Dear Friends,

In our September newsletter we described major milestones ACP has achieved in furthering MS research. ACP relies on a number of different funding sources to maintain its current programs and expand its scope to include new projects. These sources include cost recovery, grant support, private donations and third party fundraising events. All donations, both large and small, allow us to continue our work at ACP. Our first article gives an overview of the funding sources that enable ACP to work towards fulfilling our mission.

In the second article, Dr. Farren Briggs discusses the importance of preventative care in people with MS.

Our October newsletter included an article explaining some of the terminology and classifications for clinical trials. This month we focus on the approval process all clinical trials must undergo before they begin.

Volunteers are a critical part of ACP’s success. We are grateful for hundreds of donated hours that support our work each year. Some of our volunteers give of their time and talents to host third party fundraising events to benefit ACP. Our partner spotlight this month focuses on two individuals who have recently organized fundraising events to benefit ACP.

As Thanksgiving approaches, we are reminded to pause and count our blessings. We appreciate the generosity and support of our partners, donors and volunteers. We hope you enjoy our newsletter and encourage you to share it with anyone you think may be interested in learning more about ACP. We wish you and your family a happy, healthy Thanksgiving.

The Accelerated Cure Project Team
Funding ACP’s mission

While there are many different types of for-profit businesses and as many business models, people are generally comfortable with the idea that a for-profit business funds its operations through the sales of products or services or something similar. From the outside looking in, it can be more challenging to determine how a non-profit sustains operations. While the truly curious can review our annual financial reports on our website, we thought an article summarizing the funding sources that fuel our operations, including donations from individuals, might be an interesting read.

As highlighted in our September newsletter, the Accelerated Cure Project (ACP) has built valuable resources, such as the ACP Repository and iConquerMS™, to accelerate research into multiple sclerosis (MS). Improving the lives of people affected by MS with better diagnoses, treatments, and a cure has been our focus since we were founded in 2001. We are grateful for the generosity of our partners and individual donors who have provided the means to establish ACP’s programs. These programs require sustaining funds, of course, so that they can continue to impact the pace and quality of research being done in MS today.

The ACP Repository is an important source of biological samples and clinical data for researchers studying MS and related demyelinating diseases. The costs associated with maintaining the Repository include sample storage and distribution fees, hosting for our extensive database, and salary support for scientific operations, business development, and sample and data distributions. In order to recover some of these costs, ACP charges a modest cost recovery fee for samples and data, adhering to a two-tiered pricing policy with different cost levels for academic and industry partners. Our cost recovery fees are modest in comparison to other sample sources and are designed to ensure that good research into MS can be done in a cost effective manner. Donations from individuals can also be a key source of funding for the Repository as some donors specifically request their donations be applied to research activities. A donor can take great pride in knowing their dollars have supported the ACP Repository, a key resource accelerating MS research.
Our people-powered research network, iConquerMS™ has been built and maintained to date through a contract with the Patient-Centered Outcomes Research Institute (PCORI). Some of the costs associated with iConquerMS include the technical infrastructure, communications activities, and salary support for member engagement, research activities, business development, and operations. In the coming year, under the current contract, PCORI’s support for iConquerMS will be phased out and end in September 2018. As a vital and critical resource for MS research, particularly in the area of research being done on topics of greatest importance to people affected by MS, we have a sustainability task force focused on identifying potential sources of funding for iConquerMS to ensure its continued operations. As with the Repository, there is a cost recovery policy in place with modest fees outlined for academic and industry users of iConquerMS. Other sources of funding for iConquerMS may include funds from advocacy organizations, foundations with an interest in people-centered research, and sponsorships from industry partners for specific events such as our annual Leadership Summit, a gathering of the MS stakeholders who govern iConquerMS. iConquerMS is unique in the area of MS research with its governance by members of the MS community and its truly people-centered and people-powered approach to research. Individual donors who are passionate about ensuring that people affected by MS, and their interests, preferences and priorities for research, are central to the MS research agenda, are also a key part to ensuring the sustainability of iConquerMS.

ACP receives funding from industry or advocacy partners for both scientific and non-scientific grants. Scientific grants are awarded for specific science-related projects. For example, the National MS Society and EMD Serono, among others, provided grant support in the past for the MS Discovery Forum and the OPT-UP Program and Clinical Study. Non-scientific grants, or sponsorships, are awarded for other projects. For example, the ACP newsletter is funded in part by sponsorships from Biogen and Teva Pharmaceuticals. Other projects for which ACP may seek industry sponsorships for in the future include adding podcasts or data visualization to iConquerMS. ACP is always looking for grant opportunities (both scientific and non-scientific) to fund its programs.
Donations from individuals, which cover ACP’s operating costs, are a vital source of funding. There are numerous ways to make a donation. Because ACP is a 501(c)(3) charitable organization, donors may be entitled to a tax deduction for their contribution. One-time or recurring donations, large and small, are welcomed and important to ensure we are able to fulfill our mission. For supporters whose companies host giving campaigns, funds can also be directed to ACP through the United Way giving program and other programs such as Give with Liberty. Donations can be made in memory of a loved one, or in honor of an important event, such as a wedding or birthday. ACP can set up donor pages (dedicated online pages) that make collecting these kinds of gifts easier. Donors can also make a significant gift posthumously. Bequests allow individuals to make larger gifts than they could during their lifetimes.

Many corporations offer Matching Gift Programs for charitable contributions. These programs can increase the size of donations by contributing some additional amount for every dollar that is donated to an approved charitable organization. For those who shop online, Amazon will donate 0.5% of the value of purchases made on Amazon Smile to ACP. Shopping through Amazon Smile for both your everyday and holiday shopping can make a significant impact for ACP. A donation button was recently added to the ACP Facebook page for those who prefer to do their giving via social media. Of note, on Giving Tuesday (11/28) Facebook will waive all fees and the Bill & Melinda Gates Foundation will match all donations, up to $2 million. Anyone interested in making a donation via Facebook is encouraged to do so early on Giving Tuesday in order to take advantage of this wonderful benefit!

Not every donation is in dollars. Volunteers from all over the world have donated their time and talents to ACP. ACP is also guided and overseen by our all-volunteer Board of Directors. For some supporters of ACP, raising money through independent fundraising events is the perfect blend of interest, expertise, and passion for ACP’s mission. Marion Leeds Carroll produces the Music to Cure MS concert every October, and Kemp Jaycox holds his annual Walk to Cure MS in the fall. Others have hosted a wide variety of such events in the past, including rowing events (Patrick Curley), running
events (Eliza Duddy), and cross-country events (Libby Nichols and Maddy Chambers). The Medeiros family hosts an annual party to benefit ACP. In addition, Rick Szczepanski raises money for ACP through his scholarship fund. We, at ACP, are extremely grateful for the time, talent and effort these volunteers devote to organizing and participating in fundraising activities. At ACP, we are happy to offer assistance to the volunteers that run them. If you would like additional information about donating, setting up a dedicated donation page, or if you have an idea for your own fundraising event, please contact Lindsey Santiago by phone (781) 487-0013, or by email lsantiago@acceleratedcure.org.

While ACP is continually seeking to expand corporate philanthropy, we rely on general donations (both large and small) and the altruism of our volunteers to continue our work at ACP. A major donation can finance a specific project, as can a number of smaller donations. All contributions, regardless of amount, enable ACP to achieve its mission to improve diagnosis, optimize treatment outcomes and find a cure for MS. We give thanks for the generosity of all of our donors and volunteers, and look forward to your continued support in the future.

**Comorbidities and MS Disease Activity**

*By Farren Briggs PhD, ScM*

Multiple sclerosis (MS) is a burdensome condition and for decades there has been limited acknowledgement of other medical conditions that co-occur in persons with MS (PwMS). Thus, for many who sought exclusively specialty care (i.e. seeing primarily a neurologist), other aspects of health might be overlooked by excellent MS-centric care. However, that paradigm is finally shifting and there is an active and ongoing conversation about the role of comorbid/co-occurring conditions in MS. This conversation is extremely relevant to all PwMS, as 75% of PwMS will have at least one other comorbid condition (i.e. anxiety and type 2 diabetes). A 2015 systematic review reported the top comorbidities experienced by PwMS were depression (24%), anxiety (22%), hypertension (19%), hyperlipidemia (11%), chronic lung disease (10%), and diabetes (9%).¹ In the last few years, there has been a steady stream of MS publications describing the impact of
comorbid conditions on quality of life, risk of hospitalizations, healthcare costs, depression, and disability. The key reason to investigate comorbidities in MS is to understand how we can optimize care, as well as identifying shared biological mechanisms underpinning MS and the co-occurring to inform future research.

This month, two studies reported on the impact of comorbidities on outcomes related to disease activity – relapses and brain volume. The first study, by Kowalee et al. published in Neurology\(^2\), involved PwMS visiting one of four MS clinics in the Canadian provinces of Nova Scotia, Manitoba, Alberta, or British Columbia who had relapsing remitting onset. Of the 1,632 clinic patients, 1,130 met inclusion criteria, 949 consented to participate, and 885 of individuals were the focus of the analyses. The participants were interviewed at baseline, and then once at the end of year 1 and then again at the end of year 2. Participants answered questions such as: “Have you ever been diagnosed with the following condition by a physician?” Some of the conditions included thyroid disease, osteoporosis, cataracts, diabetes mellitus, migraine, and hypertension. The medical records for each participant were also reviewed and information such as date of birth, race, current disease-modifying therapies, and numbers of relapses since last clinic visit were extracted. On average 13-15\%\ of participants reported having at least one relapse in the year prior each interview, and relapses, as expected, decreased with age. The researchers then looked at the relationship between number of comorbidities reported at baseline and the number of relapses experienced over the following two years. Having 3 or more comorbidities resulted in a 45\% increased risk of having a future relapse. The researchers also looked at the individual comorbidities, and having migraines increased risk of experiencing a relapse in the following year by 38\%, while high cholesterol increased risk of a relapse by 67\%.

The second study out of Austria, by Pichler at al. published in Multiple Sclerosis Journal\(^3\), involved 82 individuals with Clinical Isolated Syndrome (CIS; those who have not yet fully developed MS) or were in the early stages of relapsing-remitting MS seeking care at an MS outpatient clinic. The primary research aim was to investigate whether vascular risk factors influence brain volume and lesion load in those in the early stages of MS. Participants completed a questionnaire and were encouraged to return to the clinic every 6 months. Details on vascular risk factors were extracted from the medical records, including smoking status and a diagnosis of hypertension, high cholesterol, type 2 diabetes, and/or heart disease. MRIs at baseline and at least 18 months after baseline were extracted as well. Using the MRIs the researchers generated multiple different measures of brain volume and lesion
The patients were divided into two groups: 1) having no vascular risk factors or 2) having at least one vascular risk factor. The two groups did not differ by onset age, age at interview, gender, and other clinical and demographic traits at baseline. When looking at all participants at baseline, those with a vascular risk factor did have a smaller than normal appearing brain volume, smaller cortical grey matter volume, and less white matter volume than those who did not have a vascular risk factor. This relationship persisted at follow-up. Similar results were observed when restricted to those with CIS. Interestingly, vascular risk factors did not affect lesion load.

Together, these results emphasize the importance of continued health promotion and preventative care in PwMS, and not care solely focused on the management of MS. These studies add to the growing literature on the adverse impact of other (common) health conditions on MS outcomes, and the need for proactive health management to address these modifiable health conditions (i.e. high cholesterol, smoking, high blood pressure, etc.). It also should motivate those with MS to be their own health champions and seek care that promotes wellness and not just symptom management.

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4361468/

**Protecting Your Rights in Clinical Research**

*By Hollie Schmidt*

Our last newsletter included an article describing clinical research – the study of health and illness in people. A key goal of clinical research is to see whether the benefits of a treatment outweigh its risks for the people taking it. Benefits and risks are also factors to consider when it comes to research itself. Nobody should be asked to participate in a study where the risks they could face are high and the possible benefits are low.

The job of making sure that the benefits and risks of research studies are in balance falls to special groups called Institutional Review Boards (IRBs). IRBs are responsible for reviewing and overseeing clinical research, and protecting the rights and well-being of research participants. IRBs were established in response to abusive, unethical studies conducted in
the past. These notorious studies put their participants at risk of undue harm, often without their full knowledge and agreement.

I've been a member of an IRB for several years and greatly appreciate the important role they play in research. I wanted to share what IRBs do and how they will look out for you if and when you choose to participate in a research study.

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Most IRBs are based in major hospitals and other institutions that engage in human research. There are also “independent” IRBs that can review studies when the researcher doesn’t have a local IRB. At ACP, we don’t have our own IRB, so we use an independent IRB to review our proposed research studies.

Researchers who want to conduct research with human participants will provide their IRB with a packet of material describing their study. When evaluating a research study, IRBs pay very close attention to the possible risks a participant might be exposed to. These might include:

- Side effects caused by a drug used in the study
- Personal information being released to someone who shouldn’t have it
- Worsening of an existing disease through taking an ineffective drug or placebo

IRBs also look at the benefits of study participation, such as:

- Improvement in a disease through receiving a helpful treatment
- Free medical care
- Important knowledge gained about a disease or treatment

Some benefits are experienced by individual participants (e.g., free medical care) and some apply to the wider community (e.g., important knowledge about a new treatment). An IRB will seek to make sure that the risks of a study are as low as possible, and are reasonable when compared with the expected benefits.
The process of inviting people to join a study also comes under IRB review. For example, everyone invited to join a study should receive the information they need to make a fully informed decision. The IRB reviews the consent form that describes the study, recruitment ads, and other information given to prospective participants, to make sure everything is accurate and complete.

To be successful, research studies must recruit enough participants to meet their needs. IRBs ensure that the methods used to find participants enable them to make a free and informed choice. Here are a couple of situations that would trigger a concern for an IRB:

- The head of a lab plans to ask his/her employees to participate in the study; it would be hard for them to say no because they are being asked by their boss.
- A researcher offers an overly generous payment for participating in a study; this might influence some people to join the study without carefully considering the risks involved.

IRBs also make sure that research being done with vulnerable groups such as prisoners or children does not take advantage of them. Special guidelines are followed when reviewing studies involving these groups. For example, in research studies involving children, the IRB would make sure the parents and guardians are appropriately included in discussions and decisions about participation.

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Group discussions are usually richer when the people involved have a diversity of experience. Likewise, IRBs benefit from having people with different backgrounds and expertise, such as doctors, nurses, and scientists working in different fields; pharmacists; data specialists; lawyers; social workers; clergy members; and so on. IRBs are required to have at least one member who isn’t affiliated with the IRB’s institution. There also needs to be at least one non-scientist.
At each meeting the IRB members discuss the different proposed studies that are on the agenda. Often one or more people in charge of the study are present to summarize the study and answer questions. Then the IRB members discuss the merits and risks of the study. They also discuss the information proposed to be used in the study, such as the consent form or recruitment ads.

The IRB can take different types of actions following its review. Sometimes an IRB votes to defer a study because the members don’t have all the information they need. The researcher is then asked to add the missing information and come back to a future meeting. Sometimes they reject the study because there are fundamental problems with it. They can approve the study outright, or approve it upon certain conditions being met. These conditions might include, for example, editing the consent form to be more complete or more readable.

Once a study is approved, the IRB stays involved by periodically checking on the study’s progress to make sure it’s being conducted correctly. The IRB also needs to approve any changes the researcher wants to make to the study while it’s in progress, such as increasing the number of participants. Sometimes unforeseen problems arise during a study that increase the risks for participants. For instance, a medical device may develop new safety problems midway through a study. Enrollment may need to be halted and existing participants may need to be notified. In these cases, the IRB will be alerted and involved in the follow-up.

Not all human studies need to be reviewed by an IRB. For example, an anonymous survey on a non-sensitive topic might not need IRB review. The same is true for a study analyzing samples that have already been collected and can’t be linked with the donors’ identities. Studies using samples from the ACP Repository often fall into this category. Low-risk studies can sometimes undergo expedited review. These studies still need to be evaluated, but this can be done by the IRB chair or one or more IRB members, not the full committee.
Although the laws and regulations that govern IRB activities are constantly changing, as long as scientists are conducting research with living people, there will be a need for careful review to make sure this research is ethical.

Participating on an IRB as a volunteer member is very satisfying. It feels good to help to protect the rights of people who are being asked to join research studies. It’s also very interesting to learn about the new drugs, devices, and approaches that are being developed to treat the range of human diseases and injuries.

If you ever get the opportunity to join an IRB, or to sit in on a meeting, consider taking it. And the next time you’re invited to join a research study, remember that a group of diverse, committed people have taken a close look at it to make sure your rights and well-being are protected.

**Keeping the Fun in Fundraising**

Volunteers make a huge difference in ACP’s success. We are grateful for hundreds of donated hours that support our work each year. Our volunteers help us with a wide variety of important tasks, from in office administrative work to tasks done from many states or even countries away! Some of our volunteers give of their time and talents to host third party fundraising events to benefit ACP. Highlighted below are two recent events, hosted by two remarkable individuals.

**Walk to Cure MS**

Kemp Jaycox has been organizing annual fundraising events in support of ACP for the last 12 years. He has been living with MS since 2003. A year after his diagnosis, he visited the ACP website and was struck and inspired by ACP’s mission. Kemp initially organized a local group in Cincinnati, OH to increase awareness about MS and to raise funds for ACP. This group was called the Greater Cincinnati Cure Project (GCCP) for multiple sclerosis. Two of their fundraising events were Canine Happy Hours during which people who enjoyed walking their dogs gathered with their canine companions to enjoy a drink.
together, while browsing items in a silent auction to benefit ACP. These events proved to be very popular, raising over $10,000 with over 150 humans and 70 canines in attendance!

Kemp and his family have since moved to Cleveland, where he has turned his focus to organizing annual walks to support ACP. Neighbors, family members and friends have gathered to participate in these walks in many beautiful places, such as Yellowstone National Park and the Canadian Rockies. This year’s walk was held locally in Cleveland on Saturday, October 14th. Twenty-three people enjoyed picture perfect weather as they walked around Wade Oval in Cleveland’s University Circle and raised over $4,000 for ACP. It’s not too late to make a donation on Kemp’s behalf. Anyone interested in making a donation can do so by visiting Kemp’s donor page.

Kemp believes medical breakthroughs are possible in MS research and that organizations like ACP are working to get us closer to them. He feels additional studies relating to myelin repair may lead to better understanding of how to stop the progression of MS and restore function and strength. He also feels studies relating to bacteria and the microbiome may lead to understanding the causes of MS.

Kemp’s fundraising efforts have raised a grand total of more than $34,000 for ACP since 2005. We are extremely grateful to him, his family and all their friends!

[Photo of people at the 2017 walk]

*Jaycox Annual 2017 Walk*
**Music to Cure MS**

Marion Leeds Carroll is an experienced opera singer and stage director from Arlington, MA who has been fundraising for ACP since 2003. Every year in October, Marion and a group of colleagues perform a concert at a local church, donating all proceeds to ACP. This concert features solo instruments and chamber-music ensembles as well as singers who perform a diverse repertoire of classical music.

Marion first studied voice privately in New York City. When she was in her 30’s she decided to formally study opera at the Mannes College of Music. With a lifelong love for the works of Gilbert and Sullivan, after college she was a founding member of the New York Gilbert and Sullivan Players. Over the course of her career, she has performed in and directed many operas in New York and Massachusetts.

Marion has lived with MS since 1988. As her MS symptoms grew, Marion began limiting her performances, concentrating instead on directing and organizing concerts. She first read about ACP in a newspaper article. In the article, she learned ACP’s founder attended the Massachusetts Institute of Technology and was a successful high-tech entrepreneur. After he was diagnosed with MS he used his skillset to work toward a cure for MS. She was inspired to use her talents and love of music to help support his work by creating her annual Music to Cure MS concert.

Approximately 40 people attended this year’s concert, which was held on Sunday, 10/22, at Park Ave Congregational Church in Arlington, MA. The event was offered free of charge and advertised on Meetup, which according to Marion, helped boost attendance numbers over last year’s concert. Marion states, “Free admission was an experiment this year – a very successful one,
which I plan to continue.” This year Marion performed “Song to the Moon” from the opera Rusalka. Despite its challenging Czech lyrics, she chose this song for its lyrical and flowing qualities. This year’s concert also featured over 15 other performers. Marion recruited these performers from her connections with groups such as the New England Gilbert & Sullivan Society, the MIT G&S Players, the Sudbury Savoyards, and the Longwood Opera. Marion makes many connections through the Music to Cure MS concerts, not only with potential performers for the future concerts, but also with other people with MS. According to Marion, “It’s all about people helping other people, people who love opera and care about MS.”

This year’s Music to Cure MS concert raised over $3,600 for ACP. Since 2003, Marion’s concerts have generated an impressive total of over $33,000. If you are interested in making a donation on Marion’s behalf, please visit the Music to Cure MS donor page. We appreciate the generosity of our donors, and Marion’s willingness to devote her time and talents to support ACP.

Funds raised from events like these help us to continue our work to improve diagnosis, optimize treatment and find a cure for MS. If you have a favorite activity friends and family members enjoy doing or talents you would like to share, hosting a fundraiser is a great way to reach out to your community, raise funds for ACP and have fun while doing it. For more information on hosting your own fundraiser, contact Lindsey Santiago at lsantiago@acceleratedcure.org or (781) 487-0013.

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