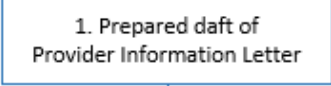
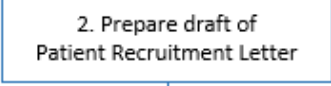
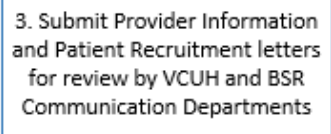
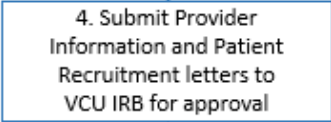
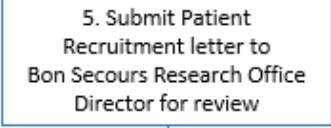
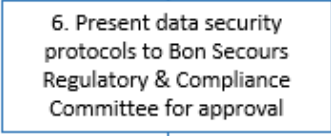
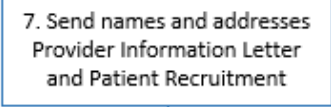
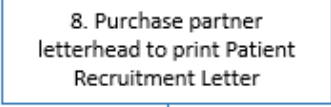
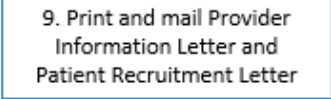


Date: May 3, 2019  
 Team: CHoR and BSR Pediatric Collaborative – Research Subcommittee  
 Initiative: Joint recruitment process to enhance access to clinical trials across health systems

Process Steps	Flow Map
1. The CHoR Investigator and Bon Secours Partner Physician drafts a Provider Information Letter to communicate information to providers about the VCUH-BSR Pediatric Collaborative and details about a specific clinical study. This letter is co-branded for both Children’s Hospital of Richmond and Bon Secours Richmond; and is co-signed by the CHoR Investigator and the BSR Partner Physician. See Example A.	
2. The CHoR Investigator and Bon Secours Partner Physician drafts a physician-endorsed Patient Recruitment Letter to communicate information to patients about the VCUH-BSR Pediatric Collaborative and details about the specific clinical study. This letter is printed on Bon Secours letterhead and is co-signed by both the CHoR Investigator and BSR Partner Physician. See Example B.	
3. The CHoR Investigator sends both the Provider Information Letter and Patient Recruitment Letter is sent to the CHoR Communications Department and the Bon Secours Communications Department for review and feedback about co-branding and messaging.	
4. The CHoR Investigator sends the Patient Recruitment Letter to VCU IRB to ensure compliance with regulatory policies (Note: The Provider Information Letter is informational only and therefore does not need to be submitted to the VCU IRB). The letter should be submitted according to the usual process for an IRB Amendment, including completion of relevant sections to describe criteria for identifying patient population, how patient names and addresses will be pulled from the Bon Secours EMR, the security protocols related to transfer and storage of patient information, and completion of the HIPAA waiver form.	
5. After receiving VCU IRB approval, the CHoR Investigator emails a draft of both the Provider Information Letter and Patient Recruitment Letter to Mark Leep, Director, Research Participant Protection Program, Bon Secours Office of Research, at <a href="mailto:mark_leep@bshsi.com">mark_leep@bshsi.com</a> . Mark Leep will provide an initial review and approval of the request and provide feedback to the CHoR Investigator.	
6. Mark Leep will submit a request on behalf of the CHoR Investigator and Bon Secours Partner Physician to present the Patient Recruitment Letter and data security protocols to the Bon Secours Regulatory & Compliance Committee. This committee requires a description of the data security protocols, to include data transfer and storage protocols (i.e., encrypted email, secure storage, data destruction plan). The committee will approve or deny the request during the meeting.	
7. The CHoR Investigator sends requests to Bon Secours Partner Physician for the provider and patient names and addresses according to the defined criteria approved by the Bon Secours RCC. Bon Secours Partner Physician sends provider and patient names and addresses to the CHoR Investigator.	
8. CHoR Investigator arranges to purchase from Bon Secours a supply of letterhead and envelopes to print the Patient Recruitment Letter.	
9. The CHoR Investigator will data merge, print, and mail the Provider Information Letters and the Patient Recruitment Letters. Cost for printing and mailing both letters will be incurred by the study team.	

## Example A Provider Information Letter



Dear Provider,

Bon Secours Health System and the Children's Hospital of Richmond at Virginia Commonwealth University (CHoR) are collaborating to increase access to pediatric clinical trials, including those addressing pediatric obesity. As you are well aware, pediatric overweight and obesity remain national crises, affecting about 1 in 3 children. The Healthy Lifestyles Center (HLC) at CHoR was established in 2012 and is dedicated to reducing pediatric obesity through both clinical and research endeavors, with an overall goal to further our understanding of effective treatment approaches. This letter is to provide you with information about a currently funded clinical trial at the HLC addressing pediatric obesity, from which your patients might benefit.

The HLC currently has active clinical trials funded by the National Institutes of Health, and offered at no cost to families. Note that a referral to one of these research trials is not a referral for clinical care. Although one of the team's medical providers will conduct an examination as part of study clearance, we refer patients back to you with any concerns identified, and do not assume clinical care for patients who have enrolled in a trial. We hope that their participation in this clinical trial might help you address their overweight or obesity, and teach them skills that last well beyond the program duration.

The trial is briefly described below, with more information in the enclosed flyers. We have also provided recruitment postcards if you have patients who might be eligible and interested. We are happy to provide more recruitment materials if you would like.

### TEENS

- Principal Investigator: Dr. Melanie Bean
- Research Question: TEENS is a large fully-powered trial **investigating the role of parents in adolescent obesity treatment**, and is based on our pilot trial. Parents are randomized to either: 1) parent skills training, or 2) their own concurrent behavioral weight loss treatment. Both are empirically supported treatments, with potential to positively impact adolescent outcomes. All adolescents participate in our established group-based weight management treatment.
- Eligibility: Adolescents with BMI  $\geq 85^{\text{th}}$  percentile, aged 12-16 years and a participating parent.
- Program duration: 4-month active treatment with follow up through 1 year.
- Format: Weekly group-based (same gender) sessions with a behavior coach and/or registered dietitian; teens also exercise with a personal trainer at least once per week at the HLC gym. Parents are in groups separate from their teens.
- Recruitment: Will begin enrolling in early 2019, with the first groups starting in summer 2019; **recruitment will be ongoing for the next 5 years.**
- Study website: [www.chrichmond.org/Teens](http://www.chrichmond.org/Teens)

For more information about research endeavors at the HLC, please visit <https://www.chrichmond.org/Services/Healthy-Lifestyles-Center.htm>. Interested patients can visit the study websites, or contact us at 804-527-4756 or [teens@vcuhealth.org](mailto:teens@vcuhealth.org) for more information or to conduct an eligibility screening.

Thank you for your collaboration as we work together to address pediatric obesity. Bon Secours and CHoR look forward to continued opportunities to increase access to research addressing pediatric health concerns in our region and beyond.

Sincerely,

Melanie Bean, PhD LCP  
Associate Professor of Pediatrics  
Co-Director, Healthy Lifestyles Center  
Children's Hospital of Richmond at VCU

Edmond "Trey" Wickham III, MD MPH  
Associate Professor, Internal Medicine and Pediatrics  
Co-Director, Healthy Lifestyles Center  
Children's Hospital of Richmond at VCU

Carl B. Rountree, Jr., MD  
Pediatric Gastroenterology  
Bon Secours Health System

**Example Letter B**  
**Patient Recruitment Letter**



Dear Parents:

Your child's health care providers at Bon Secours are committed to providing cutting edge, family-based care. As part of that commitment, Bon Secours Health System and Children's Hospital of Richmond at VCU (CHoR) are working together to increase access to comprehensive care at both health systems. This care might include the opportunity to participate in research studies like TEENS, an exciting opportunity for adolescents ages 12-16 years. TEENS is a healthy lifestyle intervention offered at CHoR, designed for teens with overweight or obesity and their parent(s). This program is led by Dr. Melanie Bean, Associate Professor of Pediatrics at CHoR, and is funded by the National Institutes of Health- thus is offered at no cost to participants. You are receiving this letter because your child has been seen as a patient by <<INSERT PRACTITIONER>> and might be eligible to participate in TEENS.

Many teens and their parents struggle with healthy eating and exercise behaviors. TEENS is designed to help teens and their parents make changes to eating and exercise behaviors with a 4-month, family-based lifestyle intervention. The program includes weekly, interactive group classes for teens and parents that cover topics such as healthy eating, physical activity, and goal setting. While participating in the program, teens also have access to gym facilities where they will work with personal trainers to improve physical fitness. For more information, please see the information below, and contact the TEENS team directly for more information.

Sincerely,

Carl B Rountree, Jr., MD  
Pediatric Gastroenterology  
Bon Secours Health System

Melanie Bean, PhD  
Co-Director, Healthy Lifestyles Center  
Children's Hospital of Richmond at VCU