



IMPROVE**CARE**NOW™

Research Change Package

A Guide to Improving Your Research Journey



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BACKGROUND AND PURPOSE

What is a change package?

A change package is a concise and practical document that includes ideas and inspiration for teams seeking to apply quality improvement methods to increasing the effectiveness and efficiency of their care processes and outcomes. This change package outlines strategies for ImproveCareNow centers to use as they begin to advance and improve their research efforts. This is a living document to be continually updated as new strategies are tested and implemented successfully at centers participating in research.

Who is this change package for?

The ImproveCareNow community is comprised of clinicians, improvement specialists, patients, parents, and researchers working together to improve outcomes for children and adolescents with IBD. This change package is a tool for all of the contributors in this system to use together to develop and improve research processes. Parts of the manual may be more relevant to different types of contributors; we hope that this will encourage discussion that leads to shared learning.

How was this change package developed?

This change package is inspired by and grounded in tools, methods, and approaches already being developed or tested by ImproveCareNow centers. The content was also informed by focus groups and interviews with ImproveCareNow centers participating in research and research teams leading ImproveCareNow studies. These participants shared their experiences conducting research including what has worked, what gaps exist, and ideas for how to bolster centers' capacity to participate in research studies.

What is in this change package?

This change package is designed to be a guide for care centers as they begin to participate in research studies or continue to improve their existing research processes. The package is comprised of three sections focusing on study initiation, ongoing study activities, and study close out.

Who can I contact to provide feedback on strategies in this change package or ask any questions?

As mentioned above, this change package is a living document and any feedback around the strategies outlined in the package is welcome. Any feedback or questions can be sent to Research@improvecarenow.org.

TABLE OF CONTENTS

This table of contents is a comprehensive outline of the materials and resources contained in this manual sorted by each phase of research. Clicking on a link will navigate you directly to the corresponding materials and resources to help you easily access the information you need. You can easily return to this page by using the bookmark function.

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ICON KEY

Throughout this manual you will see the below icons used to call out important advice, ideas or recommendations to consider as you move forward. Review the key below for a brief description of what each icon represents.

	<i>Need to Have:</i> This icon identifies best practices or the most important things to remember to do.
	<i>QI Tool:</i> There is an identified tool or method available that could be valuable.
	<i>Watch Out:</i> This warning icon is to help identify and avoid pitfalls which may include bad or ineffective activities.
	<i>Tip:</i> This icon identifies a critical concept to consider in your processes.

PROTOCOL REVIEW

Determining whether a protocol is appropriate for a site is a key initial step in performing multicenter clinical research. There are two distinct perspectives when considering a protocol for a research study at a potential site: one from the PI of the study and the other from the site who is considering it. This section of the Change Package will focus on considering whether a research study is feasible at your site.

Below is a list of feasibility factors that should be considered when determining whether or not a site should participate. These feasibility factors can be treated as a preliminary check list. However, as every site has different priorities, this list may be adapted and modified based on your site priorities.



QI Tool: It is recommended to turn this list into a checklist to evaluate a protocol in a consistent, standard manner. The checklist can include Yes/No considerations and open-ended portions (i.e. cost assessment). Find an example on the next page and a [blank checklist](#) in the appendix.

Elements to consider when determining the feasibility of a study protocol:

- **New Science** – Does this research study contribute by adding new knowledge, which will directly benefit patients and contribute to the understanding of a disease process?
- **Enrollment** – How many patients do you think you can enroll? Can you meet the enrollment goal, if one exists? If possible, retrospectively consider how many patients, based on the enrollment criteria, you would have enrolled in the last six to 12 months.
- **Methodology** – Can you follow the methodology? Consider whether you have the necessary equipment and resources, including personnel. Consider the patient/caregiver perspective.
 - **Best in Class:** Would the patient/caregiver feel the methodology is reasonable? For example, how many scopes are required? How frequent are blood draws? Are fecal samples required and if so, how often? How often does the patient need to be seen? If the methodology feels like a burden to patients and caregivers, it will be harder to recruit patients.
- **Cost / Revenue** – How much money will the study contribute to your center's revenue stream? Is this more money than the study will bring in? How much will it cost to run the study? Is dedicated coordinator time considered in the cost?
- **Inclusion / Exclusion Criteria** – Consider the choke point or bottleneck for identifying potential research patients. How many eligible patients will be seen in the given timeframe? This is strongly related to enrollment considerations.
- **Stakeholders Buy-In** - What do your fellow clinicians think about the study? If you are relying on your colleagues to enroll patients, then it is important that there is some level of buy-in. Is there local leadership buy-in to proceed with the study?
- **Incentives for Patients** – What is the benefit for patients or caregivers? Why would they consider consenting to the study?
 - **Access to new treatment** – Does the study involve access to novel treatment? Patients and caregivers might consider a study more positively, or negatively, if it involves novel treatment.
 - **Gift cards or payment** – does the study compensate participants?
- **Competing Studies** – Are you already participating in studies competing for the same patient population? Have you considered if other studies are focused on similar mechanisms of actions of the products / drugs / treatment?



Need to Have: It is important to consider if authorship guidelines are stipulated for the research project. Ideally, authorship order is agreed upon before agreeing to participate in a research study.

a. Checklist Template

Element	Was this element considered? Yes / No	Barriers	Comments
New Science			
Enrollment			
Methodology			
Cost / Revenue			
Inclusion / Exclusion			
Stakeholder Buy-in			
Incentives			
Competing Studies			

b. Example Completed Checklist

Element	Was this element considered? Yes / No	Barriers	Comments
New Science	Yes	None	Study testing a novel drug.
Enrollment	Yes	Enrollment Goal is aggressive – 20 pts	Need to ensure stakeholder buy-in
Methodology	Yes	Patients need to be every other week.	Might be too often for pts.
Cost / Revenue	No	Need to discuss with business office	Needs follow up
Inclusion / Exclusion	Yes	None	Clear and reasonable
Stakeholder Buy-in	Yes	Discussed with 3 out of 6 MDs. All receptive to enrolling pts.	Need to confirm with remaining 3. See enrollment barrier.
Incentives	Yes	No incentives	
Competing Studies	Yes	Study X is competing for similar pt population	Determine overlap for study X and this study

INFRASTRUCTURE DEVELOPMENT

At a center level, there are multiple components when considering the infrastructure to conduct a successful research study. The right staff needs to be in place and stakeholders need to be engaged, including clinicians, finance personnel, and coordinators.

Staffing

Staffing should be one of the early considerations before committing to a new study. A center PI needs to estimate how much time their staff like research coordinators will need to identify patients, approach eligible patients, collect data, and complete any follow-up requirements.



Watch Out: When considering coordinator time, remember that identifying eligible patients is time consuming. This process will depend on the study and might include the need for timely chart reviews. Be sure to include coordinators in the process of determining time requirements.

Stakeholders

A center PI should consider all stakeholders who impact or are impacted by a research study. While stakeholders do include patients and caregivers, this section will focus on internal stakeholders. Internal stakeholders include clinicians, coordinators, nurses, and administrators. Others might be included on a study to study basis. For example, dietitians or pharmacists might be stakeholders depending on the research study's focus.

It is important to not only identify and engage with stakeholders, but you should also consider to what extent you need someone's buy-in. Consider whether you need someone to be an advocate for the research or merely be okay with the study.

QI Tools: There are various QI tools you can utilize to identify stakeholders. One QI tool is a charter. In a charter, you would typically identify project champions/sponsors, leaders, and key team members. A second QI Tool is a [RACI Matrix](#). A RACI Matrix identifies stakeholders who are **R**esponsible, **A**ccountable, **C**onsulted, and **I**nformed for each step in a process. A RACI could be used for the steps in a research study—study protocol, IRB, identifying patients, approaching patients, data tracking, etc.



Meetings

Meetings can be a great forum to share information and collaborate. A center PI needs to consider what information should be communicated or discussed, who are the necessary attendees, and how much time should be devoted. Different elements of a research study may be addressed through multiple meetings.



Watch Out: As you consider the forum for discussing research, consider whether a new meeting is necessary. A research study or elements of the study may fit into the agenda of an existing meeting (i.e. PVP meetings).

Common meetings where research studies are discussed include:

- PI and Coordinator Touch Base
- Pre-Visit Planning Meetings
- Population Management Meetings
- Staff Meetings



Tip: Consider if any information can be sent ahead of the meeting as a pre-read. Sending pre-reads can save valuable discussion time during meetings.



Watch Out: Decide what information should be communicated in-person compared to a different method, like through email.

Engagement at Center Level

It can be difficult to maintain engagement for a research study. Other priorities will end up competing for resources and time which will dilute your efforts to identify and recruit patients. Therefore, it is critical to keep the team informed of progress, successes, and barriers. By providing timely, relevant information, the research study remains a priority.



Tip: Visual Management can be a powerful tool to display relevant information. It keeps studies top of mind and can inform people of a project's progress, barriers, and actions to overcome those barriers.



Tip: Besides Visual Management, a measure dashboard is another great way to visually demonstrate research study progress and potential gaps or opportunities for improvement. Reference the [Measures and Dashboard](#) section of this Change Package.

Visual Management

Visual Management is a tool used to display the current state of a project, the goal (e.g. desired or future state), barriers to reaching the goal, what is being done about those barriers, by who and when.

Visual Management should be:

- Formatted in a comprehensive and concise manner
- Easy to interpret with little or no training
- Accessible to all staff
- Displayed in a manner anyone can easily see and understand
- Kept up-to-date
- Contain standard information for all research studies
- Used to encourage enthusiasm



Watch Out: It is difficult to manage a visual management system virtually. By the very nature of a virtual visual management process, the information may not be as easily accessible. While it is possible to perform visual management virtually, the team needs to be thoughtful about how to design the process and ensure it is meeting the intended purpose.



Tip: Someone should be assigned to “own” the visual management process. That owner should be keeping the information up-to-date. The owner may or may not be assigned any other specific tasks.

Visual Management does not have one set template. The formatting and information should be customized for your needs. On the following page is an example of visual management that a center uses for research studies. For this center, the information is reviewed monthly at staff meetings where all stakeholders are present.

This particular center felt it was important to track, review, and discuss research studies and projects that are open to enrollment, in start-up phase, future opportunities, IBD projects, Open/Closed to Enrollment, and Closed/Completed. For each of these categories, general information is captured to identify the study, including: study name, overall study purpose, names of the PI and research coordinator, IRB status, and key dates. Each month, specific information is reviewed by the team including overall progress, number of patients consented, number of patients on study, and number of patients who failed, withdrew, or completed the study. If escalation is required, the progress note font is colored red and the specific escalation is discussed during the monthly review. The team assigns an action owner to address the issue, along with associated actions.

Visual Management Example

Key			
Study name is bolded			
Red font is an escalation to be reviewed the following month			
Monthly progress can include updates, risks, or escalations			
I/E	Inclusion / Exclusion Criteria	C	Consented Patients (aggregate over time)
PI	Local Principal Investigator (not PI for the whole study)	O	Patients On-Study (aggregate over time)
RC	Research Coordinator	FWC	Failed, Withdrawn, Completed (aggregate over time)
IRB	Institutional Review Board		

Research & Projects Visual Management							Owner: R. E. Search	
C = Consented O = On Study FWC: Fail, Withdraw or Complete		Red = Escalation		Dec-19	Jan-20	Feb-20		
Open to Enrollment	Names protocol # drug / Mfg Inclusion/Exclusion: PI - RC; IRB; key dates			C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	
Start Up Phases				C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	
Future Opportunities				C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	
IBD Projects				C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	
Open- Closed to Enrollment				C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	
CLOSED or Completed				C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	C: <input type="text"/>	
				O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	O: <input type="text"/>	
				FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	FWC: <input type="text"/>	

Visual Management—Completed Section Example

Research & Projects Visual Management												Owner: R. E. Search	
C = Consented O = On Study FWC: Fail, Withdraw or Complete			Red = Escalation		Dec-19		Jan-20		Feb-20				
Open to Enrollment	ABC - A biomarker I/E: All IBD, aged 6-10 PI: Smith; RC: James; IRB: rely on XYZ Hospital		On track for consenting	C:	10	Consent rate slowing	C:	15	One pt failed and one withdrew. DJ to investigate.	C:	15		
				O:	3		O:	4		O:	2		
				FWC:	0		FWC:	0		FWC:	2		
	Dietetics Study I/E: no UC s/p colectomy PI: Jones; RC: James; IRB: internal		N/A	C:		Enrollment open	C:	2	One doc withdrew pt due to medication changes	C:	6		
				O:			O:	1		O:	4		
				FWC:			FWC:	0		FWC:	1		
	Dual vs Mono Therapy (low dose LMNO) I/E: CD, aged 5 -18 PI: Smith; RC: Wright; IRB: rely on ABC Univ.; Est close Dec 2020		1 new enrolled	C:	20	5 on study! Exceeding expected rate!	C:	25	RC Wright on leave. Smith to find new RC.	C:	25		
				O:	3		O:	5		O:	5		
				FWC:	1		FWC:	1		FWC:	1		

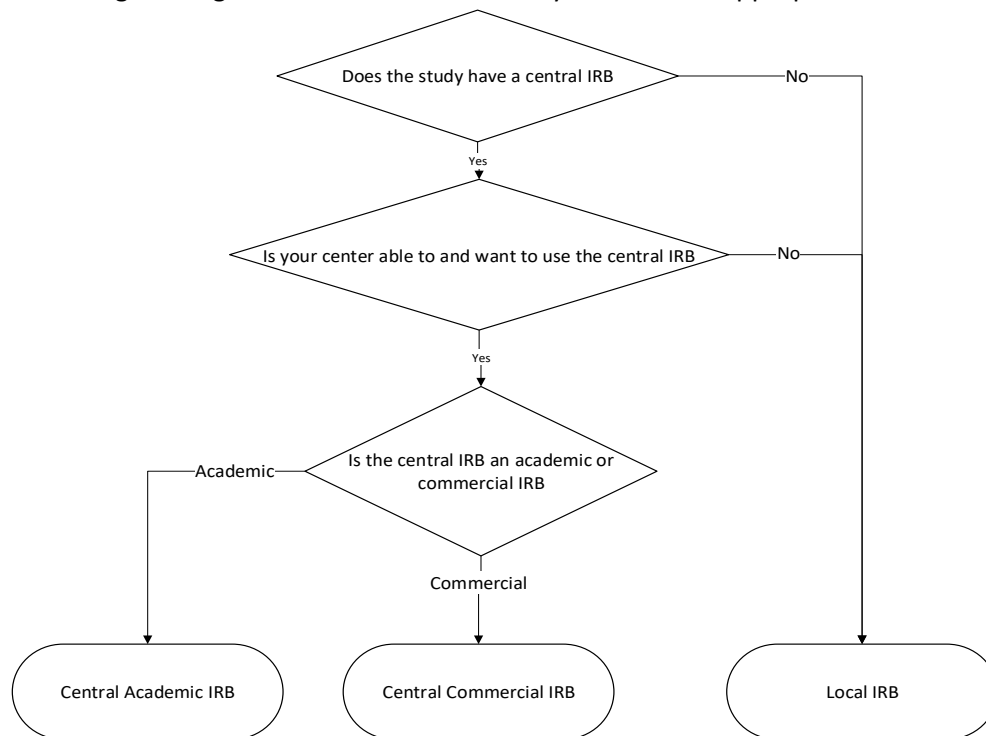
IRB PROCESS

The IRB approval process can be long and confusing for investigators. It is important to become familiar with support services and other resources available to ensure complete and thorough applications.



Need to Have: Identify the IRB point people and resources *before* beginning the application process, keeping in mind the PI is ultimately responsible for overseeing the process. Identify someone to manage and prepare the appropriate documents. Be sure to also identify who the institutional official is at a center to review and sign specific documents (see below). If a center is ceding to the coordinating center IRB, make sure to understand what this process entails.

There are different options for IRB management. IRB management can differ between research studies; the following flow chart is designed to guide a center on what IRB system is most appropriate to use for a study.



Types of IRB

Local—The IRB review and their revisions are managed at the center level. IRB agreements and their revisions are determined at the center level.

Central Academic (aka Single IRB or IRB of Record) — A center is agreeing to the terms of a single IRB (i.e. Central Academic IRB) which is located and operates from another IRB Board or academic institution. Any institution can be an IRB of record. If a center chooses this option, they agree to cede IRB review to the Central Academic IRB and follow the terms of their IRB agreement. This “all or nothing” option applies to everything regarding that project, including reviews, revisions, and documentation (e.g. consent templates).

Central Commercial (aka Single IRB or IRB of Record)—This is similar to a Central Academic IRB agreement. A Central Commercial IRB may review the initial protocol, revisions, and documentation. These entities facilitate research review and oversight, acting as a single point of contact for addressing questions, managing documentation, and coordinating communications.

The intent of Central Academic and Commercial IRBs is to streamline the IRB review for multi-center studies and eliminate the time and effort to negotiate IRB agreements.

When a site is relying on the coordinating center, or a commercial entity, documents will be provided by the coordinating center for review by the site IRB to make a reliance determination (i.e. relying on the coordinator center's IRB). A reliance determination is made at the center level based on the regulations and approval of center personnel, including the local IRB, local PI, and others. Even when a Central IRB is used, a center's local IRB will still be involved in the process including, but not limited to, ancillary reviews.



Watch Out: IRB approval can be a complicated process, and central IRB reliance can add more complexity. Be sure to track progress regularly so that things move ahead as efficiently and effectively as possible.



Tip: Understand the purpose of each document and the actions required. This will help expediate the IRB process.



Tip: There are IRB management platforms (e.g. SMART IRB) and online reliance systems for document management. The online reliance system allows investigators and institutions to request, track, and document reliance arrangements on a study by study basis.



Watch out: Do not proceed with ceding to a central commercial or academic IRB if there is no Federal Wide Assurance (FWA) number associated with the institution. A FWA documents an institution's compliance with Federal regulations and agreement to follow policies and procedures to protect human subjects. The FWA is required whenever an institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the Common Rule. For more information visit [hhs.gov](https://www.hhs.gov).

Note the elements below are examples that might be required for IRB reliance. The person who typically is required to complete the element is included in the definition.

1. **Site Information Sheet:** Completed by a representative from your local IRB and asks specific questions about a site and its policies as well as about state laws requiring IRB consideration.
2. **IRB Reliance Agreement (Protocol Specific Reliance):** Signed by an institutional official at a local site and allows the site to cede IRB review to the coordinating center IRB. If the local center is part of the SMART IRB, then it will fill out the SMART IRB Acceptance & Flexibility Agreement. The IRB Reliance Agreement is for those centers which are not part of the SMART IRB. To find out if a center is part of the SMART IRB, go to this [website](#) and click on 'participating institutions'.
3. **Protocol Specific Reliance Application:** Completed by the local site PI. This application *must be completed* if a site wishes to rely on the coordinating center or commercial entity for the study.
4. **Study Staff Log:** List of all staff at a site who will be participating in study activities and details each staff member's start/stop dates, their role on the study, human subjects protection training, and any conflicts of interest.
5. **PI Credentials:** A copy of the PI's signed and dated CV, CITI training record (or equivalent), and a copy of the PI's medical license, if applicable. This can be prepared in advance of the application process to ensure training is up-to-date (within 2 years) and ready when the IRB process is initiated.

6. **PI Responsibilities Form:** This may be provided as *information only*, as this document is referenced in both the reliance agreement and protocol specific reliance application. It outlines the PI responsibilities for both the reviewing and relying sites and explains how the PI's oversight responsibilities differ when working under an IRB reliance agreement. This document must be reviewed by the center PI prior to their signing of the protocol specific reliance application.



Need to Have: Being responsive and engaged in the process with the coordinating center is vital to moving the process forward. The coordinating center can assist with questions and next steps.



Tip: Agreeing to a reliance IRB, central or commercial, requires a level of trust from the center PI and local IRB. The center PI and local IRB need to trust the central IRB will provide a quality review that is considerate to their center. Additionally, there might be concerns about liability when using single IRBs.

SMART IRB (from <https://smartirb.org/>)

SMART IRB is currently funded by the NIH Clinical and Translational Science Awards (CTSA) Program, grant number UL1TR002541-01S1. The platform serves as a roadmap for institutions to implement The National Institutes of Health (NIH) [Policy on the Use of a Single Institutional Review Board for Multisite Research](#), though SMART IRB may be used for any study that is eligible for IRB reliance, regardless of funding source or status.

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research. Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies.

SMART IRB is **not** an IRB; rather, it's a platform that offers a master IRB reliance agreement (the SMART IRB Agreement) and a web-based system (SMART IRB's Online Reliance System) that provides a central process for participating institutions and their investigators to request, track, and document study-specific reliance arrangements. Investigators and their study teams, together with institutional (local), central academic, and central commercial IRB offices, use the SMART IRB platform to initiate single IRB review of a study.



Tip: Be sure to identify who the institutional official is at a center to review and sign specific documents. If a center is ceding to the coordinating center IRB, make sure to understand what this process entails.

CONTRACTING

Contracting for a research study can be a long and arduous process. Since executing a contract is very dependent on people, there can be a lot of back and forth communication to understand each step. These issues can lead to major delays in study start-up. Every research study has different requirements; however, there are some general practices that are transferrable across studies.



Watch Out: It can be difficult to identify the “right” person on a team to navigate the contracting process; try to identify this person early on and have a conversation with the coordinating center to have them explain and review the legal documents that will be required.

If possible, meet regularly with the coordinating center to review documents, ask questions, and build a rapport. This will help with accountability while also keeping the coordinating center apprised of the current status. While the contracting process can vary across centers, the coordinating center can be a resource to understand the requirements, expectations, and any best practices learned from other centers.



Need to Have: It’s important to stay engaged and responsive throughout the contracting process to keep it moving forward. It is helpful to cultivate a sense of urgency. If progress seems to have slowed down or is held up, ask questions, use your resources, and develop an action plan.



Tip: Create an internal team, within your center, with expertise in navigating contracting and legal processes. This team can be a great resource if you experience hurdles.

The contracting process can be time consuming. A PI might find it useful to delegate contracting tasks. A center’s PI and study support team should attend any onboarding meetings and understand all required documentation. At an onboarding meeting, the team should focus on operational matters and cover IRB and legal expectations at a high level.



Watch Out: A center’s PI is ultimately responsible for the overall success of a research study. It is important for the PI to be engaged in the process. If tasks are delegated the PI should be prepared to assist, especially when there are barriers.

For some studies, it can be useful to develop a project plan with milestones and set up meetings with internal resources to dive deeper into legal and contracting aspects of a study. If applicable, set up follow up calls or planned email correspondence between your center and the legal entity.



QI Tools: QI tools should be considered to help manage and track the contracting process. Assign roles and responsibilities for process steps. A procedural manual or process map can be useful. Visual Management can be used to track progress, current status, barriers, and action items.

Two key legal documents to familiarize yourself with are the Business Associate Agreement (BAA) and the Data Use Agreement (DUA).

The BAA is a document that clarifies which entity is the business associate. Once reviewed and signed, a center agrees that the entity acts as business associate and the center agrees to share PHI with the entity. Per [hhs.gov](https://www.hhs.gov), a “business associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity.

The DUA is a contract between your center and an entity (like an academic institution) that clarifies how your center’s specific PHI data is used and how the PHI data is protected.



Tip: It is important to know who to contact when working through a BAA and DUA. Your center’s legal team would be involved in this process. Most likely, someone from your center’s data team will also be involved. It is useful to include your center’s legal and data contacts early in the BAA and DUA process.



Watch out: Consent processes are handled under IRB and not legal contracting.



Tip: Key contacts for a study can depend on who is leading (i.e. sponsoring) the study. In an academic settings, it is likely you will need to involve internal resources like an Office of Sponsored Programs, the legal department, and Clinical Research Services.

COORDINATOR SUPPORT

Research coordinators (RC) are essential for research studies. Job descriptions define an RC's scope of work which includes maintaining awareness of the status of all active studies. RC responsibilities can vary based on the research study, the center, and PI requirements. There are qualities that are preferable and, in some cases, necessary to be a successful RC. When hiring, training, or developing an RC, consider the following characteristics.

Organizational Skills. An RC needs to be highly organized. An RC might work on multiple research studies with varied protocols at the same time. Therefore, attention to detail and demonstrating the ability to prioritize are critical skills. Not only does an RC need to be able to multi-task, but they also need to be efficient.



*Need to Have: **Effective Communicators.*** An RC needs to be an excellent communicator. An RC communicates with PIs, physicians and staff, regulatory bodies, and patients and caregivers. Each stakeholder requires a different approach. For example, an RC might need to explain a study to patients and caregivers who are in crisis or update a physician about research protocol or status. The methods of communication can also differ (e.g. in-person, over the phone, email).

Resourcefulness. An RC should be resourceful and comfortable running a team and delegating tasks. Resourcefulness not only includes answering questions and overcoming difficulties, but a successful RC needs to know where to get the answers. An RC coordinator who possesses project management skills will prove an exceptional asset.



*Tip: **Technical Expertise.*** Technical expertise with research is a valuable qualification, and even necessary for some research studies. It is a nice benefit when an RC is comfortable with technology and different platforms. RCs may need to manage spreadsheets (e.g. Microsoft Excel), data entry into REDCap, or other platforms.



Tip: While not required, it helps when an RC is passionate about research. Passion about research can be expressed in various ways: “buying in to” and believing in the advantages research, wanting to help increase medical knowledge, and aspiring to improve patient care and care delivery. When a RC is a motivating force and source of inspiration, the institution's culture of research is much improved.

The RC role can be transitional in nature with some RCs working for 1-2 years before switching to a new position. Ideally, the RC would commit to remaining in the position for a minimum of 2 years, understanding that this is not always possible. As a result, the remainder of the research team needs to be prepared with hardwired processes in place to easily transition the role. A new RC can be set up for success when the right processes and standard operating procedures (SOPs) are in place. As you are transitioning from one RC to the next, ideally there will be a few weeks of overlap (at a minimum) so onboarding can include the transfer of information and expertise from the prior RC to the new RC.



Need to Have: A well-organized plan for the active and future research studies should be a requirement for all centers. The RCs and team need a structured way to quickly reference relevant information about a study.



Need to Have: Centers need to have a standard location where relevant study information can be quickly found and referenced. Someone, typically the RC, should be assigned to manage the documentation.

There are many platforms that can be used to develop a comprehensive manual for research studies. The documentation can be electronic (e.g. Microsoft Excel) or a hardcopy. Regardless of the format, information should be easily searchable. The information should be standard across studies. While studies might require different information, having a standard format with placeholders, even if completed with not applicable (i.e. N/A), helps to more easily find relevant information.



Tip: When developing a Standard Operating Procedure (SOP) or master file for how information is organized and managed in the inclusive research manual. If an electronic manual is developed, it is useful to have quick phrases that are searchable. Hyperlinks can be used to allow for quicker references.

Below is a list of information to consider when developing a standardized manual. A standardized manual allows a team to effectively and easily reference study information and transition studies to a new coordinator.

- Study Name
- Principal Investigator (PI)
- IRB number
- Protocol
- Phase of recruitment
 - Recruitment Count
- Location of documents and materials
- If electronic, login for data system
- Key Contacts (Names / Phone numbers / Emails)
 - PI
 - IRB Representative
 - Business Office
 - Contracting Dept
 - Marketing
 - Monitor Information
 - Sponsor Information
 - Contacts for Electronic Data Capture
 - Contacts for Devices provided to Patients
 - Invoicing / Financial
 - Contacts for that technology assistance
 - Ancillary Services, if needed (e.g. Pharmacy, Radiology, Cardiology)



Tip: There is a difference between a sponsor and a monitor. The Sponsor is typically involved in funding and protocol development. The Monitor is an intermediary between sites and the sponsor. The Monitor ensures the protocol is executed correctly and the study close out is completed.



Need to Have: Ensure that the 1572 form is kept up-to-date throughout the research study. The 1572 is an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic. (<https://www.fda.gov/media/78830/download>)

RECRUITMENT

Recruitment serves as the method to educate and invite eligible subjects to participate in a research study.

Recruitment can be divided into three broad components: identifying an eligible patient, approaching the patient, and consenting the patient. How a center manages these processes is highly varied based on multiple factors, including center resources, research funding, clinic workflow, personnel and provider engagement. A single center may even have different processes for each of their active research studies and/or clinical sites.

While a center's method may vary, there are core elements that a center should implement to ensure successful recruitment. For example, integrating screening for research studies into existing processes, like pre-visit planning and population management, can help to identify potentially eligible subjects. Centers who have created a standardized system to identify eligible patients, like an Access or Excel database, can more quickly identify study eligible patients.



Tip: It is useful to understand the current state for how communication and information flows in your system. This will help answer the questions around how a center will identify eligible patients, determine which patients to approach, and then close the loop to ensure that the right patient is approached at the right time by the right person.



QI Tool: It can be useful to develop a process map or Communication and Information Flow Map. This approach can be used for current or future state of study procedures.

Modes of information gathering and communicating that information:

- **Databases** — Databases are any electronic data structure that stores and organizes information. Databases include Electronic Health Record (EHR) systems (e.g. EPIC, CERNER), ad hoc created databases (e.g. ICN patient database, Excel spreadsheets). You can use databases as a standalone tool or to develop reports.
- **Reports** — Reports are a logical presentation of information. A report organizes information in a graphic or tabular form. Reports are typically generated from information housed in databases. Reports that can be used in the recruitment process can include clinic schedules, OR schedules, infusion schedules, pathology, and watch lists.
- **Meetings** — Meetings can be a key source of presenting and sharing information. Meetings can be one on one (e.g. Center Principal Investigator and Research Coordinator) or include a larger audience. Some meetings to consider in the recruitment process are Pre-Visit Planning (PVP), Population Management (PM), Staff meetings.
- **Email** — Teams likely communicate a lot of information via email. While it is not necessary to capture every email communication, it is useful to understand what general types of information are communicated. For example, are the physicians of eligible patients notified through email?
- **Informal Discussions** — These discussions can be difficult to capture, but they likely exist at various points in the process. These discussions may manifest through various formats like in-person or through telephone. Recognizing where these occur can help identify gaps or redundancies in the how your team shares information.
- **Other considerations** — EHR messaging, text messaging, sharing notes (e.g. sticky notes)

Two challenging recruitment steps are identifying eligible patients and coordinating the approach of those patients. The two processes can be categorized as information gathering and communicating this information. Both processes are critical for recruiting patients. A team can use the following methodology to optimize the patient identification and approach processes.

Step 1: Understanding How Potentially Eligible Patients are Identified for a Research Study

Some Research Coordinators have described this step as the “secret” to successful recruitment. A study team needs to know where and how to “find” eligible patients. A team might start by documenting all sources of identifying eligible patient. The first step is to ask all stakeholders to identify how they are collecting and compiling patient information. Stakeholders might include physicians, nurses, and research coordinators. Consider the modes of information gathering identified in the “Modes of Information Gathering” list on the previous page.

See the appendix for a [sample form](#) and [case study](#) that can be used to identify how the center collects information about eligible patients.



Tip: The center’s team needs to evaluate each study’s inclusion and exclusion criteria and determine the best way to identify patients. Some studies have extensive inclusion and exclusion criteria and a pre-screening step may be needed before an eligibility step.

Step 2: Understanding How Your Team Communicates Information about Research Study Eligible Patients

The goal of this step is ensure that research study eligible patients are approached in a timely manner (e.g. during the patient’s next clinic visit). To accomplish this task, start by identifying the various modes of communication. The team needs to understand the communication flow. The communication flow is a process map for communicating information. Developing a communication flow diagram is step 3 of this approach. As with step 1, ensure all stakeholders share how they provide and receive information.

See the appendix for a [sample form](#) and [case study](#) that can be used to identify how the team communicates information regarding study eligible patients and which patients someone in the team might approach. The second column allows space to add an “X” to indicate the places and ways the team shares information.



Need to Have: The first two steps are more critical to understanding the recruitment process.

Step 3: Map the Communication Flow on a Process Map

The final and most challenging step is to place the information and communication on a process map. By using a process map, the team is visualizing how the information is “flowing”. This can allow a team to better understand where there are gaps or redundancies. As with the previous step, make sure to ask all stakeholders how they provide and receive information.



Tip: This step can feel more complicated than the first step. It is recommended that a QI resource is consulted with for assistance. A sample Communication and Information Flow map is included on the next page.



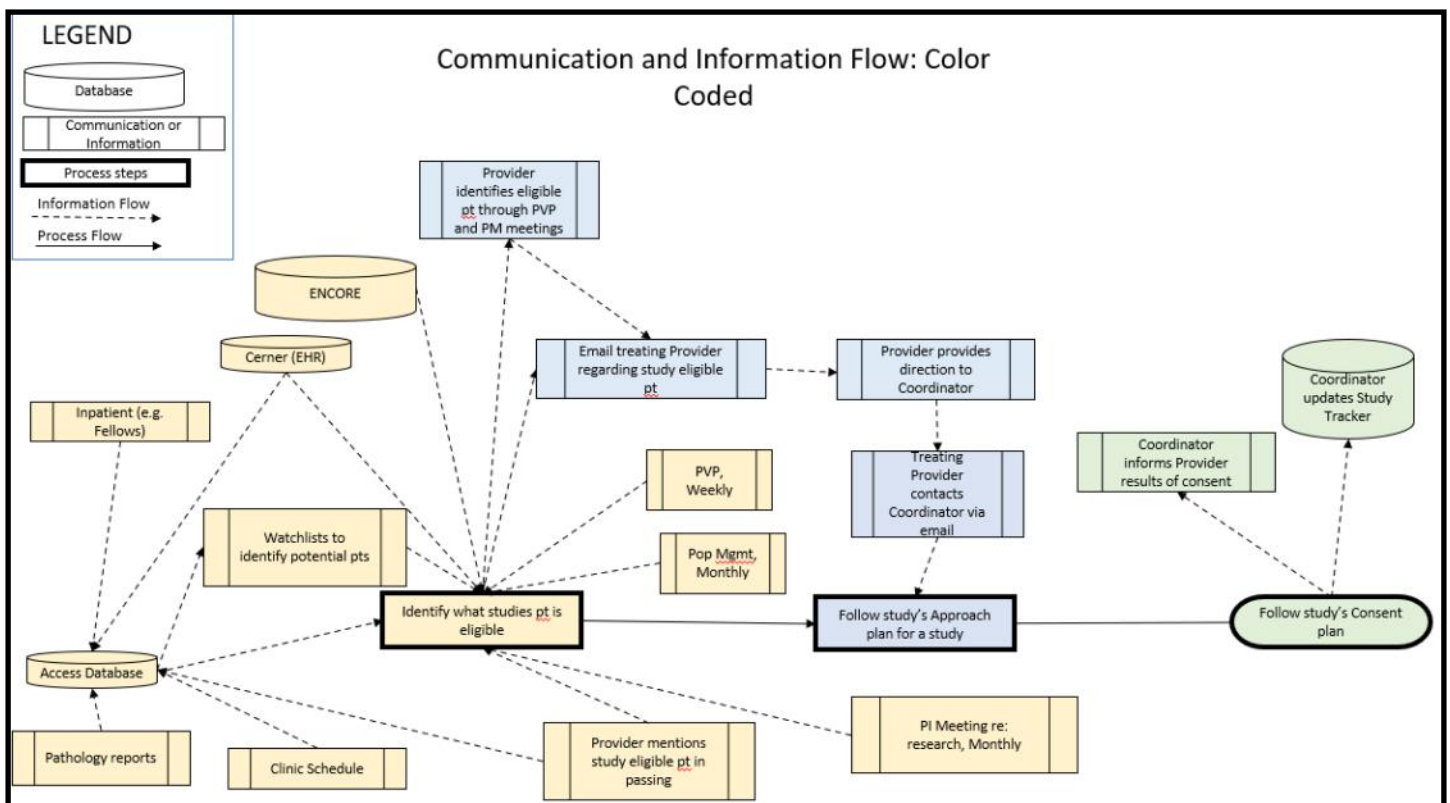
Tip: By understanding the Information and Communication Flow for your center's recruitment process you can better identify strengths and gaps in the process.



Watch Out: Each research study may require unique methods to find eligible patients. The approach to uncovering research study eligible patients is not a "one size fits all."

Communication and Information Flow maps can become complicated. It can be difficult to easily see which elements are related to a given process step. While not necessary, color coding system could be useful to identify which communication elements are related to a given process step.

Any communication that feeds into a process step is color coded the same as that process step. Any information that flows out of a process step or into the following step should be coded the same color as the following process step.



Watch out: There is a balance between how much detail should be included in the Communication and Information Flow map. It is important to be thorough in your drill down. A good objective is to reach a point when the map reasonably reflects your process and you can identify gaps, redundancies, and improvement opportunities.

Identification of Potentially Eligible Patients

Take advantage of the ICN Registry when possible to identify patients eligible for studies. If site information in the ICN Registry is up to date, the Registry can be used as a resource and tool to better understand IBD patient population. For example, query all patients who currently (or as of last entered visit) have moderate or severe disease activity by PGA. Use an established Pre-Visit Planning (PVP) workflow (or create new PVP workflow) to identify and discuss subjects who may be eligible for particular studies. Try to include clinical trial research coordinators in the ICN PVP process as they will be most knowledgeable about study inclusion and exclusion criteria. Many studies require patients to have active symptoms for eligibility.



Tip: Make sure there is protected coordinator time to identify study eligible patients.

To screen for additional active patients not identified by the current pre-visit planning process, consider the following sources to create an active list of potentially eligible patients (flare list):

1. Urgent patients (may be flaring)
2. Endoscopy schedule from week prior and upcoming 1-2 weeks
3. Current inpatients
4. Nursing phone calls (may be flaring)
5. Infusion unit phone calls/visits



Tip: Consider programming the EHR to create specific study reports. For example, when a certain drug is ordered, or a diagnosis code with a test or procedure, etc.

Once the “Flare list” of potentially eligible patients is created, ownership of that list needs to be defined and will vary according to center resources. It is a living document that will need to be reviewed regularly (every few weeks) and updated based on patient status, etc.

Communicating with Colleagues and Primary GI Providers

Once a potentially eligible patient is identified, communication with the primary GI provider should happen quickly to confirm patient details, assess provider interest, and decide on best route of approach for the patient and family. A detailed communication plan should be created to address this important step. Issues to consider include: who will do the communicating (PI, CRC, etc), timing and mode (email, phone call, etc).

Sites have found most success with a phone call directly from the PI to the primary provider, particularly with interventional trials. If given permission to approach the patient and family, the next question is who should be the one to approach and in what setting? It can be helpful to have a study briefly introduced by the primary provider or if the primary provider at least informs the family that a study team member will be contacting them.



Watch Out: Communication with patients and families about studies is often guided by IRB/local regulatory considerations so be sure to follow the communication plan in the IRB submission.

A Little Help from my Friends

A team may want to collaborate with parents and patients to develop documents and materials (i.e. FAQ sheet, introductory video) based on the feedback from sites to address common barriers. Another strategy is to develop a peer-to-peer support system for parents or patients on the study team to meet and connect with parents or patients interested in participating in the study, but looking for support.

Part of this support system could be to have parents on the study team introduce themselves when the study is introduced to a family. The letter would let the families know the parents are available to answer questions and provide more information.



Watch Out: Make sure to follow HIPAA when developing and designing a peer-to-peer support system. Note that any recruitment materials created that are patient-facing must be approved by the IRB.

COMMUNICATION PLAN

Developing a communication plan during the initiation of a study is vital to successful relationships among all stakeholders. Do not be afraid to adapt and change a communication plan as the study progresses to meet the needs of stakeholders.

Study PI and Center

The study PI should clearly communicate the expectations of a participating center during the site selection process. The expectations should include topics like recruitment, data collection, and necessary resources. An open dialogue should continue between participating centers and the study PI throughout the study. The center is responsible for communicating its overall performance including barriers or any beneficial strategies that may aid other centers. The study PI is responsible for communicating any concerns about center performance and providing praise for outstanding performance. A study PI should recognize common barriers across centers, coordinate improvement efforts, and share best practices.

Following completion of the study, the study PI is responsible for communicating all close-out plans, and importantly, involving the centers in plans for disseminating the results of the study.



Tip: If centers are experiencing barriers to enrolling patients, the Study PI can set up calls with the center (e.g. Center PI and Research Coordinator) to discuss these barriers, troubleshoot solutions, and plan improvement efforts



Need to have: Include parents and patients in these conversations to generate a more robust conversation and brainstorm novel solutions to the barriers.

Center PI and Center Staff

Prior to initiating the study, the center PI is responsible for communicating with all members of the center necessary for meeting regulatory requirements. The regulatory components may include IRB, contracting, and legal requirements. A center's Clinical Trials Office may play a central role in coordinating.

The center PI is responsible for reviewing all aspects of a study including center recruitment strategies, data collection and security, and ensuring that all members at the center are following the protocol.

The center PI should work closely with a research coordinator to review study practice, and regularly scheduled meetings are encouraged. The center PI is responsible for clearly communicating the study procedures and patient eligibility to colleagues as well as providing a plan for referring eligible patients to the appropriate person. The center PI should keep colleagues abreast of center performance regularly.



Need to Have: Set up regular meetings to review the protocol and ensure it is being followed by staff. This is also an opportunity for any risks or issues to be raised and discussed.

The center PI should always be working toward building a culture of research amongst their team. The center PI needs to have consistent communication with their colleagues to keep research and specific studies top of mind. They need to be prepared to “tell the story” of a study and emphasize its importance amidst competing studies. Using a [visual management system](#) during division meetings is one way to keep teams accountable and set an expectation for patient recruitment.



Need to Have: Set up regular meetings to review the protocol and ensure it is being followed by staff. This is also an opportunity for any risks or issues to be raised and discussed.

Center Staff and Patients/Caregivers

A center may want to collaborate with patients and caregivers to develop documents and materials based on feedback from sites to address common barriers. Previous studies have developed FAQ documents and introductory videos with the help of and input from patients and caregivers.



Need to Have: Include patients and parents in the development of any educational materials. Patients and parents offer a unique perspective and have insight about what would be important for them to know when considering consenting for a study.



Watch Out: Ensure that diversity is represented in any videos or documents. The patients and parents should relate to the actors in the video.

Caregivers can often be the best advocates for a study, not just with other caregivers, but also with providers. When caregivers are included on a study team, they can be especially effective in emphasizing the importance of a study, and best practices on how to introduce the study in a way that is appealing to patients and caregivers.

MEASURES AND DASHBOARD

The Model for Improvement asks the main questions: 1) What are we trying to accomplish? 2) How will we know a change is an improvement? 3) What changes can we make that will result in an improvement? Measurement is key to the second question: how will we know a change is an improvement?

The study and center level PIs should select measures that motivate the teams and drive the intended result. This is true at all stages of research including completing IRB, enrolling the first patient, and consenting patients. Therefore, it is important to understand what motivates the stakeholders (e.g. physicians, research coordinators, nurses). For some, knowing the consent goal is key, while for others a comparison to the aggregate is encouraging.



Tip: Measures between aggregate and site level should align.



Need to Have: Operational definitions are critical to ensure everyone understands the definition of a measure. For example, screening patients can reflect different processes depending who you ask. Below are recommended definitions for steps of the recruitment process:

- 1) Screened (i.e. Prescreened):** Patient charts/data reviewed to determine specific study eligibility
- 2) Eligible:** Patients meet a specific research study's inclusion and exclusion criteria
- 3) Approached:** Eligible patients/caregivers introduced to a specific research study
- 4) Consented:** Patients/caregivers formally agree to participate per the study's protocol

Different measures are applicable at various stages of a research study. Regardless of the measures selected, the measures should *cascade* from the study's high-level, aggregate measures to the center-level measures. This section will propose some measures that a study team might consider tracking.

Phase of Research at Aggregate Level	Applicable Measures (not inclusive)
Pre-Research	Time to Completion: IRB, Contracting, Legal
Recruitment	Comparison between Aggregate and Site Level Center to Center comparison (normalized) Eligible patient count Approach rate Consent rate

Phase of Research at Center Level	Applicable Measures (not inclusive)
Pre-Research	Time to Completion: IRB, Contracting, Legal times
Early Recruitment	Pre-screening rate, time to first patient enrollment
Recruitment	Eligible patient count, approach rate, consent rate
Post study metrics	Study to study carryover Using data for future study considerations

A study PI needs to consider the level of transparency, particularly when presenting center-level measures. There are options when sharing data—sites could see aggregate data but not site-level data or site-level could be deidentified.



Watch Out: A study PI needs to take care when sharing data. The protocol may dictate what data a study PI can share.



Need to Have: A study PI, with input, should develop a data communication plan including data update frequency.

There are many options when displaying data. Deciding how to visualize the data can be as critical as deciding what measures to track. A study PI would use charts to display data in a meaningful manner to a studies stakeholder (e.g. funders, center PIs). Some charts, like bar graphs, show a static snapshot of data over a data range. Run chart and control charts display data over time, with time frequency on the x-axis and the measure of interest on the y-axis. Both chart types have benefits and draw backs.



Need to Have: Centers need to collect data that allows the charts to be easily created. Data should be collected in a straight forward manner that facilitates data entry and analysis. Consider data elements to collect early in the process. Then, format the data entry process and analysis accordingly.



Tip: Develop Excel formulas to automatically update charts and graphs when data are added.



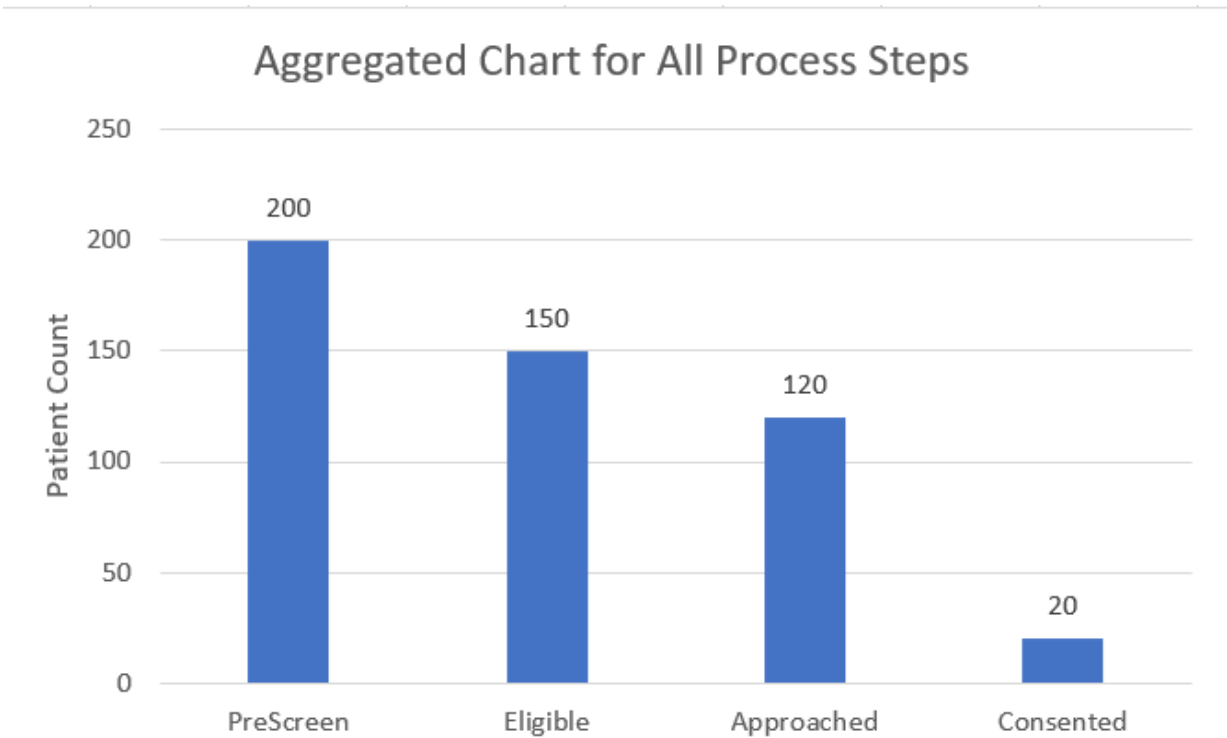
QI Tool: Bar graphs, run charts, control charts created in Excel.

Below are some sample charts with brief explanations on when the chart is used. Note the data is fictionalized.

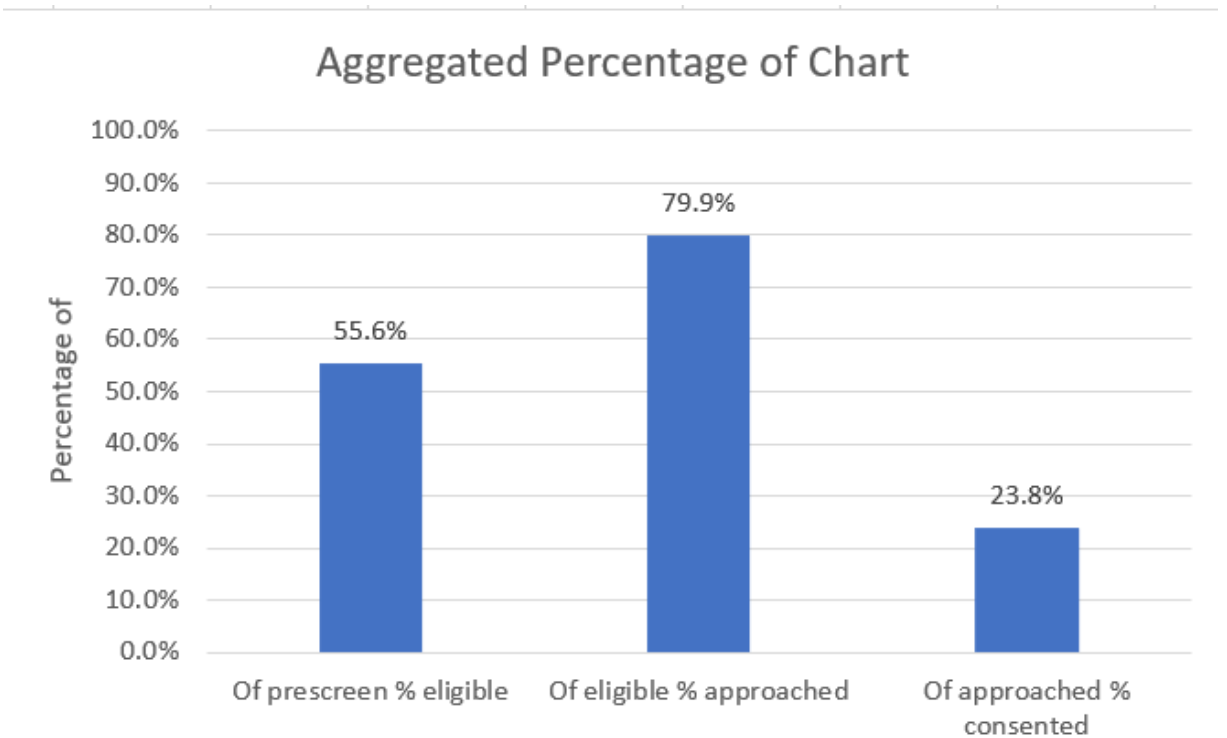
Run Chart: Displays data over time. The x-axis is the timeframe (e.g. day, week, month) and the y-axis is the measure of interest. It is useful to view data over time to identify shifts and trends. Each of the recruitment steps (prescreen, eligible, approach, and consent) can be valuable measures to determine a center’s level of activity for a study. For example, if a center does not prescreen patients, the center will find few eligible patients, and, therefore, not consent as many patients. This chart can be duplicated at the center-level to assess how a center is performing.



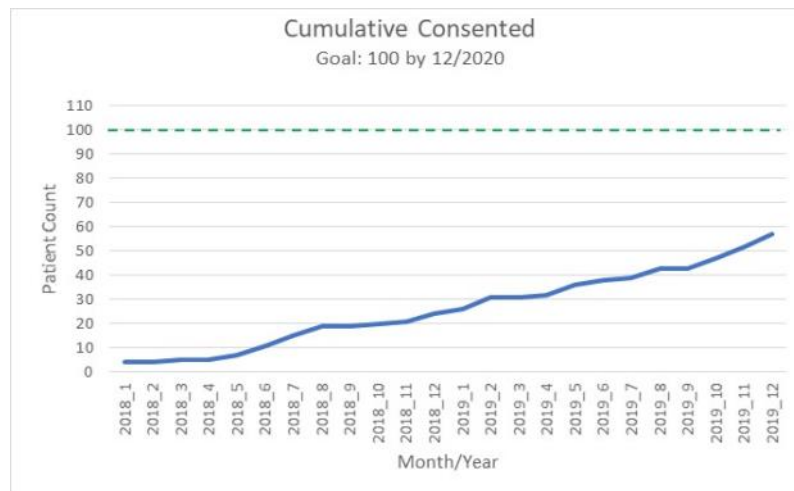
Bar Graph: Used to compare the count of discrete categories. Some categories to consider are patients who are: prescreened, eligible, approached, and consented. This data can be cumulatively displayed for a given time frame.



Bar Chart: The following Bar Chart is a variation on the cumulative chart for all process steps. The bar chart displays the percentage of each previous process step. For example, one can evaluate the percentage of prescreened patients who are eligible. This can be useful to understand how many patients a center needs to prescreen and find eligible to achieve a consent goal. Additionally, the chart can be used to compare how a center is performing overall.



Line Graph: Displays data over time. The x-axis is the timeframe (e.g. day, week, month) and the y-axis is the measure of interest. It is useful to view the count of a patients consented over time. A goal line can be inserted to better demonstrate the gap between the current state and goal. This chart can also be useful if a center set a specific recruitment goal.



Accrual Index (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4703441/>):

Accrual Index is a more sophisticated method for determining if a study is on track to meet its recruitment goal. The Accrual Index reflects the actual recruitment at any given time as a percentage of the expected recruitment at that time based on the investigator's proposed enrollment time line.

Accrual Index is calculated using the following formula:

$$\frac{(\text{Subjects Enrolled} / \text{Accrual Target})}{(\text{Months since recruitment start} / \text{Projected time to accrual})}$$

The calculation is based on a point in time and will fluctuate as enrollment changes. If the Accrual Index equals 1.0, then the study is on track to meet its enrollment goal. An Accrual Index of less than 1.0 reflects slower than planned accrual, and an Accrual Index greater than 1.0 reflects accrual ahead of schedule. See examples below:

A) If the overall goal of a study is to enroll 100 patients in 20 months, then for any given month, an average of 5 patients would need to be enrolled over the enrollment period. If a study enrolled 30 patients in the first 4 months, at the four month mark, accrual index would be:

$$(30 / 20) / (4 / 6) = 2.5$$

30= Subjects Enrolled; 20 = Accrual target at 4 months; 4 = Months since start of recruitment; 6 = Projected time to accrual of 30 subjects

Since the Accrual Index is greater than 1, the study is ahead of the planned enrollment schedule.

B) If the overall goal of a study is to enroll 100 patients in 20 months, then for any given month, an average of 5 patients would need to be enrolled over the enrollment period. If a study enrolled 10 patients in the first 4 months, at the four month mark, accrual index would be:

$$(10 / 20) / (4 / 6) = 0.75$$

10= Subjects Enrolled; 20 = Accrual target at 4 months; 4 = Months since start of recruitment; 6 = Projected time to accrual of 30 subjects

Since the Accrual Index is less than 1, the study is behind the planned enrollment schedule.

Center Level

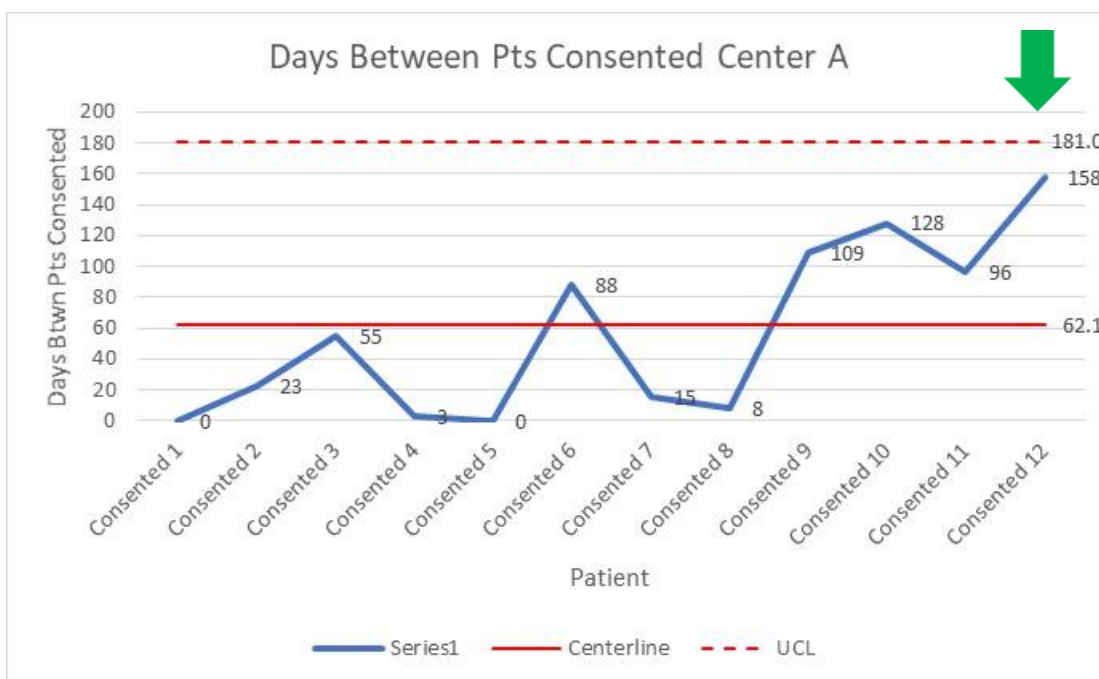
Control Chart: The following chart is an Individuals or IX chart. This chart is used to understand the variation in either consenting or approaching patients. The x-axis represents an occurrence, that is when a patient is approached or consented. date of the rare event and the y-axis is the time between events. For example, if a patient was consented on January 10 and the next patient is consented on January 17, then the value graphed would be 7. The desired direction is down, as indicated by the arrow. Less days between events translates to the event occurring more frequently.

This chart displays how often an event is occurring and the expectation is for events to occur, under “normal” circumstances. Additionally, one can see when a special cause event occurs, determine reasons for the event, and develop reaction plans, as necessary.

The chart below displays dates for consenting patients. It is also recommended to display data for approaching patients. The centerline can be indicative of how many patients will be consented.



Tip: Consider how to best present the data. Developing a dashboard can be an impactful way to view critical measures. A [sample dashboard](#) is provided in the appendix.



SITE CLOSE OUT

When a center is ready to close out a study there are certain considerations to ensure the process occurs smoothly. It may be useful to develop a checklist to assist in this process. Below is a list of common close-out tasks.

Consent

- ☐ All patients included in the study are fully consented:
 - ☐ Multiple consents may be required.
 - ☐ All consents are completed appropriately, including assent if needed.
 - ☐ Re-consent at age of majority.
 - ☐ Signatures are in the correct place.

Data

- ☐ All relevant data has been collected and formatted appropriately.
- ☐ Data has been verified.
- ☐ All data deficiencies addressed.
- ☐ Research documentation stored appropriately per contract and complies with any institutional requirements and laws (e.g. FDA, state, and local).

Documentation and Records

- ☐ Ensure all contract requirements for end of study related tasks have been completed.

Supplies

- ☐ Biospecimens collected and stored.
 - ☐ Appropriate storage conditions and labeling.
- ☐ Equipment returned.

Drug Study

- ☐ Unused drugs collected.
- ☐ Unused drugs returned or destroyed per protocol and contract.

Administrative

- ☐ IRB and Regulatory tasks closed out.
 - ☐ An IRB might have a specific close-out report that must be completed. The report may include outcomes of the study, enrollment data, any risks or problems that may have arisen, and significant findings.
 - ☐ Regulatory documents organized and filed correctly.



Need to Know: Each IRB will have specific requirements to close-out the study. Consult the IRB documentation to ensure compliance. CROs, study PIs or sponsors may all have their own close out requirements.

- ☐ Financial components closed out.
 - ☐ Bill for all outstanding work
 - ☐ Study funding is fully managed (e.g. funds are received and allocated)



Need to Know: It is important to understand the order of closing out contracts. For example, do contracts need to be closed before IRB?

Publication

- ☐ Make sure authorship guidelines (national and international) are followed.
 - ☐ If authorship and/or authorship order is previously agreed upon, ensure those terms are met.
 - ☐ If authorship and/or authorship order is not previously agreed upon, start communication with study PI.
 - ☐ Co-authors should be allowed to review and comment on draft manuscripts.
 - ☐ Co-authors should review approved final manuscript.



Need to Know: Ensure close out with patients and caregivers is conducted per protocol (i.e. provide required study close-out information, recommendations for treatment plan to continue on the medication, change, or how to proceed, etc.). Study medications and/or equipment in the family's possession may also need to be returned.



Tip: Research Coordinators (RC) should be familiar with the close-out process steps. Throughout a research study, the RC needs to be in regular contact with the monitor.

STUDY FEASIBILITY CHECKLIST TEMPLATE

Element	Was this element considered? Yes/ No	Barriers	Comments
New Science			
Enrollment			
Methodology			
Cost / Revenue			
Inclusion / Exclusion			
Stakeholder Buy-in			
Incentives			
Competing Studies			
Other: _____			

COMMUNICATION AND INFORMATION FLOW TRACKING FORM

PROCESS STEPS

STEP 1: How is information gathered to determine patient eligibility

Step 2: Where is information communicated to ensure an eligible patient is approached

MODES OF INFORMATION GATHERING & SHARING

Meetings: PVP		
Meetings: PM		
Meetings: Staff		
Meetings: PI and RC		
Database: EHR		
Database: Access (dept specific)		
Reports: OR Schedule		
Reports: Clinic Schedule		
Reports: Pathology		
Reports: Watch List (Flare List)		
Email		
In-person Discussions (informal)		
Other:		
Other:		

COMMUNICATION AND INFORMATION FLOW CASE STUDY

Children’s Pediatric Hospital for Children is relatively new to research and ambitiously signed up for four research studies. All studies began enrolling patients in the same month. Over the following six months, the clinical team has fallen behind their recruitment goals. The clinical team reached out to the ICN Community for support.

Step 1: The first recommendation was to understand what information the team is using to identify eligible patients. The center gathered a cross-functional group of stakeholders to fully understand the ways the team identifies eligible patients. The team included the center PIs for the studies, physicians, the nursing team, and the study research coordinators.

The team completed the following template by placing a “X” in the areas where information is gather to determine patient eligibility.

PROCESS STEPS

MODES OF INFORMATION GATHERING & SHARING	STEP 1: How is information gathered to determine patient eligibility	Step 2: Where is information communicated to ensure an eligible patient is approached
	Meetings: PVP	X
	Meetings: PM	X
	Meetings: Staff	
	Meetings: PI and RC	
	Database: EHR	X
	Database: Access (dept specific)	
	Reports: OR Schedule	
	Reports: Clinic Schedule	
	Reports: Pathology	
	Reports: Watch List (Flare List)	
	Email	
	In-person Discussions (informal)	X
	Other: Sticky notes from RC to Physicians	
	Other: Induction Nurse	X

Analysis: Based on the spreadsheet, the Children’s Pediatric Hospital for Children team quickly realized there were substantial gaps in how they were identifying eligible patients. The main ways that patients were being identified was via the EHR system. There were many other places that the team recognized that they need to look, like the OR schedule and in-patient lists.

Step 2: Based on the analysis, the Children’s Pediatric Hospital for Children team brainstormed, tested, and implemented several strategies to identify eligible patients. However, that was only one side of the equation. The information about eligible patients needed to then be communicated to the right people. The team gathered their stakeholders again to understand how information was communicated and used the template to below by placing an “X” in the applicable places.

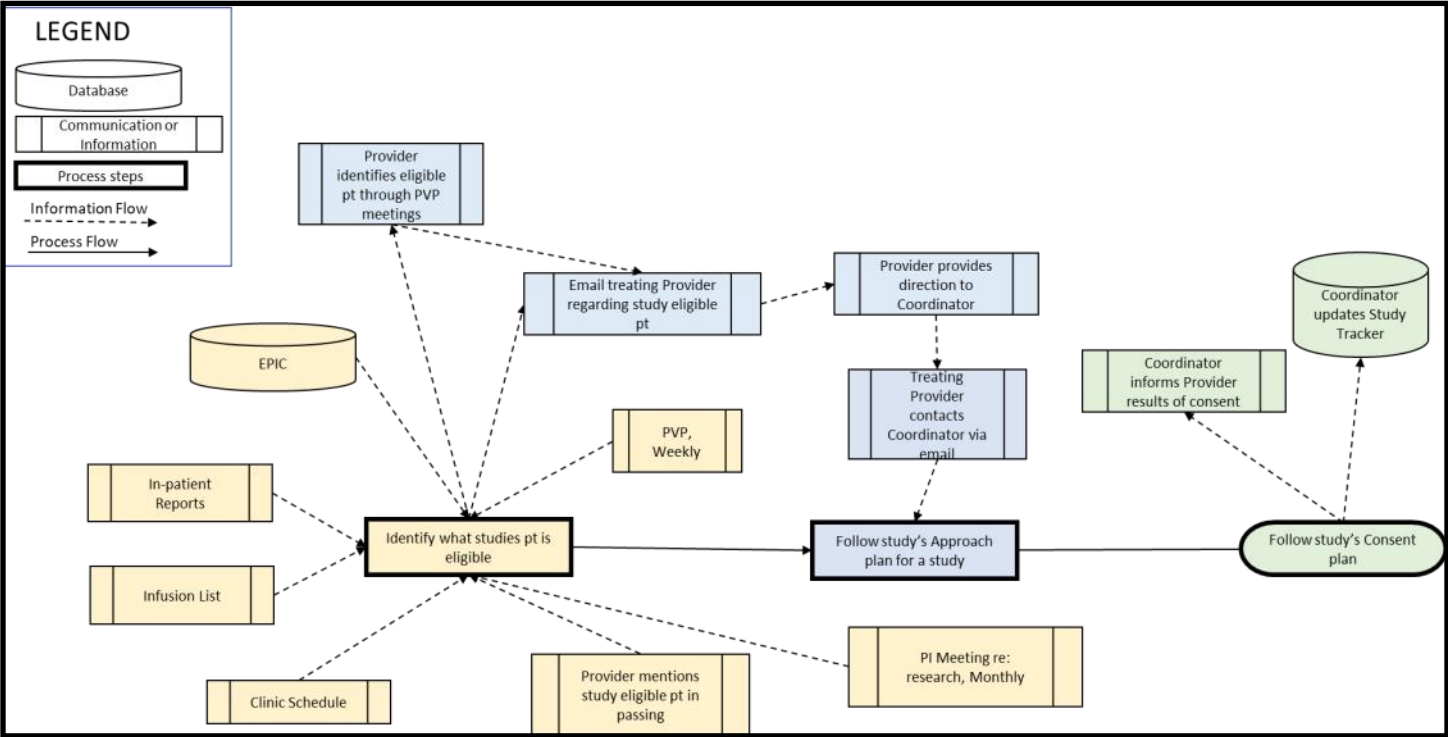
PROCESS STEPS		
MODES OF INFORMATION GATHERING & SHARING	STEP 1: How is information gathered to determine patient eligibility	Step 2: Where is information communicated to ensure an eligible patient is approached
	Meetings: PVP	X
	Meetings: PM	X
	Meetings: Staff	
	Meetings: PI and RC	X
	Database: EHR	X
	Database: Access (dept specific)	X
	Reports: OR Schedule	X
	Reports: Clinic Schedule	X
	Reports: Pathology	X
	Reports: Watch List (Flare List)	X
	Email	X
	In-person Discussions (informal)	X
	Other: Sticky notes from RC to Physicians	X
	Other: Induction Nurse	X

Analysis: Once again, the team quickly recognized there were limited ways information was communicated. For example, the team found it interesting that the PI and Research Coordinator did not have formal meetings. Without a thorough information sharing plan between the two, it would be very difficult to approach eligible patients at the right time.

Step 3: The team decided they wanted to add different sources of information where patients who might be eligible for a research study could be found. The team performed some PDSAs and decided to add different sources of information. The team felt it was important to map the new process to better understand how the information filtered into the different process steps and how those steps are communicated.

The team enlisted the help of QI support and another ICN center to assist in developing the process map. There fellow ICN center recommended using a new tool called a Communication and Information Flow diagram.

Children’s Pediatric Hospital for Children is developed the following Communication and Information Flow map.



Analysis: The team found the visualization of the Communication and Information Flow map useful. In reviewing the map and discussing the process with their fellow ICN center, the Children’s Pediatric Hospital for Children recognized they did not have a watch list (e.g. flare list) to identify eligible patients. As a future enhancement, they will create a watch list to more effectively identify patients. They decided to review the watchlist during their Pre-Visit Planning meetings. Once this is implemented, they will update the Communication and Information map accordingly.

RACI MATRIX

A RACI matrix identifies key team members and responsibilities for process steps within a project. A RACI matrix should be constructed with representatives from each key team member. RACI is an acronym: **R**esponsible, **A**ccountable, **C**onsulted, **I**nformed. For any given process step, roles are assessed to determine their level of involvement.

Responsible: The person who is doing the actual work for the project task. Multiple people can be responsible for completing a single project task.

Accountable: The person who is accountable for the success of the process task. This person is the decision-maker for a process step. Only one person should be accountable. A person can be both accountable and responsible for completing a task.

Consulted: The person who needs to be checked with for details and additional information on a task's requirements. This person might be a subject matter expert or a project manager.

Informed: The person who needs to be updated during a process step. This person might include senior leadership.

Note: A process step must include responsibility and accountability. Consulted and Informed are not required for any given process step.

Below is an example of a simplified RACI Matrix for a generic research study.

	Sponsor	Site PI	Research Coordinator	Department Head	Site Legal
Evaluate protocol	C	A R	R	C	
Complete IRB and Contracting		A R	R	I	C
Recruitment	I	R	A R	I	
Close-out	R	A	R	C	
Publication	I	A R		I	

DASHBOARD EXAMPLE—STUDY-LEVEL

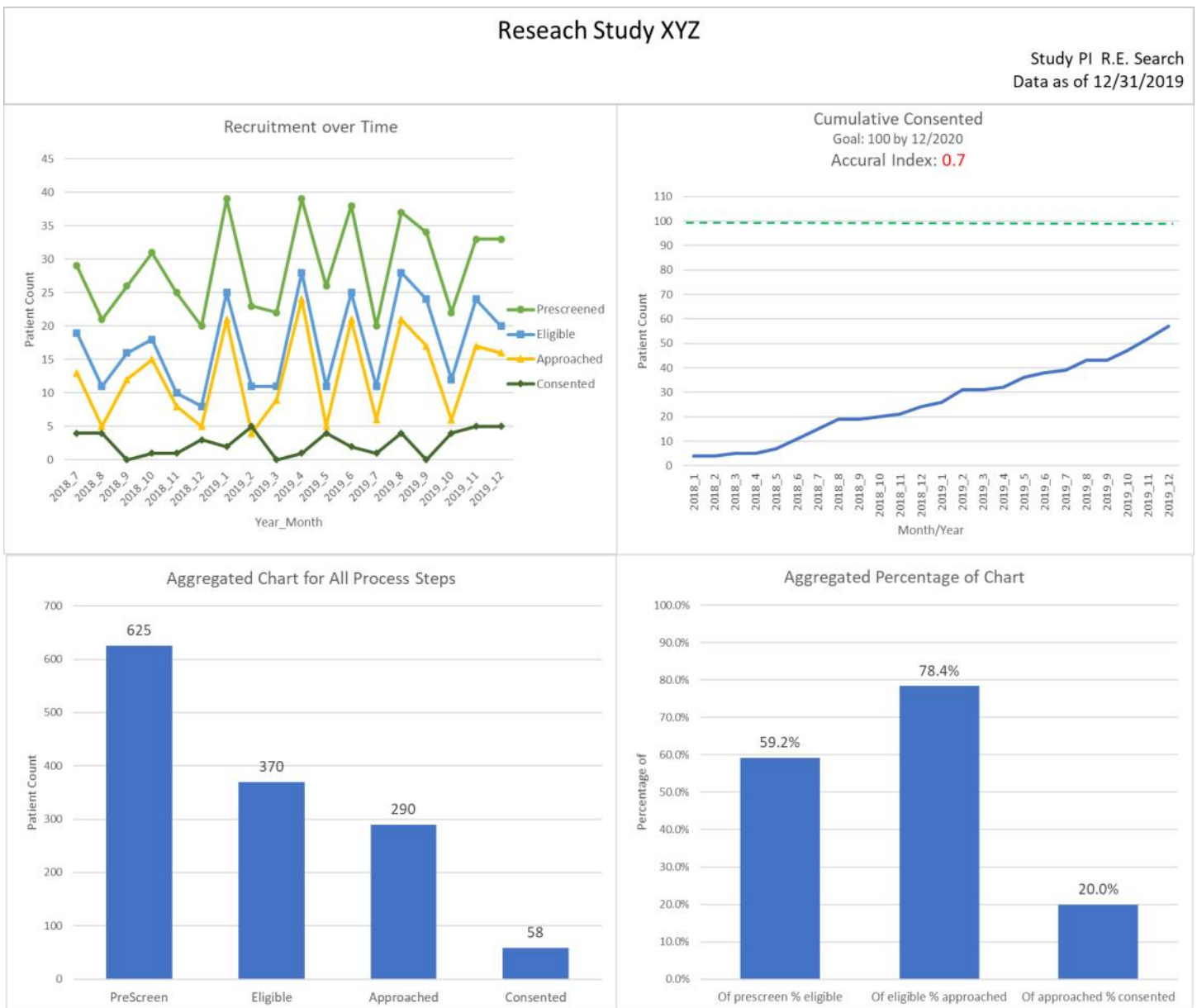
Dashboards provide a visual display allowing teams to monitor and assess the progress of a study. There are many metrics that can be selected when developing a research-based dashboard. There is no “correct” dashboard and the metrics selected should be customized for each study. The following two dashboards provide an example of how to structure a dashboard. These dashboards show cascading metrics. The measures, while similar, are tailored to the audience—study-level and center-level. [Download Study Level template.](#)



Need to Have: Determine the measures and visualization at the start of the research study. It is easier to design the data collection process upfront compared to when data is already being submitted.

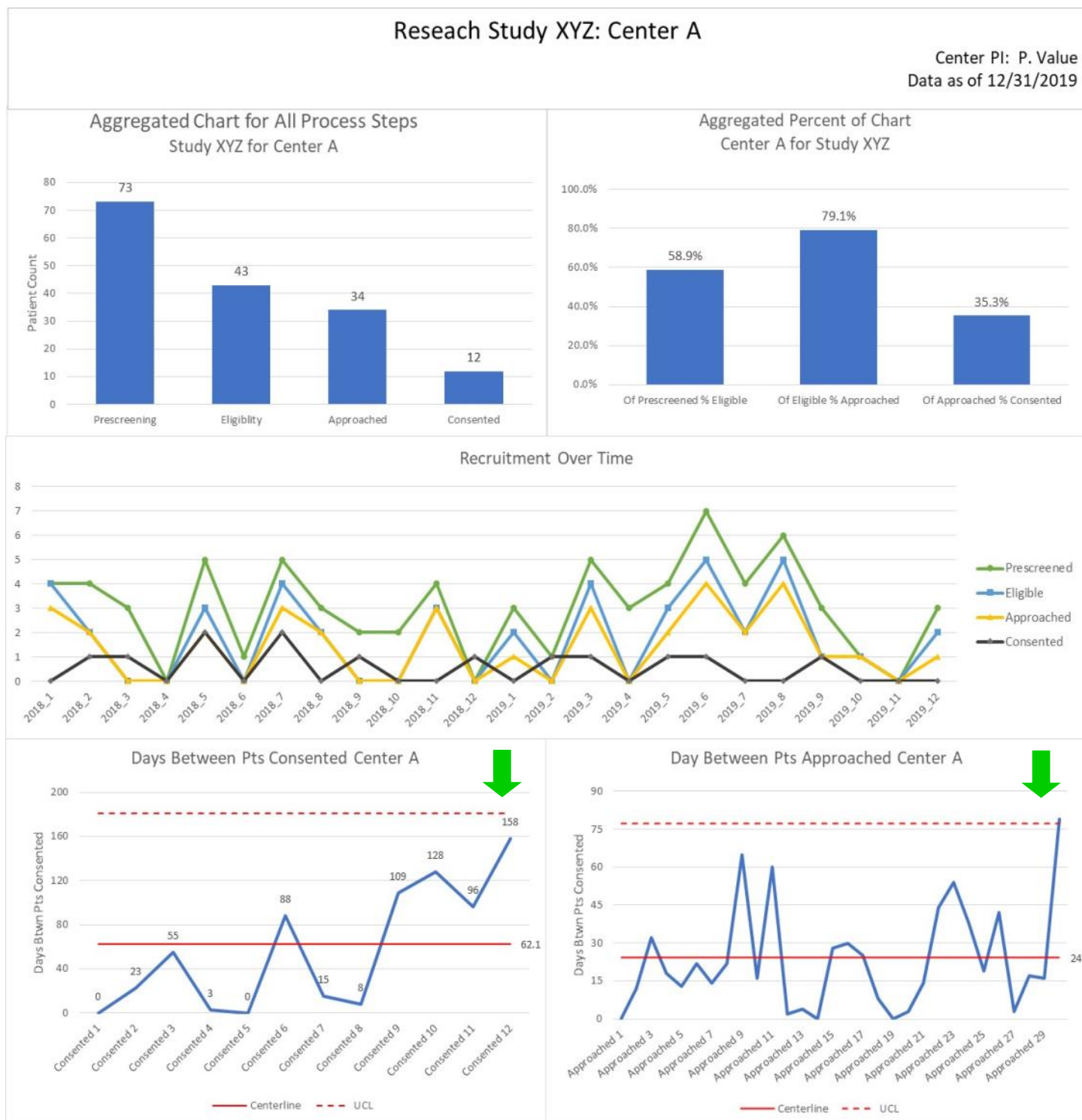


Tip: Keep it simple and do not overcrowd a dashboard with metrics. Make sure to focus on the critical metrics to track.



DASHBOARD EXAMPLE—CENTER-LEVEL

While a center-level dashboard has similar elements to a study-level dashboard, the two do not need to be identical. Dashboards should be applicable and useful to the audience, allow for status monitoring, and aid in decision-making. Dashboards can also be used as a component of [visual management](#). [Download Center Level template.](#)





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