEMORY OF BETTY AND JIM GUY

"Knowing Jim and Betty Guy for over 40 years, I can say they were good and generous people who wanted to support the great work being done at the DRI," said Frank Iannuzzi, their long-time friend and accountant. Betty passed away in 2014; Jim followed her in early 2017, but not before establishing a multi-million-dollar legacy gift ensuring their desire to advance the DRI's cure-focused research well beyond their lifetimes. Please keep an eye out for the full story in a future issue of *DRIFocus*.



The #TRIALblazers Match Challenge

as they gear up for several clinical trials aimed at tackling the challenges of the immune system. In support of this effort, the Diabetes Research & Wellness Foundation, a longtime supporter, has agreed to match every dollar donated through the end of the year — up to \$250,000. You can double your impact by making a contribution today, using the enclosed envelope or on our website: DiabetesResearch.org/Match-Challenge. Thank you!

WAYS TO GIVE

#TRIALblazers

As pioneers in their field, the scientists at the Diabetes Research Institute have been blazing a path toward a cure for diabetes. Now, we call them our #TRIALblazers



Donate Your Car

You can now donate your car to the Diabetes Research Institute Foundation via Vehicles for Charity. Regardless of condition, automobiles, trucks, vans, recreational vehicles, motorcycles, dirt bikes, tractors, boats and trailers will be accepted and towed free of charge within two to four days of the request. Vehicles will be sold at auction or to a salvage company with 100 percent of the net proceeds donated to the DRIF, and it's tax deductible. Call 1.833.430.DRIF (1.833.430.3743) or visit: VehiclesforCharity.org/Donate/DRIF.html

Corporate Matching Gift Programs

Many companies match charitable contributions made by their employees. It's a great way for you to maximize your gift to the DRI. Programs vary from company to company, but typically employees can get a matching gift form from their Human Resources department. After completing the form, send it along with your personal donation to the DRI Foundation. We'll take it from there! It's an easy way to multiply your contribution. Find out if your company has a matching gift program by checking with your HR or Personnel Department.

IRA ROLLOVER GIFTS

Direct gifts to the DRIF from your IRA can offer several benefits. It can be an easy and convenient way to make a gift from one of your major assets. It can be excluded from your gross income — a tax-free rollover. It can also count toward your required minimum distribution.

For your gift to qualify: You must be 70 ½ or older at the time of your gift, the transfer must go directly from your IRA to the Diabetes Research Institute Foundation, your total IRA gift(s) cannot exceed \$100,000, and your gift must be outright.

For more information, contact us at (800) 321-3437.

To learn more visit: DiabetesResearch.org/Ways-to-Give

"We all believe the cure for diabetes will come from the amazing work being conducted at the DRI."

A SPECIAL THANK YOU TO INSERRA SUPERMARKETS

Inserra Supermarkets is recognized by customers and communities in the Northeast as the local, family-owned supermarket company dedicated to supporting national research and community organizations. Each summer, the company hosts a number of fundraising events in support of the DRI at all of its 22 ShopRite stores and Price Rite of Garfield. This year, they raised approximately \$168,000, which was matched dollar for dollar by the Inserra Family Foundation, for a total gift of \$336,000.

"The generosity of all of the members of the ShopRite Family, from associates and customers to managers and the Inserra Family, is unsurpassed," stated Joshua Rednik, DRIF president and CEO. "I was so impressed to learn that the associates in each of the stores give with all their hearts, organizing these events during their free time – all while completely engaging the community to join in the effort. It's tremendous!"

While most of the events are focused on family fun, they always have a healthy living component, and that's something of which Lindsey Inserra-Hughes, vice president of health and wellness at Inserra Supermarkets, is extremely proud.

"Our team of dedicated, community-based registered retail dietitians provide free in-store counseling services to our associates, our customers and our communities. They provide people with the tools they need to eat and live healthy," she said. "The best compliments we receive are from people who have seen their health improve and

who share their success with us."

Diagnosed with type 1 diabetes as a child, Lindsey is a passionate supporter of the DRI and serves as the Young Professionals' Chair of the DRIF's Northeast Board. Her mother, Bonnie Inserra, serves as Vice Chair for the organization's National Board of Directors, as well as on its Executive Committee and the Northeast Region Board. The Inserra Family will stop at nothing until a cure is found, and according to Bonnie, "We all believe the cure for diabetes will come from the amazing work being conducted at the DRI."

The Diabetes Research Institute Foundation extends a very special thank you to Larry Inserra and the entire Inserra Family, as well as all the Inserra Supermarkets employees and customers who help to make these ongoing events so successful.



Lindsey Inserra-Hughes and Bonnie Inserra pose with a couple of "Minions" at one of their stores' fundraising events.

CLINICAL TRIALS *(continued from cover)*

"It is an exciting time in diabetes research because we will have five clinical trials progressing in parallel at the DRI, which is unprecedented in our history," said Dr. Ricordi. "We are directing our new clinical research efforts towards the challenge of immune tolerance, reversal of autoimmunity and islet regeneration. We've built a network of like-minded scientists committed to eradicating T1D, we're focused more than ever on linking all these centers with us as we hone in on the immune system as a central player on that stage."

The five clinical trials Dr. Ricordi refers to are:

- **DIPIT (Diabetes Islet Preservation Immune Treatment):** This study will test a combination of several clinically approved agents that target multiple immune pathways and test its effectiveness to halt the immune system attack, preserve remaining islet function, and, possibly, give the body a chance to recover and regenerate its own insulin-producing cells.
- **Low-dose IL-2 in Established T1D:** Interleukin-2 (IL-2), is a protein produced by the body that plays a key role in immune system function. Low-doses of IL-2 have already demonstrated effectiveness in correcting autoimmunity for other conditions. The trial will test the effects of low-dose IL-2 in type 1 diabetes.

- **POSEIDON Trial:** Several reports have suggested that the use of high-dose omega-3 and vitamin D, which have known anti-inflammatory properties, may offer a potential beneficial effect on autoimmune conditions. The POSEIDON study will evaluate the effects of this therapy in those with T1D.
- **Intraocular Islet Transplant Trial:** This study will test the safety and efficacy of the eye as a potential islet transplant site, and determine whether immune tolerance can be achieved locally or systemically by retraining the immune system.
- **BioHub Trial - Islet Transplantation onto the Omentum:** An ongoing study, researchers are transplanting donor islets within a tissue-engineered site to learn whether the cells can successfully engraft and achieve insulin independence.

We will continue to keep you abreast of the status of these clinical trials as they develop. For continuing updates, please sign up to Be a DRInsider at DiabetesResearch.org/Register or email us at info@drif.org.



UNDER THE MICROSCOPE

WITH JAY SKYLER, M.D.

While researchers know that type 1 diabetes results from autoimmune destruction of the insulin-producing beta cells in the pancreas, they do not know how to stop this attack – at least not yet. That is one of the primary goals at the Diabetes Research Institute, where scientists are intensely focused on tackling the immune challenges that are critical for discovering a biological cure, as evidenced by the new clinical trials on the horizon.

Thus far, preventing and reversing islet cell autoimmunity has eluded scientists, as Dr. Jay Skyler knows all too well. With a career that spans more than 50 years, Dr. Skyler, who serves as Deputy Director for Clinical Research and Academic Programs, has led countless clinical studies, the majority of which have focused on regulating the immune system to halt beta-cell destruction.

Now, armed with decades of clinical experience and important data emerging from a variety of immunological studies, Dr. Skyler, together with his multidisciplinary team of colleagues at the DRI, is developing new immunotherapy-based approaches that may ultimately achieve this goal and benefit the millions living with T1D.

Q. You have been involved with countless diabetes research initiatives to prevent and reverse type 1 diabetes. What has been learned so far? Why is T1D such a challenging disease to conquer?

A. Yes, it is a complex and challenging disease because the evolution of T1D involves not one, but several immune pathways, and this complicates the design and testing of what might be “the” ideal therapeutic strategy.

The majority of the past clinical trials involved the administration of single agents and have primarily targeted the immune system. However, there is growing evidence that type 1 diabetes is a multifactorial disease – that other things like inflammation and beta cell dysfunctions may also be important in the development and propagation of the disease process, and therefore we should look carefully at these in crafting an intervention that might arrest the disease process.

Q. What research approaches are underway at the DRI to address these immune system challenges?

A. We’ve seen that scientists have had success in applying a combinatorial approach to patients with HIV and cancer, which are also diseases involving multiple pathways. This concept needs to be applied

more extensively to T1D. Data emerging from our own clinical islet transplant trials, together with studies conducted by other research groups, have already demonstrated better outcomes in type 1 diabetes onset and progression using some combination of agents that target key immune system pathways. This is, in fact, what has led us to the next planned study design for one of the DRI’s newest clinical trials now in final planning stages: DIPIT.

Q. Can you tell us more about the DIPIT trial and what the DRI is looking to achieve?

A. The Diabetes Islet Preservation Immune Treatment (DIPIT) trial uses drugs that alone have been shown to be beneficial in T1D, at least transiently, and combines them in terms of timing and dose so as to test a new combinatorial approach to immune system regulation. Taken in combination, these FDA-approved drugs – some at very low doses and some for short periods of time – may prove to be uniquely capable of targeting several of the specific immune pathways we need in order to preserve insulin secretion in recent-onset T1D patients. Many medical centers have already expressed interest in participating in this multi-center trial and it will be the first such trial of its kind conducted.

Q. What makes this such an exciting time for those with diabetes?

A. While I don’t think there will be one single “magic bullet,” I think that there will be a variety of different approaches that we might use at different times in people with different characteristics. I think the field is moving in that direction, and I think some time in the future we will be able to prevent type 1 diabetes, perhaps be able to stabilize type 1 diabetes and keep beta-cell function going for a protracted period of time, and we will be able to replace beta-cell function in people who have already lost it. I want to see this disease cured in my lifetime, and I am highly enthusiastic in where the future is going. With dedicated people working on it and the resources needed, we will beat it.

Jay Skyler Receives Prestigious Award

In recognition of an impressive career that spans five decades, Jay S. Skyler, M.D., M.A.C.P., Deputy Director for Clinical Research and Academic Programs at the DRI, was recently awarded the ADA Josiah K. Lilly, Sr. Distinguished Service Award during the annual gala held in Indianapolis, IN. The award honors an individual who is making an outstanding contribution in the field of diabetes, and it was created to honor the vision of Eli Lilly's only son, J.K. Lilly, who was the driving force behind the manufacture of insulin for worldwide commercial availability.

Dr. Skyler's principal research focus is in modulating the type 1 diabetes disease process through immunoregulation. He has been author, editor, or co-editor of 21 books or monographs; has written more than 490 articles, book chapters, or editorials; and serves as a scientific advisor to the pharmaceutical, biotechnology, and medical equipment industries.



Norma Kenyon Appointed a DRI Deputy Director

Norma Sue Kenyon, Ph.D., who has been a member of the DRI team since 1990 and who has more than 25 years of experience in preclinical and clinical studies in type 1 diabetes research, was recently named one of the DRI's Deputy Directors. Due to her stature in the field, Dr. Kenyon has received sustained support from the National Institutes of Health, as well as other organizations, and she has been committed to finding a cure for type 1 diabetes ever since her daughter was diagnosed with it as a baby years ago.

Dr. Kenyon serves as the Martin Kleiman Professor of Surgery, Medicine, Microbiology and Immunology and Biomedical Engineering; the Executive Director of the Wallace H. Coulter Center for Translational Research at the University of Miami; and Chief Innovation Officer at the Miller School of Medicine. Her work is concentrated in the area of transplant immunology and tolerance.

Immunologist Roberto Mallone Participates in Seminar Series at the DRI

Leading immunologist **Roberto Mallone, M.D., Ph.D.** (right), Research Director, DeAR Laboratory (Diabetes and Autoimmunity Research) in Paris, France, recently served as the guest speaker at the ongoing Lindsey Inserra-Hughes Immune Tolerance Seminar Series, a forum for the exchange of scientific findings aimed at tackling the challenges of the immune system. Dr. Mallone's research focus is the understanding of the immune pathogenesis of type 1 diabetes and other autoimmune disorders, and he has collaborated with the DRI on multiple projects, working closely with the DRI's Dr. Alberto Pugliese (left).



DIABETES EDUCATION SHINES DURING DUSTIN'S T1D ALL-STARS PROGRAM

Offering diabetes education was paramount to a great new program called Dustin's T1D All-Stars, which gave dozens of kids with type 1 diabetes a one-of-a-kind baseball experience with Miami Marlins pitcher Dustin McGowan, who also has T1D, along with his young daughter, McKensy.

Dustin and his wife, Jilly, teamed up with the DRIF to create a fun opportunity for kids and parents to meet other families affected by

the disease, have an informative diabetes discussion with experts in the field and enjoy America's favorite pastime. After attending batting practice, participants gathered for a Q & A with the McGowans and then took part in an educational seminar.

Led by the DRI's Education and Nutrition Service Team, these interactive discussions featured a variety of topics for newly diagnosed families, as well as those who have been living with diabetes for years. Educators offered useful tips on diabetes management, like insulin pumping, making easy diabetes-friendly snacks, tips for back to school and more. They also delved into some of the psycho-social issues of diabetes, including a session that was specifically for dads.

This free program was launched in partnership with the Miami Marlins and generously sponsored by Insulet Corporation, the makers of Omnipod®, the Miami Marlins and the McGowans. It attracted families from around South Florida, as well as other states like Massachusetts, New Jersey, Pennsylvania, and Kentucky. Participants called it an "incredible experience" that they "will remember forever."

Jilly and Dustin McGowan with DRIF Vice President Tom Karlya address attendees at a behind-the-scenes section of Marlins Park.



“The real motivation is that finding a cure is so important for so many struggling with this epidemic.”

BOARD SPOTLIGHT Sandra Levy



Every year, like clockwork, Sandra Levy rallies her Love and Hope Committee for another fundraising season solely dedicated to helping the Diabetes Research Institute (DRI) reach a cure.

This has been her tradition for more than four decades, and a true labor of love.

“Our committee are all volunteers. Wonderful ladies,” said Sandra, who is the group’s Executive Chairman and has led dozens of galas and luncheons that have raised more than \$53 million for the DRI to date.

“We give our time, talents, and money, and reach out in our community to help fund this important work,” she said of her group of enthusiastic members – who originally banded together to help a neighbor whose child had been diagnosed with the disease.

Since then, Sandra and the group’s mission has evolved from helping one person to helping the millions affected.

“The real motivation is that finding a cure is so important for so many struggling with this epidemic.”

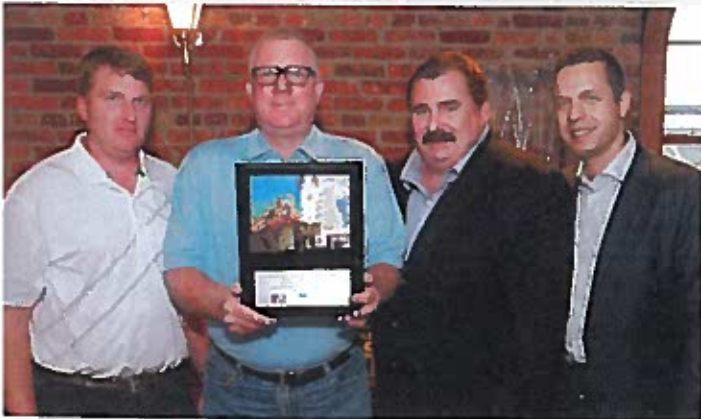
Sandra says she personally feels a great sense of responsibility for helping people with diabetes and the DRI. She serves as a member of the National Board and Florida Region Board of the DRI Foundation. In recognition of Sandra and her husband, Sid Levy, for their extreme generosity, the Institute’s sixth floor Cell Biology/Signal Transduction room was named in memory of her late daughter, Jennifer.

“We must support our scientists, and the work they are doing,” she said. “They are diligent...sharing information and collaborating with other scientists to cure this disease.”

The longevity and commitment of the Love and Hope committee have also inspired a younger generation of women who formed the Young Society of Love and Hope. They hold events that benefit the DRI year-round and often look to Sandra and the committee for guidance.

Sandra doesn’t hesitate when it comes to this cause and is showing no signs of slowing down. Her latest endeavor? The Love and Hope High Rollers event slated for spring 2018 – it’s a new casino event that Sandra and the committee hope will attract new supporters and raise big money.

“It has been 44 years and we are still together working,” said Sandra. “We’ll hopefully be able to celebrate when the cure is found.”



North America’s Building Trades Unions’ Best Year Ever

After more than 30 years, the dedicated men and women of North America’s Building Trades Unions (NABTU) continue their passion and strong relationship with the DRI Foundation.

Through the Labor of Love & Softball Slam and D.A.D.s Day Campaign (Dollars Against Diabetes), NABTU recently presented a check to the DRI for the largest amount raised to date, adding to the more than \$53 million dollars they have donated to the DRI over decades of support.

Held May 20-22, the Labor of Love & Softball Slam featured a weekend of softball, 142nd Running of the Preakness, poker and golf tournaments, and awards reception. Honorary host Peter G. Angelos, a long-time supporter and true friend to NABTU and its philanthropic efforts, welcomed the event back for the fourth year at Oriole Park, Camden Yards in Baltimore, MA.

“It is because of everyone’s continued support for our programs that we are in the midst of seeing a cure become a reality, and we can all take pride in that,” said Sean F. McGarvey, NABTU President and member of the DRIF’s National Board of Directors. (Pictured: Brent Booker, NABTU Secretary-Treasurer, President McGarvey, DRIF’s Tom Karlya, Vice President, and Josh Rednik, President and CEO.)



EVENTS

1. Co-chairs Steve and Tammy Klein and Amy and Scott Greenwald strike a pose at the fourth Out of the Kitchen foodie event, where 21 top South Florida chefs treated guests to a unique culinary experience inside St. Regis Bal Harbour Resort.
2. Dare to Dream Honorees Leslie Hsu Besner, Lana Besner, Willa Besner and Greg Besner celebrate family and philanthropy at the 12th annual DREAMS in the City in New York City, where they were recognized, along with Willa's Wish Foundation, for their commitment to a cure.
3. Chairman Bruce Fishbein and former Miami Dolphins Quarterbacks Don Strock and Dan Marino getting ready to kick off the 34th annual Don Strock Diabetes Golf Classic at the Miccosukee Golf & Country Club, which drove in more than \$125,000.
4. Glen Cove Councilmen Roderick Watson and Tim Tenke, Event Co-chair Jon Holzer, Nassau County Legislator and DRIF board member Delia DeRiggi-Whitton, Glen Cove Mayor Reggie Spinello, Co-chair Joe LaPadula, Glen Cove Councilman Nick DiLeo Jr., Glen Cove Councilwoman Pam Panzenback, committee member Anthony Jimenez and emcee Joe Manfredi at the Long Island's Gold Coast Concours/Bimmerstock exotic car show.
5. Chris Tsioros, Brian Goldberg and Rich Nastasi were the winners at the Buy In For a Cure tournament at Long Island's Garden City Hotel, where they, along with more than 80 players, brought in approximately \$62,000.
6. Tournament Director Eric Reeps, Honorary Chair Rod Gilbert, and Tournament Director Bob Zuckerman on the green at the sold-out Rod Gilbert DRI Golf Classic at the Pine Hollow Country Club in East Norwich, NY.
7. The Empire Ride for the DRI team gets ready to start the 2017 Massapequa Park Bicycle Club Tour of the Hamptons, where they raised more than \$50,000 and helped spread awareness for the DRI.
8. This family foursome, Doug, Matthew, Ty and Bob Donaldson, helped raise more than \$680,000 at the 7th annual Donaldson Organization Golf Outing, held at the famed Winged Foot Golf Club in Mamaroneck, NY.

There are additional photos and event recaps on our website. Please visit DiabetesResearch.org/Photo-Gallery

DRIFocus

Diabetes Research Institute Foundation

National Office
200 South Park Road
Suite 100
Hollywood, FL 33021

address service requested

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CALENDAR

For information on the events or to make reservations, visit DiabetesResearch.org or call one of the DRI Foundation offices listed below.

Empire Ball

December 13, 2017 / **NEW YORK**
NYC's real estate and construction industries will come together at the Grand Hyatt for this black-tie affair that has raised millions for the DRI.

A Gift of Love...A Gift of Hope Luncheon

February 26, 2018 / **FLORIDA**
This afternoon luncheon features card playing and fun with friends at the Polo Club of Boca Raton.

DRI Walk for Diabetes

March 3, 2018 / **FLORIDA**
Thousands of families will join together at Marlins Park for this family fun day, presented by Walgreens and featuring

a walkathon, 5k/10k run, music, giveaways, refreshments, health booths and more.

Kids' Carnival for a Cure

March 4, 2018 / **LONG ISLAND**
Enjoy an afternoon of family fun at Dave & Buster's, featuring video games, face painting, a buffet lunch and more.

Love and Hope High Rollers Night

Spring 2018 / **FLORIDA**
This exciting evening will feature cocktails, dinner, casino night, prizes and more. Stay tuned for date and venue!

Cooking for a Cure

April 2018 / **LONG ISLAND**
To be held at The View Grill in Glen Cove, this flavorful event includes an auction, sweepstakes drawing and live entertainment.

Sportsmen for Charity

April 2018 / **LONG ISLAND**
An all-day event for sporting clay shooting enthusiasts, to be held at Pawling Mountain Club.

Out of the Kitchen

April 2018 / **FLORIDA**
This spectacular four-course dinner, prepared by up to 20 chefs cooking tableside, will be paired with specially-

selected wines for each course. The night will also feature live and silent auctions, a wine bar and much more.

Concert for a Cure

April 21, 2018 / **CONNECTICUT**
To be held at The Acoustic in Bridgeport, this event will feature an open bar, prizes, and musical entertainment.

DREAMS in the City

May 3, 2018 / **NEW YORK**
The 13th annual event will feature specialty cocktails, dinner, dancing, silent auction and a mission-based live auction.

DRIFOCUS

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Marketing & Communications Dept.

Lori Weintraub, APR / Lauren Schreier
Joelle Parra / Nicole Lesson / Laurie Cummings

Contributors

Gary Kleiman / Jill Salter / Aimee Siegel-Harris / Mitra Zehtab, M.D. / University of Miami Medical Communications

Photography

DRI - DRIF staff and volunteers / Marc S. Levine Photography / Joe Marzo Photography / Andrew Milne Photography

Design

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DIABETES RESEARCH INSTITUTE FOUNDATION

National Office Florida Region

200 South Park Road,
Suite 100
Hollywood, FL 33021
Phone: (954) 964-4040
Fax: (954) 964-7036
Info@drif.org

Northeast Region Manhattan Office

259 West 30th Street,
Suite 402
New York, NY 10001
Phone: (212) 888-2217
Fax: (212) 888-2219
neregion@drif.org

Northeast Region Jericho Office

410 Jericho Turnpike,
Suite 201
Jericho, NY 11753
Phone: (516) 822-1700
Fax: (516) 822-3570
neregion@drif.org