



Volume 5, Issue 1

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*General Editor:*  
Ruth Bowling

*Assistant Editor:*  
Tim Goss  
303-315-9011

## Recruiting for Clinical Trials: My Experience at CHN

*By Kristen Cassic, M.A.*

As every researcher knows, without volunteers who are willing to participate in a study, we have nothing. As important as protocol development, data collection and statistical analysis are, without the subjects who comply with procedures, agree to be evaluated, and provide numbers to be crunched, we're lost.

Recruitment is often the most challenging, time-consuming, and expensive part of starting a new study, but it can also be the most rewarding. Even before an intervention occurs and results are seen (or not!), it is empowering for people to take responsibility for their health and make a commitment to change. This is particularly true for the research we conduct here at CHN, since we often work with an overweight or obese populace. These people are well aware of the health risks they face and will voice how positively they view a study that requires them to change their diets and/or exercise habits. This is especially true if they've tried and failed to do this on their own.

From our first telephone contact, the Clinical Trials staff strives to build and maintain a professional yet friendly relationship with our subjects. Those who are not interested in or are ineligible for a specific trial are asked if they would like to join our database in order to be considered for future studies. The majority responds with a resounding, "Yes!" They see inclusion in our database as a valuable service we provide; one they want to take advantage of. We see it as a chance to capitalize on every contact we have with our potential subject pool. Once we've identified someone who is interested in what we do, we don't want to lose him/her. I highly recommend starting a simple database of your own. The effort (which consists of dropping a medical release and history form in the mail and entering the data once it's received) is worth it. We begin every recruitment effort with a database search for qualified candidates, and we have a good hit rate.

Lisa Zucker spearheaded the current incarnation of the CT database. Working closely with University HIPAA officials, she implemented a system that allows us to collect PHI (Personal Health Information) and keep it on file indefinitely. This is a huge boon to our recruitment efforts.

Since I have been here, we have completed recruitment for 3 studies and are currently seeking participants for two more. A couple of these studies evaluated nutritional supplements' effect on biomarkers (lab values). One combines meal-replacement products with an internet-based lifestyle coaching program, and the other two are multi-center investigational new drug studies. As different as these studies are, the recruitment procedures we follow are nearly identical and involve searching our database, drafting newspaper (and sometimes radio) ads, posting flyers, sending out campus-wide emails, and encouraging current participants to tell their friends.

Recruiting for weight loss studies is relatively easy—there is an unmet need. Other types of studies are more challenging, particularly ones that require participants to have specific lab values (i.e. measures of glucose or lipid levels above a certain level) in order to be included. We know our screen fail rate (those that we consider for the study but who don't meet inclusion/exclusion criteria) will be substantially higher and that recruitment will take longer than for studies that don't rely on lab results.

### **Retention: What Comes after Recruitment**

Our study coordinators are, hands down, our best retention tool. They make their subjects their top priority, and it pays huge dividends in subject satisfaction and retention. This is where CHN professional research assistants (PRA) truly shine. From the first meeting with potential subjects, we greet them warmly, recall small details about their daily lives, and ask them about themselves. A positive relationship between the coordinator and the subject is the single most important factor affecting retention, and it pays dividends that

last long after the final weight is measured. These folks WANT to participate in our future studies. They like coming here and seeing us, and they're happy to tell their friends, family, and coworkers about us. Newspaper advertising runs thousands of dollars, and recruiting through the radio costs even more. Positive word-of-mouth? Priceless!

## **Colorado Weigh® Update**

*Kim Gorman, MS, RD*

Colorado Weigh®, the scientifically proven, adult weight management program developed by researchers at the Center for Human Nutrition, is currently operating as a weight loss intervention in three arenas: community, corporate and research.

On a need basis, CW classes are being held at the Jewish Community Center on S. Dahlia. Phase 1 or the weight loss phase has been our most demanding followed by Phase 2 or the transition into weight maintenance. Our third course, the Graduate Program, is currently underway and geared for six-month support with weight maintenance strategies. For more program information, visit [www.coloradoweigh.com](http://www.coloradoweigh.com).

CW has joined efforts with the University Physicians, Inc. team to offer Phase 1 to their employees with an incentive-based fee structure. Among the 50 participants at UPI, there has been a weight loss in excess of 240 pounds in only five weeks! The UPI administrative team has shown significant support in rehabilitating the work place environment as well. CW and UPI are collaborating with America On The Move™ to create an internal committee of wellness to support increased physical activity and heightened calorie awareness throughout the facility.

Lastly, CW is functioning as the weight loss intervention for a Breast Cancer Survival Pilot to begin in early spring with Drs. Tim Byers and Rebecca Sedjo. CW will facilitate 24 weeks of continual intervention, weight loss through weight maintenance specific to the

issues that arise with breast cancer treatment and survival. Plans are underway to collaborate on a much larger scale during 2008.

## **America On the Move & Fit 4 Colorado**

*Helen Thompson, MS, RD*

If you have watched Channel 4 since January, you might have noticed the **Fit 4 Colorado** campaign. CBS4 has partnered with America On the Move (AOM) and Anthem Blue Cross/Blue Shield to promote lifestyle behavior changes to the public. Registration for the campaign is through AOM. This helps people get started, gives them the small change messages we promote, and lets us capture aggregate data on participants of the campaign.



CBS4 has created an informational website [www.fit4colorado.com](http://www.fit4colorado.com) linking to AOM. Please

visit to see what we are up to. CHN Director Jim Hill has a weekly column called "Dr. Hill Weighs In" where he talks about areas of interest in health and wellness as it relates to weight management/chronic disease. Guest editors are welcome to contribute.

In the near future, we are planning worksite challenges and family programs to engage the various sectors in the CBS4 audience. The goal is to register 100,000 people over the next 2 years and assist these individuals in making the small behavioral changes to achieve a healthier lifestyle.

### ***In Other news...***

Recently, the "...first consolidated annual report on all externally supported projects at UCDHSC..." was published, according to UCDHSC Chancellor M. Roy Wilson, M.D., M.S. In this report is a list of the Top 50 Sponsored Program Awards (pp. 26-27). We are proud to note that 2 programs connected with the Center for Human Nutrition were included in that list: the Look AHEAD study (James Hill, Principal Investigator) at number 32 and the Colorado Clinical Nutrition Research Unit (James Hill, Principal Investigator) at number 46. This represents both the importance of our research and the contribution CHN makes to the overall operation of UCDHSC.

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## **RESEARCH STUDY RECRUITMENT**

### **IS YOUR HEALTH AT RISK?**

**Metabolic syndrome is a collection of health risks that increase your chance of developing heart disease, stroke, and diabetes. The Center for Human Nutrition is researching how well an internet-based lifestyle modification program reduces risk factors associated with metabolic syndrome. We will also provide you with low-glycemic meal-replacement shakes, snack bars, foods, and a daily vitamin/mineral supplement.**

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**You may qualify for this healthy weight management research study if you:**

- Are 20-60 years old
- Are obese, with excessive fat tissue around your abdomen
- Are **NOT** currently taking medicine for cholesterol or diabetes
- Have high cholesterol, high blood pressure, OR high glucose
- Have reliable access to email/the internet

**Qualified participants will receive a study-related internet-based lifestyle modification program, laboratory tests, and food products at no cost. Participants will be paid.**

Please call 303-315-9101 for more information  
Principal Investigator: Holly R. Wyatt, M.D. COMIRB Protocol # 06-0765

## **ARE YOU READY TO LOSE WEIGHT?**

**The Center for Human Nutrition is looking for obese adults in otherwise good health to take part in a weight loss study using an investigational combination of two medications and a behavior change program. The study will last about a year. Participating subjects will receive compensation.**

**You may qualify if you are:**

- 18-65 years old
- Obese (BMI between 27-45) <http://www.nhlbisupport.com/bmi>
- A non-diabetic
- A non-smoker for at least the past 6 months
- Not taking antidepressants
- In overall good health
- Willing to attend weekly weight loss classes for the first 3 months, and less frequently thereafter.

Please call 303-315-9101 for more information

Principal Investigator: James Hill, PhD COMIRB Protocol # 06-1164

## Employee News

### New at CHN

**Mary Tschopp, B.A., R.N.**, began working at The Center for Human Nutrition in June, 2006, after retiring from the Clinical Research Center, University Hospital. It appears that 'sticking people' is one of her passions, so her new role as nurse/phlebotomist is a natural 'fit'. Working under Kristen Cassic's direction, she is learning about the academic side of the University system. Her first impression, after starting her new career, was "how quiet it is in Academia!" The contrast between nursing on a busy research floor, and having time to research the obesity issues affecting our culture, is very striking. She loves the change!

When not busy at work, Mary can be found in her large organic garden. She won Matt Mateyka's Gardening Contest on Channel 4 in 1991, so spreading the word about the importance of "knowing where our food comes from" is an on-going passion. This translates into lots of good produce being brought in to work, to share with all her new friends and co-workers. The plan for this year is to have these same friends and co-workers actually 'get their hands dirty' with her, by working in her garden in Montclair.

Mary has been married for 38 years to Hank Tschopp and is the mother of two children, Erik and Michelle, and two grandchildren. Since Hank is currently in Casablanca, Morocco, directing the start-up of a Core Knowledge English-speaking elementary school, Mary has a 'lot of free time' that she uses to indulge in her other hobbies, 'thrifting' and studying the Stock Market. "Life is good!" she says.

**Amber Pfister, B.S.** started in January of this year as a study coordinator in Clinical Trials. Amber formerly worked as a clinical research coordinator at National Jewish Medical and Research Center for several years, focusing on pediatric asthma and allergy clinical studies, as well as adult COPD studies. She has also worked on other clinical studies in the areas of Obesity, Restless Leg Syndrome, and Depression. She has a Bachelor's degree in Human Nutrition and Dietetics from Colorado State University and is currently applying to Nursing School and to Masters programs in Nutrition to further her education. Amber and her husband, Jason have a two and a half year old son, Ethan, and all reside in Aurora.

**Emily Schwall, B.S.** is a Professional Research Assistant for Carrie Brill and will be working at the CHN and the Energy Balance Lab primarily on the Carb Study and the upcoming Energy Gap study. Emily is from Steamboat Springs, CO and comes to CHN with an undergraduate degree in Exercise Physiology from CU-Boulder. She actively participates on various boards, committees and coalitions of interest to her, leads an active, healthy lifestyle and hopes to one day further her education as a student at UCDHSC.

### The Director's Corner James O. Hill, PhD

Once again, in this issue you will get a glimpse of just a small portion of what we do at CHN and how we do it. I am pleased with the skill and professionalism of our staff, and of course, with our research results as well. I am excited about our accomplishments and about our future.

Because of things like this, 2007 holds the promise of great things for us. While I cannot share specifics now, I expect to see significant strides forward in our research capabilities. Thanks for your support!

With best wishes,  
*Jim*