**Recruitment Plan References:**

The Center for Clinical and Translational Science (CCTS) requires a study specific **Recruitment Plan**, prior to receiving approval for services or funding. The considersations below are designed to assist investigators and coordinators with developing study-specific plans. The Recruitment Plan should provide the “who, what, when, and where” of the strategies to recruit participants for the study. You will need to add this Recruitment Plan to your IRB Research Description.

1. **Study Population**

**With this information you will be able to** provide a brief study summary that includes major components of the study that will be relevant to the accrual of participants [e.g. inclusion/exclusion criteria, age range, gender, ethnic background, health status, pregnant women, fetuses, children, institutionalized adults with impaired consent capacity, prisoners (or other vulnerable populations)].

**Considerations**

* + 1. Does this study have an investigational drug or device
		2. Study schema information
		3. Where and how do you plan to recruit participants
		4. What is your projected monthly and annual targetd accrual
		5. Total number of participants
1. **Recruitment Planning Framework**
2. Determine the potential impact of the protocol design elements on recruitment feasibility. Have you conducted feasibility searches, do you plan to use Enterprise Data Trust (clinical data warehouse), REDCap (data collection & surveys), i2b2, TriNetX (aggregate counts on patient population), UK participant registries or conduct research in the community.
**Resources to assist potential or obtain patient data for study populations:**
Study design: [Biostatistics, Epidemiology, and Research Design (BERD);](http://www.ccts.uky.edu/ccts/study-design-consultation)
Feasibility searches: [Biomedical Informatics (BMI) Feasibility searches](http://www.ccts.uky.edu/ccts/BMI_Core)
[Factors affecting predicted time to accrual completion](http://www.ccts.uky.edu/ccts/sites/default/files/Factors%20affecting%20accrual%20completion.docx)
Participant Registries: [ResearchMatch.org](https://www.researchmatch.org/?rm=@UKhome), [Women’s Health & You](https://www.uky.edu/why/), [Sanders Brown Center on Aging](http://www.uky.edu/coa/adc/investigators-research-resources), other
Community engagement: CCTS [Community Engagement and Research (CE)](http://www.ccts.uky.edu/ccts/community-engagement)

**Considerations that may impact recruitment or accrual rate**

1. Will eligibility criteria effect availability of targeted population
2. Consider things that will impact accrual rate (e.g., number of populations per month and annual)
3. What are the possible effects of placebo, control arm, and randomization on recruitment
4. What are the possible effects of experimental study drug or devices
5. How complicated is your entry criteria and/or burdensome protocol procedures that may
affect recruitment
6. How far will your participants travel, is there parking available, length of time study issues

Is this for internal patient records? Is the last sentence for outreach?

1. For subject recruitment methods & privacy, develop a plan to identify and how initial contact will be made with potential subjects by those having legitimate access to the subjects’ identity and the subjects information. Describe the setting in which an individual will be interacting with an investigator. If applicable, describe proposed outreach programs for recruiting women and minorities as participants in clinical research.
**Resources:
To start**, review [IRB Guidance](http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf) and [IRB Ad Development and Approval Research Recruitment & Advertising](http://www.research.uky.edu/ori/ORIForms/89-research-advertising-for-web.pdf) or watch video at [IRB REVIEW Recruitment and Advertising Video](https://youtu.be/lsuaacaVeGQ)

**Considerations for going out into the community to recruit.**

* 1. Know your appropriate target population, what are their interests, what media venues do they use (e.g., do you have a wide age range, recruiting male, female, LGBTO, Latino, African American, Asian and Appalachian, specific conditions or diseases or healthy volunteers)
	2. Will you use a survey, referral letters, emails to UK or community physicians (IRB approval)
	3. Obtaining letter of commitment from groups, association, etc. that are agreeing to help promote your study. This IRB approval can vary. Request permission to promote research study.
	4. Know local institutional, sponsor and federal policies and regulations
	5. Do you plan to contact and discuss study with other local, state or federal agencies
		1. Community centers (may be associated with religious or ethnic groups)
		2. Retirement communities, Senior Centers, nursing homes
		3. YMCAs, Health Clubs, Health department, public libraries
		4. Local corporations, churches
		5. Alliances with disease specific organizations (e.g., participant advocacy groups, support groups, charitable organizations)
	6. Describe minority, recruitment strategies – Include above strategies as culturally appropriate
		1. Perform or utilize available cultural assessment of local community
		2. Tailor key messages, talking points to targeted populations
		3. Consider centralized minority coordinator
		4. Have translator available: [UK HC interpreter Services](http://www.research.uky.edu/ori/FormsHELP/S2H.htm)
		5. Identify minority community liaison
		6. Meet with minority community leaders, attend community meetings
		7. Establish relationships with community churches (e.g., [Faith Moves Mountains](https://uknow.uky.edu/research/faith-moves-mountains-initiative-continues-31-million-grant-study-diabetes-care-appalachia))
		8. Do you plan to recruit in the local community, surrounding counties, or other areas (e.g., Appalachia, Western KY, surrounding states, across the nation)
1. Will subjects be provided with incentives?

**Considerations:**

1. The IRB considers whether listing payment amounts could be considered as undue influence on recruitment materials. In some cases it is more ethical to state that participants will be compensated, but not list the dollar amount
2. Generally, ads for Phase I-III clinical trials and other significant risk research should not state the amount to be paid to potient subjects.
3. For other studies, the IRB considers requests to list payment amounts on a case-by-case basis
4. Will a stipend be provided for time/travel, gift cards, other forms of remuneration
5. If students, will credit hours be provided
6. Will some type of incentive be given for snowballing
7. Plan recruitment strategies and advertising
For this section, also **refer** to [IRB Guidance](http://www.research.uky.edu/ori/SOPs_Policies/7-Recruitguidance.pdf) and [IRB Ad Development and Approval Research Recruitment & Advertising](http://www.research.uky.edu/ori/ORIForms/89-research-advertising-for-web.pdf) or watch video at [IRB REVIEW Recruitment and Advertising Video](https://youtu.be/lsuaacaVeGQ)
**Resources:**Template advertising language for IRB Research Description: [Advertising](http://www.ccts.uky.edu/ccts/sites/default/files/IRB%20Research%20Description_Subject%20Recruitment%20Methods%20MAY2017.docx) section
[Study promotion campaign and contingency plan](http://www.ccts.uky.edu/ccts/sites/default/files/PRS_FEB2018.pdf)
[Participant Recruitment/Marketing](http://www.ccts.uky.edu/ccts/participant-recruitmentmarketing)
Cancer Prevention: [NIH Accrual Quality Improvement Program (AQuIP)](http://www.dcpaquip.com/Default.aspx)

**Considerations**

* 1. Develop key messages
		1. Provide general education materials, as to Why Participate in Research Studies: e.g. [NIH](http://www.ccts.uky.edu/ccts/FreqQuestions)
		2. Develop protocol-specific recruitment materials with key messages for promoting study to participants (e.g., flyers, social media/internet ads, Researchmatch flyers, monitor screens, brochures, posters, business cards, app advertisements)
		3. Develop protocol-specific materials, (e.g., RedCap prescreening forms to help with online screening of potential participants, phone screening script)
		4. Develop and plan educational sessions by investigator or coordinator for relevant community organizations, (e.g., develop short videos to educate study participants)
	2. Use low cost methods when possible
		1. CCTS can create and promote recruitment materials at no cost
		2. Promote on Social Media: CCTS Facebook/Twitter, UK HC Facebook/Twitter/Instagram, your dept. or college, other social media venues
		3. CCTS Participate in Research website: [UKclinicalresearch.com](http://www.ukclinicalresearch.com/)
		4. We provide dedicated CCTS research wall mounts, if using other wall mounts ask for permission and remove at close of enrollment
		5. For direct mailings to community physicians, contact [Physician Liaison Program](https://ukhealthcare.uky.edu/medical-professionals/physician-liaison-program)
		6. For mailings, contact [UK Post Office](https://www.uky.edu/AuxServ/postalservices/bulk_mail.html) for bulk rates, processing, handling, and mailing
		7. Attend community outreach events relevant to your study populations
	3. Use paid advertisement, if low cost ads are not reaching your study population (advertising budget)
		1. PRS can create media venue ads: radio, newspaper, apps, etc., plus negotiate and obtain rates
		2. Develop mass media and press releases
		3. Facebook paid boost ads, geo-targeting, Google Word, iPhone app ads, texting, other
	4. Tracking participant metrics
		1. Every 3, 6, 9, 12 months and at the end of the study PRS will request metrics on how enrollment is progressing. (e.g., metrics on dates of 1st participant, screening #s, enrollment #s, and which promotional efforts are or are not working for participant recruitment
		2. Study Team will be asked to complete [Enrollment Study Status Check](https://redcap.uky.edu/redcap/surveys/?s=XACTHTHN7K),
		3. PRS can provide a simple spreadsheet for data collection: [How did your participants learn about the study?](http://www.ccts.uky.edu/ccts/sites/default/files/Recruitment_Enrollment%20Metrics_2016-2017.xls)
1. Do you have an advertising budget for recruitment**?**

**Resource:**[Ideas for multiple approaches](file:///C%3A%5CVolumes%5Cukcro%5CMARKETING%20UNIT%5CCCTS%20Participant%20Recruitment%20Services%5C2018%20Recruitment%20Efforts%5CAccrual%20monitoring%5CNIH%20Recruitment_Retention%5CIdeas%20for%20multiple%20approaches)

 **Considerations**

1. If sponsor study, will they provide an advertising budget and recruitment materials
2. Will your budget cover the length of the entire enrollment period
3. Do you have a contingency plan, if recruitment efforts are not working
4. **Evaluation Plan – Accrual Assessment**

How will your recruitment plan be monitored over the course of your study.

 **Considerations:**