Recruitment and Screening of Potential Participants: Understanding the Regulatory Requirements and Nuances

MR. OMAR ECHEGOYEN

PATIENT RECRUITMENT SPECIALIST,
CC OFFICE OF PATIENT RECRUITMENT

JONATHAN M GREEN

DIRECTOR, OHSRP

OFFICE OF PATIENT RECRUITMENT

MARCH 19, 2026

Speaker: Omar Echegoyén, MSA

NIH National Institutes of Health
Clinical Center

NIH Office of Intramural Research
Office of Human Subjects Research Protection

OBJECTIVES

- Introduction to the NIH CC Office of Patient Recruitment
- NIH clinical trials and phases
- Development of a recruitment plan
- Assessment, strategies, materials, implementation, and evaluation
- Current challenges & opportunities
- Future…is now!

OFFICE OF PATIENT RECRUITMENT
OFFERED SERVICES AND RESOURCES

RECRUITMENT SERVICES

- Helps inform the public of NIH studies using various outreach tools
- Conduct consultations with NIH institute researchers
- Develop customized recruitment campaigns catered to each clinical study
- Recruit volunteers using social media ads, Listservs, posters, flyers, newspaper ads, etc.
- Attends health fairs and related events to raise awareness, educate and engage the public

To start recruiting for a study, complete a Service Request Form:
http://intranet.cc.nih.gov/recruit/opr.html
Or call us 833-JOIN-NIH (5646-644)

CONTACT CENTER

- How the public reaches NIH for studies
- Responds to public inquiries by phone or email
- Help patients + healthy volunteers find appropriate research studies at NIH
- Performs telephone screenings and refers eligible volunteers to the research team

How we can be reached:
800.411.1222 or 833-JOIN-NIH
TTY users call via MD relay 7-1-1
Monday – Friday
8:00 a.m. – 4:00 p.m. EST

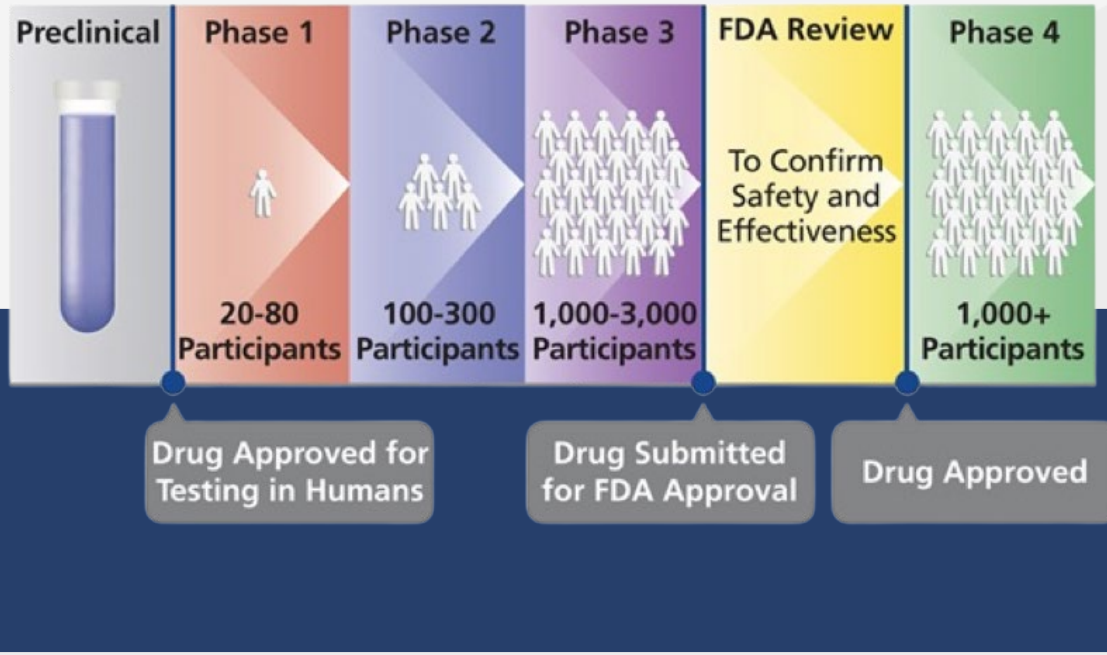
CLINICAL RESEARCH VOLUNTEER PROGRAM

- Program specialists train researchers on study compensation
- Payment office provides payments to study participants
- Our team maintains a database of healthy volunteers for studies

If you need a list of healthy volunteers for your studies or want to learn how to compensate your volunteers, call:
301.496.4763

PHASES OF CLINICAL TRIALS

- **Interventional**
- **Natural History**
- **Training**
- **Screening**



- **Phase 0**
- **Phase 1**
- **Phase 2**
- **Phase 3**
- **Phase 4**

CLINICAL CENTER PATIENT ACTIVITY REPORTED IN 2024

HTTPS://WWW.CC.NIH.GOV/SITES/DEFAULT/FILES/ASSETS/ABOUT/PDF/2025CCDATAREPORT.PDF

1,281 physicians are credentialed to care for patients at the NIH Clinical Center.

As of October 1, 2024.

The NIH Clinical Center had 11,894 queries about clinical trials in the 2024 fiscal year.

Participate in research!

Contact 1.800.411.1222 or visit **www.cc.nih.gov/recruit**

Patient Activity 2022-2024

	2022	2023	2024
Inpatient Admissions	2,908	3,110	3,340
New patients	5,887	6,301	6,385
Inpatient days	26,448	26,676	27,347
Average length of stay (days)	9.1	8.1	8.1
Outpatient visits	74,871	81,596	81,434

Clinical Research Activity 2020–2024

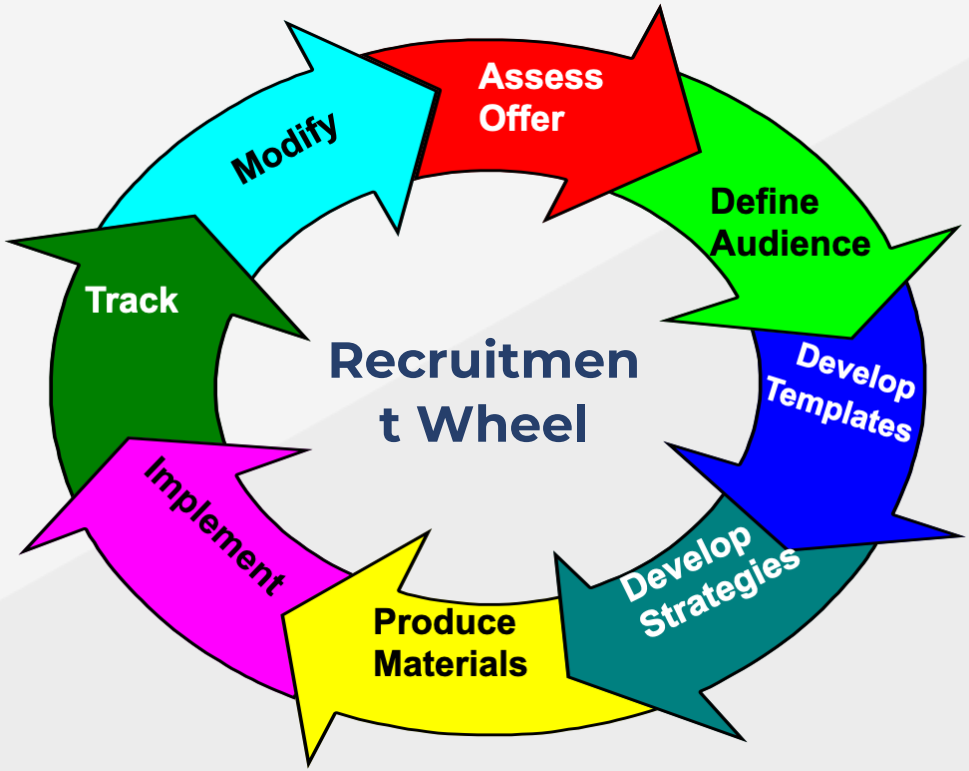
	2020	2021	2022	2023	2024
Active Onsite Protocols	1,535	1,525	1,499	1,501	1,515
New Onsite Protocols Active onsite protocols are clinical research studies being conducted at the NIH Clinical Center.	158	150	108	119	101
Unique Principal Investigators Principal Investigators are the lead researcher for laboratory studies or clinical trials.	496	502	482	492	499

2024 Research Protocols	
Interventional/Clinical Trials Assigns participants one or more interventions, a placebo or no intervention so researchers can evaluate the effects on biomedical or health-related outcomes.	810
Natural History Collects information about the natural history of a disease in the absence of an intervention.	640
Screening Collects information about the natural history of a disease in the absence of an intervention.	43
Pharmacokinetics Collects information about the movement and activity of medication within the body.	22
TOTAL	*1,515*

DEVELOPING A RECRUITMENT PLAN

- Assess the offer
- Define the audience
- Development of strategies
- Production of materials
- Implementation
- Track-Modify
- Evaluate

RECRUITMENT PROCESS CYCLE



NEEDS ASSESSMENT

- Begin relationship with the PI and research team
- Learn about the disease and research objectives
- Identify and define the target audience
- Conduct feasibility assessment
- Evaluate existing recruitment efforts and results

TYPES OF VOLUNTEERS

Patient Volunteer

- A volunteer with a known health problem
- Participates in research to better understand, diagnose, treat, or cure a particular disease or condition
- Participation may or may not benefit individual study volunteers

Healthy Volunteer

- Has no known significant health problems
- Standard is to provide compensation for time and inconvenience

DESIGN PROCESS

- **Brainstorm ideas**
- **Creativity Develop**
- **Brainstorm again**
- **Modify**

STRATEGY DEVELOPMENT

Choose available recruitment outlets based on population, reach, cost, availability…

- **Social media (Facebook, Instagram…)**
- **LISTSERVs**
- **Newspaper**
- **Community mailings (clinics, libraries, community centers)**

TRACK EFFECTIVENESS

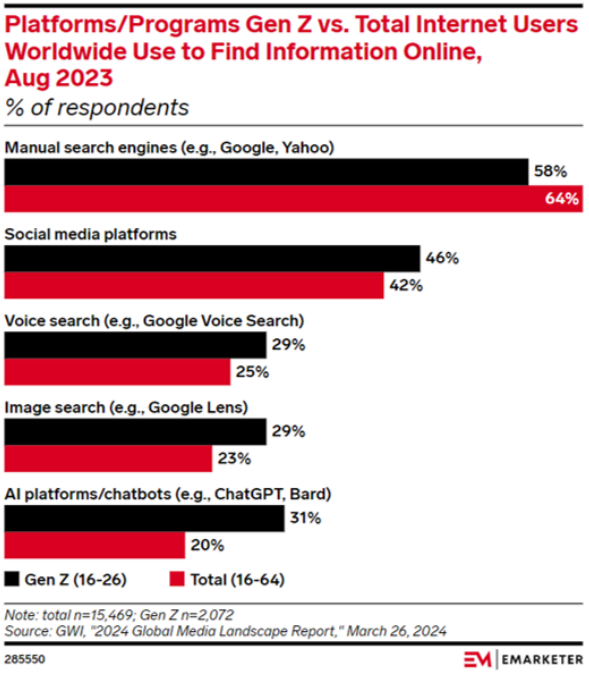
Compare results to goals/objectives

- **Number of inquiries**
- **Source of inquiries**
- **Number of patients enrolled**
- **Number disqualified/declined & reason**

IMPLEMENTATION

- Planning and timelines
- Small vs large
- Repeat / Repeat / Repeat
- Continuous evaluation

TOP WAYS PEOPLE FIND INFORMATION INCLUDING CLINICAL TRIALS:



The best online advertising platforms (+who should use them)

No two advertising platforms are the same, just like no two businesses are the same. What works for one business may not work for you or your target audience. But it's important to know the best, most popular online advertising platforms and how they might work for your business to figure out where to start.

Here are the best online advertising platforms for 2024:

1. Google Ads
2. Microsoft Advertising
3. LinkedIn
4. YouTube
5. Facebook
6. Instagram
7. TikTok
8. Snapchat


Contribute to Medical Research
Clinical trials are part of medical research. You can help researchers study how a new test or treatment works. Trials are planned and done very carefully to keep you and other participants as safe as possible.
Access Care
You can get more information about treatments and disease. Through participation in a clinical trial, you may have earlier access to potential new treatments.
Participant
Discover Better Tests and Treatments
You can help researchers find better ways to detect or treat a disease.
Help Improve Quality of Life
You can help researchers study other aspects of care, such as improving the quality of life for people with a disease.

Motivators for participating in medical research

Driver Distribution

REASON	THIS WAS THE MAJOR REASON	THIS WAS ONE OF THE MAJOR REASONS	YES, BUT THIS WASN'T REALLY WHY	THIS WASN'T REALLY THE REASON BUT WAS A SMALL FACTOR	NO, THIS WASN'T THE REASON
I wanted to help future patients who come after me.	34%	41%	13%	6%	6%
I wanted to improve my quality of life.	33%	36%	12%	7%	12%
I wanted to receive the best care possible.	31%	32%	15%	7%	15%
I wanted to receive the most up-to-date therapies without the high expense.	25%	28%	14%	9%	24%
I joined to extend my life.	20%	21%	10%	11%	38%
I was following my doctor's recommendation.	13%	19%	10%	9%	49%

Source: Antidote Technologies and SCORR Marketing Survey

Table 1. The influence levels of common drivers of trial participation reported by survey respondents.

The Patient Perspective on Clinical Trials
March 1, 2019
By Lindsey Wahlstrom-Edwards
Anne-Marie Hess

Motivators for participating in medical research

In 16 potential motivators. Each motivator was placed in the following categories: safety concerns, institutional support, health benefits, logistical concerns, , and financial benefits. The percentage of the survey population rated the type of consideration as very important and the average ordinal ranking (where a lower number indicates a higher ranking) is as follows:

Motivational Factors

	AVG.% "VERY IMPORTANT"	AVG. ORDINAL RANKING
Safety concerns (3)	63%	4
Institutional support (2)	58%	6
Health benefits (3)	54%	8
Logistical concerns (5)	45%	9
Financial benefits (3)	25%	14

Source: Antidote Technologies and SCORR Marketing Survey.

Table 2. Respondents ranked potential motivators for trial participation by category.

The Patient Perspective on Clinical Trials
March 1, 2019
By Lindsey Wahlstrom-Edwards
Anne-Marie Hess

PUBLIC AWARENESS OF CLINICAL RESEARCH

Viewpoint

- Fear about clinical research
- No desire to be "guinea pigs"
- Suspicion and mistrust of medical experiments

Barriers

- Time
- Language
- Transportation
- Childcare
- Limited awareness
- Access

CURRENT STATE OF **RECRUITMENT**

- **Recruitment difficulties**
- **Cost of advertising**
- **Seeking no-cost outlets**
- **Appealing to potential volunteers**
- **Reaching target audience**

OTHER CONSIDERATIONS

- Production
- Participant Assistance / Incentives
- Compensation
- Retention

OPPORTUNITIES

TRUST

RELATIONSHIP

& TIME

STILL GROWING

GOVDELIVERY

CCTV

Facebook

LinkedIn

Instagram

Flickr

YouTube

Nikita Curry, MHA
Supervisor, Office of Patient Recruitment (OPR)
NIH Clinical Center
833-JOIN-NIH
nikita.curry@nih.gov

OFFICE 0F PATIENT RECRUITMENT

833-JOIN-NIH (5646-644) | TTY users dial 7-1-

1 ccopr@nih.gov

https://www.cc.nih.gov/recruit

Screening for Research

JONATHAN M GREEN

DIRECTOR, OHSRP

Regulatory considerations for recruitment

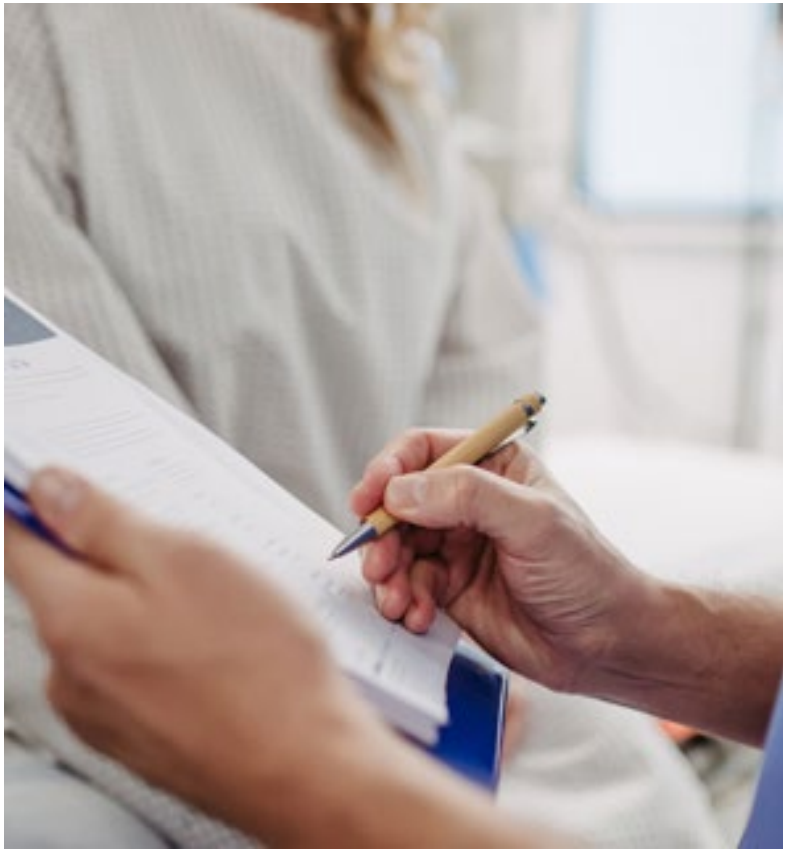
Another successful recruitment drive for the Collins University Medical Research Center.

Recruitment cannot commence until IRB approval

- IRB must review recruitment material.
- Plan for recruitment must be described in the protocol.
- FDA regulated research subject to additional requirements

What is screening?

Screening is…..



An activity designed to determine if an individual may be eligible for participation in a research study.

It is part of the research protocol.

It is not the research intervention.

Screening may include

Review existing medical or research records.

Analyze existing biospecimens obtained for clinical purposes or under other research protocols.

Collect new information or specimens explicitly for the purpose of determining eligibility.

Screening is a human subjects research activity

In order to screen an individual for participation in research, the investigator:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Definition of Human Subjects Research

Pre-2018 Common Rule (45 CFR 46.102(f) (Jan. 3, 2017))

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

2018 Common Rule (45 CFR 46.102(e) (July 19, 2018))

(1) ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Screening is research

Screening meets both the pre-2018 and 2018 definitions of research involving a human subject.

All research involving human subjects (screening or full-blown research) requires informed consent, or an IRB approved waiver of informed consent.

That consent must meet the full regulatory requirements for informed consent.

Pre-screening: the screening before the screening

Minimal activities, conducted prior to obtaining consent, that might be conducted address whether it is appropriate to pursue more detailed screening procedures.

- Age/sex
- Is the person able to come to the study site
- Should not include collection and retention of any biospecimen or identifiable private information

Pre-screening is part of the research too.

Minimum necessary

Pre-screening and/or screening should collect the minimum necessary to determine if the person meets the I/E criteria for the study being considered. **PARTICULARLY IMPORTANT IF PRIOR TO INFORMED CONSENT.**

- Least risky activity/intervention that will rule a person in or out
- If not necessary to determine eligibility for the trial, it is not considered screening.

Consent requirements

Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. (45 CFR 46.116(a)(1) (July 19, 2018))

Pre-2018 Common Rule

For pre-2018 Common Rule studies (approved by the IRB on or before January 20, 2019), screening activities require either the prospective informed consent of the participant OR IRB approval of a waiver of informed consent.

- The waiver should be described in the protocol and approved during the review and approval process.

2018 Common Rule

Research approved by the IRB on or after January 21, 2019.

Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. (45 CFR 46.116(g) (July 19, 2018))

Must be described in the protocol and approved by the IRB

Waiver of documentation of consent

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; (45 CFR 46.117(c)(1)(ii) (July 19, 2018))

Waives the requirement for a signed document. Does NOT waive the requirement to get consent. All the required elements of consent must still be presented.

- Online consent process
- Oral presentation

Screen fails

Those individuals that were screened but determined to not be eligible.

- Identifiable data obtained prior to informed consent cannot be retained.
- General demographic data (not identifiable) may be kept to allow for comparison between enrolled and not enrolled persons.
- Screen fail data obtained after informed consent may be kept if this is disclosed to the individual in the informed consent document.

How to conduct screening

Protocol specific (preferred)

Described in the individual protocol

Allows for the most targeted, minimum necessary collection of data/specimens from an individual

Screening Protocol (permissible but less ideal)

Kitchen sink protocol that feeds into other protocols

Many people will have procedures done that were not necessary

The screening protocol and consent must be explicit that the data will be shared with many other (some as of yet unknown) investigators to determine eligibility for other studies

Downstream protocols must explicitly reference that they will be accessing the screening protocol to assess eligibility for the protocol.

Example

Natural history study of multiple sclerosis. Study includes interval clinical exams, blood work, imaging studies and lumbar punctures. Requires 48-hour inpatient stay at the Clinical Center

Inclusion criteria:

- Age ≥ 18
- Confirmed diagnosis of multiple sclerosis
- Basic lab work within normal range at time of enrollment
- Lesions on MRI consistent with MS within 3 months of enrollment
- Elevated CSF protein at the time of enrollment

Exclusion Criteria

- Serious concomitant cardiovascular disease
- Use of specific medications

Prescreening/screening

Prescreening (conducted by phone)

- Confirmation of age and diagnosis
- Willingness to stay inpatient at CC for 48 hours

Screening (in this order)

- Review of concomitant diseases and medications
- Review of medical records to confirm diagnosis
- Collection of blood for new blood tests
- MRI (if one within window not available for review)
- Lumbar Puncture

Prescreening/screening

Prescreening
- Confirmation of age and diagnosis
- Willingness to stay inpatient at CC for 48 hours

Prior to consent OK

Screening (in this order)
- Review of concomitant diseases and medications
- Review of medical records to confirm diagnosis
- Collection of blood for new blood tests
- MRI (if necessary)
- Lumbar Puncture

Pre-2018 CR: consent or waiver
Required
2018 CR: not required
If described in protocol

Written consent required

Use of 3rd party vendors

Private commercial entity engaged to identify, recruit and screen potential research participants.

- Similar functionality to NIH Office of Patient Recruitment but may have broader reach.

Concerns:

- Collecting PII and medical information on behalf of NIH.
- Potential participants may conflate the vendor with NIH.
  - Cannot display NIH logo without formal approval.
- NIH Information security and privacy requirements must be met.
- Vendor may retain and re-use (even sell) the collected information.
  - NIH has no control over what happens to the information once collected.

The PI is responsible for assuring that the vendor meets all NIH policies.

Take home points

- Recruitment and screening are essential elements of the research.
- Research starts with your first interaction with the potential participant, their data or their biospecimens.
- All recruitment and screening activities should be clearly described in the protocol.
- Consent, a waiver of consent, or a waiver of documentation of consent may be required, depending on the activity and whether the study is subject to the pre-2018 or 2018 CR.
- Minimal and least risky/burdensome procedures that will rule in or out first.
- Use of 3rd party vendors for recruitment and screening require additional considerations.

Resources

IRBO website (irbo.nih.gov)