On September 28, 2017, HCC staff members Cheryl Calhoun and Stan Reaves attended the Vermont Cardiac Network (VCN) Conference held in picturesque Woodstock, Vermont. VCN was established in 1984 to assure cardiac health status of Vermonters and other nearby residents. It is a group of physicians and nurses committed to providing quality educational programs in cardiac care and networking for the healthcare communities within Vermont and western New Hampshire. More information can be found about the organization here. VCN holds three conferences each year and this year approximately 100 people attended this Fall conference.

Stan Reaves presented “Late-Breaking Cardiac Clinical Trials Update” to the group. Stan presented introductory materials on the evolution of clinical trials, emphasizing the key elements of patient safety, informed consent, and ethics. By illustrating mistakes made in the past, he drove home the message of safety and ethics; capitalizing on the importance of patient advocacy in all that we do. Stan also reviewed recent drug and device clinical trials relative to cardiac care with the premise of using clinical trials to “build a better pump, better pipes, or better valves”.

Stan’s presentation was well-received by the group, garnering positive comments on the evaluation form, such as:

As a result of this presentation, …

- I will look into nursing research as a career; better understanding of symptom control, and when to make referrals.
- I will be more careful to spend extra time with patients describing procedures to ensure they make informed decisions, i.e., consents.
- I will better walk patients through explanation of the informed consent process.
Vermont Cardiac Network
2017 Fall Conference
Woodstock Country Club
Thursday, 28 Sep 2017
Other presentations included:

“Sleep Disorders and the Impact on the Heart” by David Alsobrook, MD (North Country Hospital, Newport VT), which addressed the normal sleep cycle, where in the cycle certain sleep disorders interfere, and the structural changes that occur in the heart and circulatory system as a result of prolonged periods of increased intrathoracic pressures and hypoxia.

“The Structural Heart Journey-Learning to walk, to running the Marathon” by Faye Straight RN, BSN CRCC (University of Vermont Medical Center, Burlington VT), which presented the evolution of the Structural Heart Program at UVMC, from their start with the Medtronic CoreValve Evolut R trial for high risk (high STS scores) aortic stenosis subjects to their current program on target to treat 200 patients with severe aortic stenosis by Transcatheter Aortic Valve replacement (TAVR) this year.

Hats off to VCN for their fabulous work for the people of Vermont and New Hampshire! Check them out [here](#).

Many thanks to Chery, who has served on VCN’s Board of Directors since 2012, and who provided excellent feedback on the conference for this post, and to Stan Reaves who gave an engaging and informative talk at this year’s Fall VCN Conference.
Our CRAs are located across the US, allowing for regional coverage of your project.

Experience managing all phases of clinical trials.
Extensive on-site monitoring experience using a variety of data collection processes.

Experts at implementing FDA GCP regulations and ICH guidelines for clinical trials.
Vulnerable Populations: who are they?

This is the fourth in a series of articles about medical ethics. Our previous posts in this series included the basics of medical ethics, the difference between utilitarianism and deontology, and the Belmont Report.

Today we will review vulnerable populations. The idea of vulnerable populations falls under the ethical construct of respect for persons. Remember that this principle is about autonomy, where an autonomous
individual is capable of making decisions about their personal goals and beliefs. In research, this means that participants of research voluntarily agree to participate and have enough information provided to them for them to make that decision reasonably. Individuals who lack this capacity, either fully or partially, are considered vulnerable because they may not have the maturity or capacity to make an informed decision.

Vulnerable groups include children, the poor, elderly people, homeless, the mentally ill, and racial or ethnic minorities. It can also include the uninsured or uneducated. In the case of prisoners, soldiers, or other institutionalized individuals, they may be under the influence of subtle coercion or undue influence. Vulnerabilities may be classified as physical, psychological, or social according to the American Journal of Managed Care.

The FDA regulates clinical research in certain vulnerable groups specifically. Children, prisoners, pregnant women, mentally or physically handicapped or disabled persons, and economically or educationally disadvantaged persons are specifically addressed in the US Code of Federal Regulations Title 21, Part 56.111, Criteria for IRB approval of research, and under Health and Human Services regulations, Title 45, Part 46.201, Subpart B—Protections for pregnant women, human fetuses, and neonates involved in research, Subpart C—Protections pertaining to biomedical and behavioral research involving prisoners, and Subpart D—Protections for children involved in research.

With approximately 1% of US residents incarcerated as of 2013, the issue of research ethics in this population is an important one. A 2002 report indicated that despite the requirements of 45 CFR 46, Subpart C that curtails most research on prisoners, the majority of this type of research occurs outside the purview of federal regulations and without review or approval by an IRB. Little research is conducted in prisons as medical clinical trials or biomedical studies, however, most studies were social, behavioral, program evaluations, or record review in nature.

Using prisoners as an example, we’d like to remind you that the number of vulnerable individuals is growing in the US. The issues surrounding medical care, and specifically research in these populations continue to challenge
bioethicists and clinical researchers. So, continue to ask questions during protocol and informed consent development, while consenting potential participants, and while reviewing medical records to be aware of patients who may fit a vulnerable description.

Thank you for tuning into HCC’s ethics series.

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**Essential documents Deep Dive: Agreements**

Good Clinical Practice glossary series

Welcome back to the Hart GCP knowledge series. We have been reviewing *essential documents* that are typically generated before the clinical phase of the trial begins. We have looked specifically at the Investigator brochure, clinical protocol/protocol amendments, informed consent tracking, and the use of advertisements. Today we will be reviewing financial documents and insurance required prior to beginning a clinical trial.

The Good Clinical Practice (GCP) guideline, ICH E6 R2, doesn’t go into great detail regarding how financial agreement should be arranged, but it does state that it should be addressed. The guideline states that financial aspects of a trial should be documented in an agreement between the sponsor and the investigator or institution (page 19), and defines a contract as a “written, dated, and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters” (page 3).

Many research institutions have checklists for what should be included in a contract between a study sponsor and the institution. Things that may be required to address in your agreements yet may be overlooked include:

- Agreement that procedures will be used to protect research participants
• Dissemination of findings—roles that investigators and sponsors will play in publications, presentations, or other disclosure of results to the medical community, regulatory bodies, and patients
• Responsibility for medical care for research-related injuries
• Agreements for sponsor reporting of safety issues to the institution
• Handling of intellectual property
• Indemnification or insurance

If required by the applicable regulatory requirements, the sponsor should provide insurance or should indemnify the investigator or institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence (page25). In years past, it was virtually unheard of for sponsors in the United States to be required to purchase this type of insurance for U.S.-located studies. However, in recent years, the trend is growing for large institutions to require such a policy.

Generally, it is good business practice to have written agreements for each area that could be of value to the parties, such as intellectual property, for each area of potential liability, such as payments for research-related injuries, and for potential areas of disagreement, like dissemination of information. It is no different for a clinical trial and the ICH E6 R2 GCP guidelines speak to the importance of having these documents in place without dictating exactly how they should be implemented.

Thank you for reading HCC’s glossary series!

Hart Health Hints for September 2017: Atrial Fibrillation

This installment of Hart Health Hints celebrates a year of this blog series that aims to inform our viewers about some important health tips. We especially love finding out about events in our communities that help bring awareness to health problems that our friends, our families, or ourselves may have.
In our industry, we are experts in technical details of the disease processes and cutting-edge treatment solutions, but sometimes we are not as involved in community health, and know much less about the opportunities available to educate ourselves and our loved ones about various conditions.

This month we are highlighting **National Atrial Fibrillation Awareness Month**, sponsored by the [American Foundation for Women’s Health](http://americanfoundationforwomenshealth.org).

Many people in our communities may ask, “What is A-FIB?” Atrial fibrillation, or A-fib, is a condition where the heart beats irregularly. This condition is very common, but often little is known about it. If left untreated, it can lead to dementia, heart failure, stroke, and death. [StopAfib.org](http://stopafib.org) is an advocacy organization dedicated to raising awareness around A-fib, and describes the condition in detail, provides links for A-fib resources and treatment information, and fosters communication among the A-fib community.

So, even if you don’t know anyone with atrial fibrillation, we encourage you to take a few moments this September to learn more about the resources available in your community for people wanting to learn about this interesting, and often ignored condition. Try looking here and here for more information.

![Image](knowthrombosisday.org)
Have a great September, and keep learning!

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Hart Health Hints: August 13-19, 2017 is National Health Center Week

August 13-19, 2017 is National Health Center Week

Did you know that community Health Centers provide care for over 25 million Americans at more than 9,000 locations across the country?

This August, the National Association of Community Health Centers, is sponsoring the National Health Center Week, with a theme of “Celebrating America’s Health Centers: The Key to Healthier Communities.”

Health centers are community-based and community-directed organizations that provide high quality, comprehensive primary and preventive health care services to some of the nation’s most vulnerable individuals and families. The centers help to reduce health disparities with integrated care management by providing patients with access to pharmacy, mental health, substance abuse, and dental services, as well as health education and transportation services.

The Health Resources and Services Administration (HRSA), which manages the federal program, states that by providing healthcare to adult and children living in poverty, patients in under-served rural communities, and veterans, these health centers reduce costs to the system. Spending on high-cost emergency rooms and hospital inpatient stays was reported 24% lower in patients of health centers than in non-health center patients in a 2016 multi-state study.

So, this August, check out the health centers programming to see what they do in your community (find the closest center to you here). For reference, below are examples of various community-based efforts in support of National Health Center Week 2017.
You can also help bring awareness to how these organizations help the underserved in your area by tweeting #NHCW17.

**Message from the President: A mid-year celebration**

This, HCC’s 50th blog post, is a message of celebration. Since we are halfway through 2017, I’d like to share with you some things I am exceptionally happy about and graciously thankful for.

One of our goals for this year was to continue to provide high-quality
service in the areas in which we excel. As Risk-Based Monitoring (RBM) continues to grow and become accepted as an effective and sustainable study monitoring option, I am grateful to have been able to take part in a panel-discussion on RBM recently in California that was sponsored by Emanate Life Sciences, Collaborations in Clinical Research Series. The focus of the discussion was on what works and what doesn’t work for RBM as we move forward into an era guided by the E6 R2 Good Clinical Practice Guidelines. I started HCC because there was a need for highly skilled technical advisors to serve as liaisons between sponsors and research sites. I am so very thankful that device training and study monitoring have been the backbone of our business and that we have been able to provide high-quality service to our customers to fill those areas of need.

Another of our goals this year was to expand our services and to solidify our commitment to process improvement and quality while doing so. We have spent the first half of 2017 focused on finding and filling any gaps in our processes and in our internal quality system. In the second half of this year, we will be announcing expansions in our service offerings to become a full-service, specialty CRO. I’m very excited about the culmination of our team’s efforts into what we have affectionately named our Pillars of Service and hope you will be too. Stay tuned for more information!

I’d like to leave you with what I feel is the most important piece of all—the personal connections we make as we travel this road of life. Throughout these last six months, I have seen the power of the connections in our community, and among our staff, employees, and clients to do great things. It is an adventure to build and grow HCC, but more than that, as Bear Grylls once said, “Adventure has always been to me the connections and bonds you create with people when you’re there.” It is my continued hope that HCC can be there with you to continue to make those connections.

Sincerely,

Jim Hart
We have successfully completed our 2017 Hart Healthy Month and our Hartians all did a phenomenal job of becoming more aware of their day-to-day activities and eating habits.

As was expected, some people were able to do more than others, but the point is to start somewhere, even if that somewhere is contemplation and awareness. The funny thing is... that advice applies to all parts of life! Then the next step is finding one small thing to do differently that you can manage to fit into your life and doing it!

Activities for the month were entered as separate tickets into a lottery pool, with more activities logged equaling more tickets in the lottery. At the end of the month, two names were drawn from a hat to win a $250 Fitness Toolkit. Our winners were:

- **Dan Beck**, who said he’ buy a FitBit activity tracker and gym clothes as part of his fitness toolkit, and
- **Cheryl Calhoun**, who said she might get a personal trainer with hers.

No matter what they decide to put in their toolkit, Congratulations to them both!

Some fun items that other Hartians said they would like in their dream fitness toolkits include:

- Athletic shoes and clothes
- Zumba!
- TRX equipment
- Yoga gear (mat, studio gift card)
- Elliptical or rowing machine
• Swimming accessories (goggles, fins, kickboard)
• Words of encouragement
• Extra time in the day
• A clone

Above is a Grand Finale, in case you’re wondering.

So, now that our month long challenge is completed, we challenge our Hartians and all of you to continue to make small changes in your lifestyle. To truly form a new habit, it takes on average 66 days according to a study in the European Journal of Social Psychology. Depending on the behavior you are trying to change, individual characteristics, and your circumstances, it could take anywhere between 18 and 254 days to ingrain a new habit in your life.

This month was a great start, but think of lifestyle change as a long game. Slow and steady improvements, patience, and time will get you to where you want to be!

Stay tuned to learn which charities HCC is donating to as part of our Hart Healthy Month!

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March is National Kidney Month

March is National Kidney Month

Did you know that 1 in 3 US adults is at risk for kidney disease and that it can go undetected for a very long time? Did you also know that chronic kidney disease or CKD affects 26 million American adults? Main risks for CKD are diabetes and high blood pressure, which are responsible in approximately two-thirds of all cases.
Although symptoms of CKD may go unnoticed, doctors recommend watching out for these symptoms:

- Being more tired and having less energy
- Trouble concentrating
- Poor appetite
- Trouble sleeping
- Muscle cramping at night
- Swollen feet and ankles
- Puffiness around your eyes in the morning
- Dry, itchy skin
- Increased urination

At your annual physical, talk to your doctor about any symptoms you may be experiencing. Your doctor can prescribe a few simple tests to determine how well your kidneys are functioning. He or she can order a urine test to evaluate your Albumin Creatinine Ratio (ACR), which tests for the protein albumin in your urine. Albumin should be in your blood, so its presence in your urine means that your kidneys may not be filtering properly. Your doctor can also order a simple blood test to evaluate your Glomerular Filtration Rate (GFR), which estimates how well your kidneys are filtering out creatinine, a muscular waste product, from your blood.
In March this year, the American Kidney Fund will be offering free kidney health screenings, and other nutrition, fitness, and medical referral services around the country to help people keep their kidneys healthy and to identify disease earlier. Check here to find a screening location near you! Check here to find out more about National Kidney Month!

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Hart Healthy Challenge continued: happy eating

We are just about three-quarters of the way through our Hart Healthy Month and wanted to share some of our activities with you!

Along with our physical activity goals, our team is engaging in nutritional goals as well. Here is a sampling of those goals:

- Reducing food intake by 25%
- Eating more veggies
- Eating less junk food
- Reducing sugars and caffeine
- Drinking more water
- Eating dinner earlier

Some additional tips for healthy eating come from the American Heart Association webpage for Happy, Healthy Eating for Kids, which applies to kids of ALL AGES!

Eat the Rainbow – try to get as many different colored vegetables and fruits as you can in each meal. Make it fun for you and your family!
Choose fruits and vegetables instead of French fries in the cafeteria and at restaurants.

Stay hydrated with water so you aren’t tempted to eat to satisfy your thirst.

Our team is also putting together an e-book of our favorite healthy recipes. Yummy options like this [Green Soup with Yams and Sage](https://www.eatingwell.com) from EatingWell and others abound! Check out these links as well for tasty and healthy options: [allrecipes](https://www.allrecipes.com) and [foodnetwork](https://www.foodnetwork.com)

Stay tuned for the results of Hart Healthy Month early in March! In the meantime, stay active and make incremental changes to improve your heart health!

[Hart Clinical Consultants Contact page](https://www.hartclinicalconsultants.com/contact)

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**Essential documents Deep Dive:**

Advertisements Hart’s Good Clinical Practice glossary
Essential documents Deep Dive: Advertisements

Hart’s Good Clinical Practice glossary series

Welcome back to the Hart GCP knowledge series. We have been reviewing essential documents that are typically generated before the clinical phase of the trial begins. We have looked specifically at the Investigator brochure and clinical protocol/protocol amendments and informed consent tracking in this portion of our glossary series.

The Good Clinical Practice (GCP) guideline states that an advertisement in a clinical trial is used for subject recruitment. These documents must be reviewed by the IRB/EC and filed in the Investigator’s portion of the trial master files. Thorough review and documentation of these files is required “to document that recruitment measures are appropriate and not coercive.”

Another guidance from FDA regarding recruiting study subjects provides direction on direct media advertising of potential research participants as well as receptionist scripts. Direct advertising is any form of communication that is intended to be “seen or heard by prospective subjects” for soliciting their participation in a study. As long as these materials are accurate and are not coercive, this type of recruitment is not objectionable.

Advertisements include things like flyers, posters, and bulletin board postings, but also may include newspaper, radio, or television ads. Recruitment materials for health professionals, like “dear doctor” letters or articles intended for the general public, like news stories, do not fall under the description of study recruitment “advertisements.”

Any communication with a prospective study participant is required to be reviewed by an IRB in order to confirm that the wording does not unduly influence the individual. Undue influence can include leading the subject to believe they will be receiving a newly approved drug, by using words like “new treatment” instead of “investigational treatment” or by making promises of “free medical treatment”, when the actual scenario is that the subject won’t be charged to participate in the study. Another regulatory no-no is to
make any claim about the investigative product, either implicitly or explicitly, that the treatment is safe or effective for the purposes used in the study or that it is the same or better than any other treatment.

Generally, an advertisement should contain the following types of information:

- Name and address of the clinical investigator and of the research site
- Purpose of the research
- Study eligibility criteria
- Benefits of participation
- Commitment required of the subject
- Location of the research
- Who to contact

This guidance provides general information on internet advertisements, but we will address the use of social media in clinical trials in an upcoming post (stay tuned!). Until then, look here for some tips on social media in clinical studies.

Thank you for reading HCC’s glossary series! Next time we will continue to examine key essential documents by looking at insurance requirements for a trial in the US.

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