Solve M.E. Grows ME/CFS Research with Seven NEW Studies

SOLVE M.E.’S RAMSAY GRANT PROGRAM provides pilot funding for investigative studies into the symptoms and underlying causes of ME/CFS. Since 2016, the Ramsay Program has successfully attracted new scientists to the field and kept them engaged. Ramsay funding allows researchers to generate preliminary data and refine hypotheses for further research, providing a key bridge to pursue larger grants. Solve M.E. will fund seven studies in 2019; welcoming over 30 investigators and collaborators, including a number of early career stage scientists. Over half of these research teams include a Principal Investigator (PI) leading an ME/CFS study for the first time. Learn more about the exciting projects that will unfold over the next year and meet the researchers behind them at www.solvecfs.org.

Altered T cells in ME/CFS

Liisa Selin, PhD, is a University of Massachusetts Medical School researcher with deep knowledge of immune defense against viruses. Dr. Selin and her co-PI, Anna Gil, PhD, will examine the role of specific immune cells called T cells that play a key role in tailoring the body’s immune response. The researchers previously identified elevated numbers of a subset of T cells in blood samples from people with ME/CFS. This study is designed to examine whether these cells reflect a specific infectious or autoimmune response that could be driving immune dysfunction in ME/CFS.

Possible class II MHC deficiency in patients Impact with ME/CFS

Bruno Paiva, PhD, (University of Navarra) is an expert researcher in immunology and diseases of the blood. This is his first study in ME/CFS. Working with six multidisciplinary co-Investigators, Dr. Paiva will investigate if inherent defects in class II molecules of the major histocompatibility (MHC)—a specific immune system pathway foundational to your body’s defense—is driving ME/CFS symptoms for a subgroup of patients. Decreased expression of these molecules would be consistent with previous reports...
Solve M.E. This Quarter

**RESEARCH:** Engaging the entire ME/CFS community and accelerating the discovery of safe and effective treatments.

This year marks the fourth cycle of the Ramsay Grant Program and we were pleased to announce the grant recipients in October. Read more about the impressive group of researchers who will be leading pilot studies over the next year on page 1.

**JARRED YOUNGER, PHD,** University of Alabama at Birmingham, used promising findings from a Solve M.E. Ramsay pilot study to secure a $2.9 million R01 grant from the National Institutes of Health. Dr. Younger will use an innovative imaging technique to scan the brains of a large cohort of ME/CFS and healthy control subjects for markers of inflammation. Dr. Younger’s Ramsay pilot data was also used as proof-of-concept to obtain funding from the Department of Defense to scan the brains of patients with Gulf War Illness (a condition related to ME/CFS) using the same method.

Solve M.E.’s Chief Scientific Officer, **SADIE WHITTAKER, PHD,** presented on the Ramsay program to a room full of early career researchers at the “Thinking the Future” breakout session at the 14th Invest in M.E. Research International M.E. Conference in London.

The **NANDS COUNCIL WORKING GROUP FOR ME/CFS,** which included Carol Head (former Solve M.E. President & CEO), Sadie Whittaker, and other researchers and advocates, published its report on how the National Institutes of Health (NIH) can address gaps in ME/CFS research. The report was unanimously accepted by the NANDS Council in September, laying the groundwork for a meaningful change in how ME/CFS is addressed at NIH.

Solve M.E. continued to develop tools for the **YOU + M.E. REGISTRY AND BIOBANK** that will enable people living with ME/CFS to contribute health information to a rich repository of data available to researchers around the world. The community helped us beta test a mobile application to record health information on an ongoing basis and the tester feedback was incorporated to make the app ready for the You + M.E. launch.

Solve M.E. partnered with **EMERGE AUSTRALIA, LA TROBE UNIVERSITY,** the **CURE ME BIOBANK,** and other dedicated partners in a successful bid for a $1 million grant to establish an Australian registry and biobank. We are continuing to build partnerships with other registries and research groups that will allow us to work toward a global data collaborative.

Solve M.E. addressed the President of the European Union Parliament in a letter that continues to seek international collaboration and partnership for the You + M.E. Patient Registry and Biobank.

Solve M.E.’s Director of Research Programs, **ALLISON RAMILLER,** attended the Annual Meeting of the Patient-Centered Outcomes Research Institute (PCORI) in Washington, DC. PCORI has funded more than $2 billion in patient-centric research with the goal of studying outcomes that matter most to patients.
ADVOCACY: Bringing government support, funding and public awareness to ME/CFS

SOLVE M.E. led a successful 18-month campaign targeting Senate funding decision makers to add ME/CFS as an eligible research topic area in the Peer-Reviewed Medical Research Program (PRMRP). If included in the final federal budget, ME/CFS researchers can apply for new funding up to $350 million next year.

In collaboration with #MEAction, SOLVE M.E. pushed for a $4.5 million funding increase for ME/CFS programs at the CDC. This effort was successful in securing continued funding of $5.4 million.

SOLVE M.E. closely tracked budget decisions at the federal level, providing updates and analysis for the ME/CFS community by regular email news announcements and presentations to ME advocates groups.

SOLVE M.E. joined the National Health Council and participated in generating key tools for including severe and disabled patient participation in research and engagement programs.

SOLVE M.E. submitted official commentary to the United States Access Board for additional research regarding current accessibility guidelines and their effectiveness in addressing the needs of up to 2.5 million Americans with ME/CFS.

Solve M.E. Director of Advocacy and Community Relations EMILY TAYLOR presented at the Regents of University of California Health Services Committee.

INFLUENCE AND EDUCATION: Providing trusted, up-to-date medical information, current research, & policy work on ME/CFS

Disability Insurance Attorney ANDREW KANTOR from Kantor & Kantor, LLP presented the Solve M.E. educational webinar, “Fighting the Good Fight,” outlining for people with ME/CFS how to file for disability under an ERISA (employer-sponsored) policy.

Solve M.E. published a first-person account of ME/CFS patient SANNA STELLA’s experience as a participant in the NIH Intramural Clinical Study on ME/CFS with the goal of encouraging other people with ME/CFS to join the study.

Solve M.E. featured GABE HASSLER, son of Board Member BILL HASSLER, in a series of educational social media posts documenting his participation as a healthy control in the NIH intramural clinical study on ME/CFS.

EMILY TAYLOR and MARYELLEN GLEASON represented Solve M.E. at the ME/CFS Benefit Show “An Evening with Marian Call” in Petaluma, California. Taylor’s presentation, “From Caregiver to Advocate: An ME/CFS Journey” preceded the concert.
of altered populations of immune cells in people with ME/CFS and could account for recurrent infections experienced by many patients.

**Defining the postural contributors to PEM**

*Shad Roundy, PhD*, a highly accomplished engineer from the University of Utah, will validate whether a wearable sensor device worn on the ankles accurately measures the amount of time spent in an upright posture and whether this reflects ME/CFS disease severity. Working with his co-Investigator, Dr. Cindy Bateman, measurements will be taken at baseline and after provoking post-exertional malaise (PEM) in a group of moderate to severe patients. The results will be compared with control subjects. If successful, this proposal could result in a clinical endpoint for disease severity that would significantly impact ME/CFS research and clinical practice.

**Extensive characterization of the ME/CFS blood and CSF microbiome + virome**

*Nikos Kyrpides, PhD, David Paez-Espino, PhD*, microbiome data scientists from the Joint Genome Institute at Berkeley University and *Kris Fobes* from GeneSavvy, will lead a large, collaborative team from multiple institutions to examine known and novel organisms in ME/CFS blood and cerebrospinal fluid. The study will link with current Alzheimer’s research at Harvard University that is shedding light on how persistent pathogens in human brain tissue can drive neuroinflammatory symptoms. Studies of the microbiome in ME/CFS have primarily focused on bacteria in the gut. So, this study of the entire microbiome, including viral (human and phage), bacterial, archaea and other microorganisms, could open new frontiers in the study of ME/CFS.

**Unraveling endothelial function in ME/CFS**

*Francisco Westermeier, PhD*, from the FH JOANNEUM University of Applied Sciences in Austria, has experience in diabetes research and in the study of the renal and cardiovascular systems. Dr. Westermeier and an international, collaborative group of researchers want to know if inflammation is impacting cardiovascular function in people with ME/CFS. They will measure the health and function of the endothelium—cells lining the entire cardiovascular system that are responsible for controlling normal blood flow and adequate oxygen supply to all tissues in the body. These clinical measures will be correlated with inflammatory markers in the blood that are linked to endothelial dysfunction.

**PARsing post-exertional malaise: does post-exertional autonomic recovery (PAR) impact post-exertional malaise?**

*Kegan Moneghetti, PhD, MBBS (hons), FRACP*, a Stanford University cardiopulmonologist, will work with *Lily Chu, MD, MSHS*, young investigator *Tullia Lieb*, and other collaborators, to test the hypothesis that a poorly functioning autonomic nervous system (ANS)—which regulates many vital body functions—fails to help people with ME/CFS recover appropriately from exertion. ANS activity will be measured by how quickly the heart rate returns to baseline and heart rate variability during recovery from a standardized exercise test. The investigators will also record symptoms, overall function and mental ability at various time points during the study, allowing them to examine the relationship between ANS and PEM following a challenge.

**Brain Perfusion Changes in chronic fatigue syndrome before and after exercise challenge**

*Michael Van Elzakker, PhD* a researcher at Massachusetts General Hospital and Harvard Medical School, has been an influential thought leader in how the field might leverage imaging techniques to assess neurological features of ME/CFS. *Kenneth Kwong, PhD*, and *Suk-tak Chan, PhD*, experts in functional magnetic resonance imaging (fMRI), will co-lead the study. The research team will use fMRI to assess blood flow in the brains of participants at baseline and during PEM provoked by an exercise challenge. They aim to identify brain regions that are related to ME/CFS by correlating the fMRI measures with patient-reported fatigue levels.
Record-Breaking Advocacy Yields Positive Forecast for ME/CFS Federal Funding in 2020

Records are made to be broken! Solve M.E. anticipates a win for ME/CFS 2020 funding requests with strong congressional direction to federal agencies.

"ME/CFS Advocacy Week 2019 got results. Despite budget process delays, ME/CFS researchers can expect new federal funding opportunities and program security next year. And we’re just getting started."

—Emily Taylor, Director of Advocacy and Community Relations

In 2019, ME/CFS congressional advocacy efforts broke another record by gaining 63 supporters from both parties and both chambers (House and Senate) to support ME/CFS appropriations requests in 2020. That represents 11% of the entire membership of Congress supporting ME/CFS federal funding. This is the most members of Congress to sign onto an ME/CFS appropriations request, ever.

It’s no surprise after Solve M.E. board and staff facilitated 28 high-level appropriations meetings in February. Additionally, over 15,000 electronic messages about ME/CFS were sent to Congress using the Solve M.E. online Congressional tool.

Our ME/CFS Advocacy Day Impact

www.SolveCFS.org

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Record-breaking Advocacy Yields Positive Forecast for ME/CFS Federal Funding in 2020 (cont’d)

Defense Request: We Won!

In September 2019, the Senate Appropriations Committee advanced its FY2020 Defense Funding Bill including full funding of the Peer-Reviewed Medical Research Program (PRMRP) at $350 million, despite the earlier House version of the legislation which eliminated the program. If the Senate bill (S. 2474) remains unchanged during the remainder of the budget process, next year ME/CFS will be an eligible research topic area in the PRMRP.

If the House and Senate versions are combined in the final November budget, ME/CFS researchers could apply for up to $360 million in new research funding in Fiscal Year 2020.

More Good News

Both the House and Senate proposed budgets fully fund the CDC Chronic Fatigue Syndrome program, rather than eliminating it as they have in previous years. The proposed House budget package also included $41.1 billion for the National Institutes of Health (a $2 billion increase), $8.3 billion for the Centers for Disease Control and Prevention (a $938 million increase), and $7.6 billion for the Health Resources and Services Administration (a $485 million increase).

The final 2020 Federal budget is still under consideration and the deadlines for the budget process have been extended to November 21, 2019. Stay tuned to Solve M.E. email newsletters for analysis and updates. If you would like to receive Solve M.E. newsletters by email, sign up at www.solvecfs.org.

Solve M.E. to Form Community Advisory Council

Solve ME/CFS Initiative operates many programs and efforts for ME/CFS advocacy, education, and engagement. The new Community Advisory Council will create a formal mechanism for stakeholder input.

Solve M.E. is calling for nominations for the new Community Advisory Council (CAC). The CAC will serve as a stakeholder mechanism to improve and promote communication and collaboration between Solve M.E. and the broader ME/CFS community. We hope the CAC will increase community awareness, facilitate community education and support, and provide valuable input to improve programs and projects executed by Solve M.E.

To learn more about the CAC or to submit a nomination for the inaugural class of Community Advisory Council members, please visit www.solvecfs.org/CAC.
An Interview with Dr. Steve Roberds, Chair of the NANDS Council Working Group for ME/CFS Research

In summer 2018, the National Institute of Neurological Disorders and Stroke (NINDS) announced the creation of a National Advisory Neurological Disorders and Stroke (NANDS) Council Working Group for ME/CFS Research. The Working Group, made up of scientists, clinicians, advocates and people with ME/CFS, was tasked with providing scientific guidance on how best to advance research on ME/CFS at the National Institutes of Health (NIH) in a formal report. The Council unanimously voted to accept the report in September 2019, opening up the potential for NIH to take expanded action on this disease.

Solve M.E.: Your focus area isn’t on ME/CFS, but on a rare, complex genetic disorder called tuberous sclerosis complex (TSC). Now that you’ve spent a year with other working group members to dig in on the ME/CFS field and develop this report, what are your impressions of the gaps holding back progress in this disease?

Dr. Steve Roberds: A major impediment to progress in ME/CFS is lack of clear, evidence-based diagnostic criteria. Simply put, we need to have criteria which enable any physician to determine objectively, not subjectively or by excluding other diagnoses, that a person has ME/CFS and not something else. We cannot create evidence-based criteria by thinking and talking more. We need medical data, patient-reported data, and biosamples (such as blood) from people with ME/CFS and related disorders to be collected in standardized ways across many different centers and made available to a wide variety of researchers with diverse backgrounds and skillsets to stimulate creative science. Developing a strategic plan to focus and encourage these activities will help in the development of scientifically based diagnostic criteria.

Solve M.E.: The report outlines a number of recommendations for NIH to accelerate research in ME/CFS. Which opportunity are you most excited about?

SR: The most important and exciting to me is the first gap and opportunity addressed in the report: the suggestion that the Trans-NIH ME/CFS Working Group should coordinate a strategic planning process to create an overarching roadmap for ME/CFS research. This is key to all the others. The strategic planning process will build consensus around the most important research goals for the near- and long-term with input from patients, clinicians, and researchers. The resulting plan will encourage new research directions and advances by making it clear that NIH places a priority on funding ME/CFS research which is aligned with the strategic plan.

Solve M.E.: You mentioned in your presentation at the NANDS Council meeting that we need to get everyone on the same page so they can bring their resources to bear. What have you found to be successful approaches to foster a culture of collaboration in your work on TSC?

SR: Most important to fostering collaboration is to ensure the needs of the patient community are first and foremost in everyone’s mind. The Tuberous Sclerosis Alliance hosts biennial research conferences including scientific and clinical experts and trainees, catalyzing collaboration by allowing them to share research findings and interests with one another in a setting where they can discuss and seek ways to work together. Diversity and inclusivity of researchers is also critical; we work hard to ensure we don’t “play favorites” among researchers and clinicians, and we invite scientists outside the TSC field to speak at our conferences and advise us on research strategy. We make Tuberous Sclerosis Alliance-funded research resources such as natural history data, biosamples, and animal models available to all qualified researchers, and fund a few research grants every year. Although small in dollars compared to NIH, these grants “seed” research by enabling investigators to get preliminary data critical for successful applications for larger NIH grants.

Solve M.E.: To some, this might just feel like a report with uncertain impact. Why does the unanimous vote to accept the report have potential to provide traction within NIH?

SR: Primarily, I expect the report to provide traction within NIH because NIH staff have been very supportive of this Working Group from the beginning. They want to help. This report gives staff the guidance and affirmation to do more for ME/CFS because NANDS Council is authorized by law to give advice to NINDS. Not all votes of the Council are unanimous or even affirmative, and sometimes Council has unanswered questions and postpones a vote. Thus, the unanimous vote to accept this report demonstrates Council’s recognition of the urgent and important need to stimulate research on ME/CFS. As a Council member, I expect NIH staff to follow-up on Council’s suggestions with respect to ME/CFS and anticipate reports on progress and impact in the near future.
PATIENT VOICES

Every quarter, The Solve M.E. Chronicle features the creativity and talent of the ME/CFS community. In this edition, we feature the art of Kathy Bungard of Ione, WA.

Kathy lives with her artist husband, Terry, and Jasper, a VERY lively Chesapeake Bay Retriever. Kathy began cross stitching after getting sick with what became ME/CFS in 1981. She wanted to stitch designs that she wasn’t seeing for sale anywhere and began using software programs to create patterns. This turned into a rewarding mini-career as a designer of needlework patterns. Her work has been featured in well-respected cross stitch publications and she sells her designs on her website and through publishers in the US and Europe.

Her company is Gracewood Stitches and you may visit her website (http://gracewoodstitches.com/) and blog (https://fridayschild-dorrit.blogspot.com/) to see more of her work.

All of her designs are free to ME/CFS patients, who may send a note to her directly at bungard.gracewood@gmail.com telling her that they are a patient and which design they would like to have made. (Recipients must have access to a printer because she sends the charts out in PDF format.)
Solve M.E. Answers Reader Questions

Solve M.E. addresses questions we receive from the ME/CFS community.

Q: There are a number of us who are quietly getting better right now, and I am convinced, wholeheartedly, that there are lessons to be learned from these patients. We may not be totally cured, but we have much of our quality of life back. Is there any way the You+ M.E. Patient Registry and Biobank could question us about our symptoms, our triggers, our progress (or lack of it) and which treatments we’ve tried, singly, or IN COMBINATION, that have helped us make progress?

A: We are in complete agreement with you. This community is the most informed and knowledgeable about their own disease and we feel patient-reported information is essential.

The Registry will collect much of the information you’ve listed, with the intention of compiling natural history and phenotypic information. The Registry will include a secure user portal where people with M.E. and healthy controls can complete electronic consent and a series of surveys; including medical history, comorbidities, symptoms assessments (DSQ and the UK ME Biobank symptoms assessment), medications/treatments/supplements, quality of life and functional measures. After completing the baseline surveys, people with M.E. will receive a link to download the mobile app for ongoing tracking of symptoms and other factors.

Future versions of the app will include a better way to record changes in medications/treatments over time and opportunities for peer-to-peer engagement, to share responses to treatment. Incorporating additional forms of data, like physiologic data or genetic data, is on a longer timeline but is absolutely a goal.

We recognize the immense value of the individual patient experience (including potential treatments) and capturing, codifying, and utilizing that data for researchers is one of the key targets of this work.

Q: There are 535 Senate and House Members. What is keeping us from meeting with all of them? Do you know how many of the advocates from ME/CFS Advocacy Day were patients and how many were their supporters?

A: We schedule our meetings for ME/CFS Advocacy Day based on the congressional districts of those who attend. We must have a constituent from the district, or someone representing a constituent from that district, in order to schedule a meeting with the member of congress from that district. So, the number of Members we meet with reflects the number and diversity of participants and the folks they represent. The more people from different states and districts who participate, the more members of congress we can meet with!

Of 535 members of congress, we requested 239 meetings—about 45% of all Congressional members. We successfully held 185 meetings out of 239 total requested. That’s a success rate of 77%!

Of the folks who registered, 55.5% said they were people with ME, 29.5% said they were caregivers, 31.8% said they were Advocates, 5.5% were researchers/physicians, and 19% were "other." You may notice that doesn’t add up to 100%—people selected multiple categories in the registration forms.

ME/CFS Advocacy Week and our Advocacy Day on Capitol Hill are powerful events to amplify our work in Washington D.C. To find out more about next year’s events, visit www.MEAdvocacyWeek.com.

www.SolveCFS.org
Your Support Makes a Difference

People like you are building an ME/CFS research workforce by supporting the Ramsay Grant Program

So far, we’ve funded 23 original research projects within a network of over 60 research collaborators. Half of the Principal Investigators leading projects were able to apply their expertise to ME/CFS for the first time ever with support from Ramsay. Seventeen of the funded projects have involved early-career stage researchers.

When you make your gift today, you’re funding critical research and ensuring that more first-class researchers will focus their careers on ME/CFS.

“The Ramsay [grants] have spawned a cadre of eager investigators—and that’s exactly what we need in this field.” —Cort Johnson, Health Rising

We know the data that Ramsay researchers collect through their projects can effectively position them for much larger grants. This means that your support may make it possible for Ramsay researchers to successfully compete for National Institutes of Health funding and advance promising research.

Your gift, whether large or small, could be the catalyst for change so we can one day have a world without ME/CFS. Please also consider leaving Solve M.E. in your will.

WE’RE ALL IN THIS TOGETHER!

An envelope is included for your convenience, or you can give online at https://solvecfs.org/donate

*Gifts to Solve M.E. are not restricted to individual programs.
Dear Friends,

Here at Solve M.E., we are unrelenting in our fight to help the almost 2.5 million Americans who suffer so terribly with Myalgic Encephalomyelitis, even as research into possible causes and cures remains severely underfunded. Solve M.E. is the only organization working holistically to solve this whole-body problem and we are proud to advance research, advocacy, and disease education through programs that create greater and more effective resources to battle ME/CFS.

Solve M.E. continues to award Ramsay grants to seed ME/CFS research as the most effective approach to building a ME/CFS researcher workforce. Dr. Jarred Younger has already leveraged a Ramsay grant to secure nearly $3 million in additional NIH funding to complete his brain imaging study over the next five years.

The development of a Registry and Biobank to collect patient information online will create a data set to aid the research and discovery of possible ME/CFS causes and cures. Global partnerships have been created and are focused on gathering the largest data set possible for use by all researchers around the world. We’ve relied upon community input to build the You + M.E. Registry and Biobank, and we’re inviting our community to jump on board and enter their own data to help connect patients and researchers.

While federal funding for ME/CFS is still terribly inadequate, our Advocacy program opened up $350M in new potential Federal research funding next year. Our 2019 ME/CFS Advocacy Day event in Washington D.C. connected 246 registrants with their members of Congress, totaling 185 meetings on Capitol Hill. And, our online advocacy efforts sent over 15,000 messages about ME/CFS to Congress so far this year. All of this was made possible through community participation and support from our donors.

Financial support for Solve M.E. creates impact through our Ramsay Research Grants, You + M.E. Biobank and Registry, and advocacy efforts influencing change on a federal level. But we can’t do this without your help! In 2019, we achieved record fundraising from generous donors enabling more research and progress than ever before. With your help, we can accelerate our work in 2020.

Join us as we fight together to find causes and cures for you and your loved ones.

Onward, and with real hope!

Maryellen Gleason
Interim President & CEO

Sadie Whittaker, PhD
Chief Scientific Officer

Emily Taylor
Director of Advocacy & Community Relations

As you know, our beloved Carol Head stepped down from her role as President and CEO this spring and moved into a board leadership role, where she will be chairing our all-important Development Committee. In the meantime, our board has been actively seeking a replacement who can work effectively across many constituencies, and raise the dollars needed to drive the work we do to discover treatments and a cure.
FALL 2019
Solve ME/CFS Initiative (Solve M.E.) is the leading disease organization solely dedicated to solving the devastating disease Myalgic Encephalomyelitis (M.E.). Solve M.E. is unrelenting in our drive to make the disease widely understood, diagnosable and treatable.

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Join the You + M.E. Registry and Biobank and help bring the big data revolution to ME/CFS!
Pre-register here so you're the first to know when we launch: https://solvecfs.org/you-m-e-registry/