RECRUITMENT PLAN FOR CLINICAL TRIALS

CHANNELS

Please select all channels (i.e., outreach methods) that will be utilized to bring awareness to the study and to attract/recruit potential study participants.

Social Media Advertising ☐ WhatsApp ☐ Facebook ☐ Instagram ☐ TikTok ☐ X (formerly Twitter) ☐ EventBrite ☐ Meetups ☐ SnapChat ☐ YouTube ☐ Pinterest ☐ Spotify ☐ Quora ☐ via Influencers ☐ Local Social Media platforms ☐ Other:	Community Outreach ☐ Host a table at a health fair ☐ Host a talk at a local library ☐ Advertise in community centers or senior centers ☐ Advertise at local fundraising walks ☐ Advertise with neighborhood outreach organizations ☐ "Lunch 'n Learn" or "Dinner 'n Dialogue" hosted by study team/Principal Investigator ☐ Present study to local government ☐ Present study to local media ☐ Form a "mobile health/study promotion team" (to address questions/rumors) ☐ Form a Community Advisory Board with local community members (village elders, religious leaders, women's organizations, youth groups, local leaders) ☐ Other:	Other Digital Outreach ☐ Custom study webpage ☐ Link the study webpage to the appropriate trial registry listing for the study ☐ Dedicated study Facebook page ☐ Advertise on the study site's or Institution's website ☐ Text messages with study advertisements ☐ Text messages to telecommunication companies' subscribers ☐ Create a recruitment app via a clinical software development tool ☐ Create a QR code to add to study ads/materials that links to study webpage ☐ Advertise on niche-connected websites ☐ Other:
Word of Mouth Advertising ☐ By physicians ☐ Other: *Utilize current study participants to share study info with friends/family via:* ☐ Postcards ☐ Web link to study page within an email ☐ Other:	Public registries of study participants (volunteers) or patient networks ☐ Rare disease registries ☐ Other:	Collaboration with Advocacy Groups ☐ Share study info with support groups ☐ Advertise in patient advocacy groups ☐ Build alliance or advertise with disease-specific charitable organizations ☐ Other:
Television ☐ Advertisement ☐ Interview ☐ Local talk show ☐ Public Service Announcement ☐ Jingles and/or songs ☐ Other:	Newspaper ☐ Advertisement ☐ Article ☐ Other: Magazine ☐ Advertisement ☐ Article ☐ Other:	Radio ☐ Advertisement ☐ Interview ☐ Public Service Announcement ☐ Jingles and/or songs ☐ Other: Podcasts ☐ Advertisement ☐ Interview ☐ Other:
Collaboration with Internal Physicians	Schools/Institutions	Advertisements via Local Businesses

DOI 10.17605/OSF.IO/MW5YA

☐ Build working relationship with clinic staff to facilitate referrals ☐ Other:	☐ Collaborate with local community influencers to promote education about studies and opportunities at schools ☐ Other:	☐ Hair/beauty/barber/nail shops ☐ Post flyers in local stores ☐ Other:
Collaboration with external Physicians ☐ Ask for direct referrals ☐ Send “Dear Doctor” (“Dr to Dr”) letters ☐ Place study flyers in referral physicians’ offices/clinics ☐ Engage physician at another site as Co-Investigator ☐ Engage a physician group (e.g., present at their internal meetings) ☐ Request access to referral physicians’ medical records ☐ Request providers send “Dear Patient” letters to inform potential participants ☐ Post ads in free community clinics ☐ Other:	Physical (paper) Advertisements ☐ Recruitment Flyers (e.g., for clinic waiting rooms, hospital hallways, bulletin boards) ☐ Study Brochure (e.g., for clinic waiting rooms/patient visits) ☐ Small information cards with study details and inclusion/exclusion (for clinic staff/patients) ☐ Direct mailings ☐ Bulletin board tear-offs ☐ Posters ☐ Other:	Religious Institution Outreach ☐ Liaise with church leaders ☐ After church event ☐ Choir ☐ Other:
Financial Incentives *Requires explicit IRB/EC review/approval* ☐ For physician referrals (requires Institutional Review Board/Ethics Committee review/approval) ☐ For study sites that quickly enroll (e.g., competitive enrollment studies) ☐ Other:	Electronic Medical (Health) Records ☐ Recruitment Alerts (aka Best Practice Alerts) – requires Information Technology (IT) assistance ☐ Contract with hospital to screen electronic health records of partner hospitals ☐ Other:	Third Party ☐ Contract with a recruitment agency ☐ Utilize recruitment apps ☐ Contract with a Public Relations agency ☐ Contract with a Contract Research Organization to develop a media campaign (e.g., targeting their health network) ☐ Use of "social mobilization experts" to find index cases (e.g., Ebola outbreaks) and their contacts, who then encourage consent and participation ☐ Other:
Other ☐ Create a study slide deck to present at events/webinars ☐ Establish a call center to prescreen interested participants ☐ 24hr hotline for questions about the study ☐ National awareness campaign (not focused on an individual study) ☐ Other:		

STAKEHOLDERS

Please use this section to identify the key stakeholders to the study’s recruitment strategy. The stakeholder should be an entity that will be engaged with directly to recruit, advertise or to spread awareness of the study. This always includes the study participant and any clinicians referring patients to the study but may also include the participant’s family or community members.

Common Stakeholders

DOI 10.17605/OSF.IO/MW5YA

☒ Study participants (including potential participants)	☐ Peers	☐ Sponsors
☐ Caregivers	☐ Site Investigator	☐ Patient advocates
☐ Husbands, wives or partners of study participants	☐ Study Coordinator	☐ Contract Research Organizations
☐ Parents	☐ Site study team	☐ Other:
☐ Families	☐ Referring physicians	
☐ Friends	☐ Doctor	

Potential Additional Stakeholders (As Applicable)

☐ Researchers	☐ Community leaders at clinical trial sites	☐ The village
☐ Clinicians	☐ Community advisory group or board	☐ Traditional healers
☐ Nurses	☐ Local religious institutions	☐ World Health Organization (WHO)
☐ Medical specialists	☐ Religious leaders (Imam and Pastors)	☐ Ministries of health
☐ Clinics	☐ Local schools	☐ National scientists
☐ Colleagues	☐ Women's groups	☐ Development partners
☐ Members of Ethics Committees	☐ Youth groups	☐ Pharmaceutical companies
☐ Key Opinion Leaders	☐ Human rights groups	☐ Drug or device industries
☐ Hospitals	☐ Not-for-profit organizations	☐ International organizations
☐ Elders	☐ Regulatory agencies	☐ Journals
☐ Pharmacists	☐ Public health authorities	☐ Media (local and national)
☐ Pharmacy employees	☐ Professional societies	☐ Funders
☐ Representatives from affected communities	☐ Professional service organizations	☐ Sponsors
☐ Academic institutions	☐ Civil-society organizations	☐ Government
☐ Key populations	☐ Non-Governmental Organizations (local and national)	☐ Parliamentarians
☐ Members of representative organizations of populations eligible for the clinical studies	☐ Private sector	☐ Policymakers
☐ Business leaders	☐ Opinion Leaders	☐ Local politicians
☐ Social Media Influencers	☐ Chief of the village	☐ Leaders of trade unions (e.g., president of bike riders association)
☐ Academia	☐ Chief of the tribe	☐ Anthropologists
☐ Community liaison		☐ Other:

DOI 10.17605/OSF.IO/MW5YA

From the Practitioner's Desk

"Often, as researchers, we fail to meet our recruitment targets not due to the scarcity of study participants with the desired diseases condition but due to the lack of the recruitment skills and strategy of the study team. If you cannot convince me that you know what your clinical trial is all about, how can you convince me to risk myself to be part of it as a participant?"

-Elvis Ndansi, BSN, MSN, MH

STUDY DETAILS

Item/Question	Response	
Lead Principal Investigator name		
Site Principal Investigator names		
Study Sponsor name (if none, select: ☐ Investigator-Initiated)		
Funder name, if applicable ☐ Not applicable		
Contract Research Organization name, if applicable ☐ Not applicable		
Full Study Title		
Study Design	Interventional ☐ Open-label ☐ Randomized, controlled ☐ Non-randomized, controlled ☐ Crossover ☐ Other:	Observational ☐ Case-control ☐ Cohort ☐ Cross-sectional ☐ Registry ☐ Retrospective cohort ☐ Other:
Is there any pre-screening required?	☐ Yes* ☐ No *If yes, total # of participants to be pre-screened:	

DOI 10.17605/OSF.IO/MW5YA

Total # of participants to be screened (please estimate)	
Total # of participants to be enrolled	
Estimated recruitment start and completion dates	(DD-MON-YYYY) - (DD-MON-YYYY)
Estimated First Participant Visit (i.e., study start date)	(DD-MON-YYYY)
Estimated number of study sites	
Type of study sites	☐ Hospital ☐ Outpatient clinic ☐ Other health facility: ☐ School ☐ Workplace ☐ Other public site: ☐ Households ☐ Other:
Estimated enrollment rate (estimated # of participants/site/month)	
Please provide specific details regarding how the enrollment rate was determined (e.g., published historical study experience or prevalence data in similar study population, internal historical study experience).	
Please describe any seasonal variation in the disease or historical seasonal lulls in recruitment (e.g., holidays) that are anticipated to affect enrollment.	
Will enrollment across study sites be balanced (all sites will enroll the same number of participants) or competitive (all sites enroll participants until the sample size is reached, without concern that each site enrolls an equal number of participants)?	☐ Balanced ☐ Competitive
Other study details relevant to recruiting	

SITE VISIT TO OPTIMIZE RECRUITMENT

Some believe the best way to recruit the full sample size in low-resource settings is to visit the study sites as early as possible—even before the study design has been finished. The only downside to this approach may be to make the study team and designers wait a little (time) and invest some minimal

DOI 10.17605/OSF.IO/MW5YA

expenses (money). The upsides include assessing acceptability—and many other factors—of recruitment techniques and study design to the exact population to be studied.

Details of site visit(s)	Answer
The site visit(s) will inform a final recruitment plan. So having a complete plan before visiting is not a good idea. It is better to make your recruitment visit(s) with some informal notes or questions written down. Will you have written notes or questions when you make your visit(s)?	
The conversations at the site with key opinion leaders, significant others, chiefs, parents, and possible participants will be like a peer review of your recruitment ideas and study design. How will you record that site visit data? How do you plan to transmit it to the study designers?	
Will you visit the chief and the chief's elders when you first arrive at the site?	
Would you ask elders to be allowed to have later meetings only with mothers or young men or special groups of interest that might not talk with older members present, to get those groups to be more talkative away from elders?	
How many will be on the team doing the site visit? While it depends on the needs of the place, one typical mix would be a senior communication expert, a translator, and two mid-level or junior science communication experts.	
Do you plan for a 1-day, or a 2-day visit at each site to gather data toward optimizing recruitment?	
What % of the total study sites will have a visit?	
If you have a multi-continent study, how will you decide which recruitment expert will act as 'lead' to coordinate site visits across countries?	
How will you decide which country and study site will be the pilot or first site to be visited to optimize recruitment practices?	
Will you organize and bring some activities for children to do, to keep them busy while asking questions of parents during your visit(s)?	
Will you confirm spouses can receive email or text message notifications and reminders from a study staff without causing marital strife?	
Will you ask what the major employment in the area is, so that if it is a morning occupation like farming, you won't do trial visits in the mornings?	
Will you ask about which is the community's 'market day' or other special times or holidays that are either recruitment-positive or recruitment-negative?	
Will you plan for recruitment staff to set weekly targets of how many participants need to be recruited, consented, and passed to the clinical team?	
How will the team visiting communicate their findings to the site PI?	
Will you ask about the perhaps most important item: what unknown context of the community makes it unacceptable to participate in the study? (e.g., to know there is cultural stigma to give blood at night, so a trial schedule or calendar	

DOI 10.17605/OSF.IO/MW5YA

that takes blood at night/evening will make people refuse to participate)	

PARTICIPANT POPULATION

For the following questions, please add new content in the entry boxes below, or use content from the study protocol. Feel free to consult the boxes below for example of participant population characteristics.

Item	Response
Please enter, or paste from the study protocol, the participant population details for the study.	
If the study has multiple parts, such as multiple sites, or multiple periods, and the details of the participants included change across those parts, please describe the differences in participant population.	
For each listed geographic category, please list the number of each that participants are likely to be living in.	*Countries:*
	Regions:
	Counties:
	Cities:
	Kebeles:
	Towns:
	Neighborhoods:
If applicable, please list any demographic differences (or other segmentations) directly specified in the study, which could be considered study population characteristics (e.g., urban vs rural, refugees vs indigenous, Muslim vs non-Muslim).	
Please describe the participant population's likely access to the following digital platforms.	*Social media:*
	Web applications:
	Internet access:
	SMS/text messages:

Please specify participant population characteristics

Item	Response

DOI 10.17605/OSF.IO/MW5YA

Disease/Condition status (select all that apply)	☐ Healthy volunteers ☐ All comers/anyone (health/disease status unknown) ☐ Pregnant females ☐ Participants with a confirmed medical diagnosis (specify diagnosis) ☐ Participants with a suspected medical diagnosis (specify diagnosis) ☐ Other:
Age Group (select all that apply)	☐ Preterm newborn infants ☐ Newborn (0-27 days) ☐ Infant and toddler (28 days – 23 months) ☐ Children (2 – 11 years) ☐ Adolescent (12 – 17 years) ☐ Adult (18 – 65 years) ☐ Elderly (> 65 years) ☐ Other:
Sex (select all that apply)	☐ Male ☐ Female
Gender (select all that apply)	☐ All ☐ Male ☐ Female ☐ Nonbinary ☐ Trans male ☐ Trans female ☐ Other:
Ethnicity (please describe)	
Race (please describe)	
Miscellaneous Identifiers (select all that apply)	☐ Incarcerated ☐ Men who have sex with men ☐ Refugees ☐ Antenatal women ☐ Postnatal women ☐ Students ☐ Other:

CHALLENGES

Please select/describe any foreseen challenges to recruitment (e.g., related to accessibility, eligibility criteria, other). Describe the planned actions to overcome these recruitment hurdles.

Foreseen Challenge to Recruitment	Proposed Solution to Overcome the Challenge

DOI 10.17605/OSF.IO/MW5YA

☐ Strict eligibility criteria, specify:	
☐ Complexity of protocol (site-level)	
☐ Participant fears of side effects	
☐ Unreliable transportation	
☐ Lack of internet	
☐ Lack of or limited cell phone service/plans/data	
☐ Limited (participant) knowledge about clinical trials	
☐ Lack of (participant) awareness of clinical trial and opportunities to participate	
☐ Participant trust and/or privacy concerns	
☐ Participant fears of or concerns with research in general or the healthcare system	
☐ Participant preference for a particular treatment	
☐ Participant or loved ones' attitudes towards participating in research	
☐ Participant aversion to random allocation of study treatment	
☐ Social and/or cultural issues related to study participation	
☐ Study staff's lack of knowledge on how to culturally tailor recruitment strategies	
☐ Insufficient relationships with community organizations serving the targeted population	
☐ Burdensome or time-consuming study visit/study schedule requirements (for the participant)	
☐ Childcare costs	
☐ Study participation requires time away from participant's work/lost wages	
☐ Competing trials	
☐ Lack of time available to integrate research into clinical activities	
☐ Lack of site resources	
☐ Lack of study management expertise	
☐ Negative footprint: effect of previous trials in the community	
☐ Other:	
☐ Other:	
☐ Other:	

DOI 10.17605/OSF.IO/MW5YA

From the Practitioner's Desk

"When recruiting a research participant, especially in a study dealing with a culturally sensitive population, it is important to assign this task to certain staff members. These staff members are aware of the context and can adjust and be emotionally intelligent to handle unconscious biases that may emanate during the recruitment process."

-Elvis Ndansi, BSN, MSN, MPH

COSTS AND BUDGET CONSIDERATIONS

Please use this section to help determine the anticipated costs for the study's recruitment efforts, including any costs for participant compensation, clinician referral compensation, physical materials, advertising fees, and/or personnel fees.

Item (choose all that apply)	Estimated Cost
☐ **Participant compensation (ensure the compensation is realistic in the context of the communities in which the trial is taking place, and is neither exorbitant nor too little)**	*Approximate the amount of compensation the study will offer to participants and describe what it is intended to cover (e.g., "$25 compensation per study visit to cover participant's parking fees, transportation and lunch reimbursement"):*
☐ **Clinician referral compensation (reminder that all referral compensation must have explicit Institutional Review Board/Ethics Committee approval)**	*Approximate the amount of the referral compensation that will be offered to clinicians and describe the frequency (e.g., "$250 referral compensation for every 1 patient that is referred to the study and consents to participate"):*
☐ **Social Media advertising costs**	
☐ **Other media (e.g., newspaper, television, radio, magazine) advertising costs**	
☐ **Digital or technology-based recruitment method costs (e.g., website hosting fees, domain names, mobile app development)**	
☐ **Physical materials' costs (e.g., cost of paper, printing, post cards)**	
☐ **Staffing/personnel fees (e.g., wages/hourly rate of recruitment coordinator, if applicable)**	

DOI 10.17605/OSF.IO/MW5YA

☐ **Third-party contracts/fees (e.g., Contract Research Organization, Public Relations firms or participant recruitment agencies)**	
☐ **Costs related to organizing community gatherings and social events to talk about the trial**	
☐ **Other**	*Describe any other anticipated costs associated with recruitment efforts:*

ETHICS

Ethics Statement	✓
Please kindly ensure that the study's protocol or material includes participant informed consent forms, and any related necessary ethical documents required for consent and safety tied to participation, since the study protocol is the best single place for those details. This recruitment plan will not cover the detail of that topic, policies or document	☐
Please kindly ensure that all details of how the study team might communicate results of the study with local significant others, participants, or participants family is documented in a Communication Plan separate from this Recruitment Plan. Any policies of communication of any type outside of Ethics and Recruitment ought to appear in the study protocol, a Communication Plan, or other document, not in the Recruitment Plan.	☐

Question	**Response**
When recruiting participants, in the lead-up and in the moment they are deciding to participate, are they…	…receiving pressure from any stakeholder to join, due to the study team? ☐ Yes ☐ No
	…empowered to refuse? ☐ Yes ☐ No
Will the internet be used to disseminate information about the study, or post informational material for participants?	☐ Yes* ☐ No *If yes, is this discriminating against those who do not have stable or free internet? ☐ Yes ☐ No
Is it ethical for participants to receive sorts of "in-kind compensation", such as bus vouchers or money for motorbike transportation to and from required study visits?	☐ Yes ☐ No
Is it ethical to compensate doctors or others for referring participants to the study?	☐ Yes ☐ No Please describe why you believe it is ethical or not:

DOI 10.17605/OSF.IO/MW5YA

When working with vulnerable populations who may have others deciding whether or not they should be recruited to participate, what steps are being taken to ensure ethical handling of that situation?	
Will study participants be chosen or recruited in a way that is fair and free of prejudice?	☐ Yes ☐ No
"The selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied."[1] Aside from inclusion/exclusion criteria of this study, is the study selectively recruiting participants described above?	☐ Yes ☐ No
If the study is 'competing for participants' with another study happening close by, what actions will be taken, if any, to be ethical, ethically coordinate, or otherwise accommodate this dynamic affecting both studies?	
Are any steps being taken to understand relationships between study team members and local recipients of study funds, as those funds are expended for advertisements, gifts, or services meant to help recruitment?	☐ Yes* ☐ No *If yes, please describe:
Will there be a waiting list for participants wanting to enroll?	☐ Yes* ☐ No *If yes, what steps, if any, will be taken to ensure participants are selected fairly as spots open for participation:

[1] Department of Health, Education, and Welfare; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. Ethical principles and guidelines for the protection of human subjects of research. J Am Coll Dent. 2014 Summer;81(3):4-13. PMID: 25951677. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xrespect

DOI 10.17605/OSF.IO/MW5YA

From the Practitioner's Desk

"Administering the informed consent is a very important step in the screening and recruitment process for trial participants. The staff performing this task is required to have a good mastery of the study protocol. They ought to be able to answer participants' questions and concerns. When this is poorly done and the recruiter does not demonstrate mastery of the study protocol, we lose the opportunity to recruit a potentially eligible participant. A recruitment training exercise including mock recruitment sessions are essential to prepare and access the study team's capabilities."

-Elvis Ndansi, BSN, MSN, MPH

TIMELINE

Question	Response
What is the total expected or estimated study duration (months, years)?	
What is the total expected or estimated time (months, years) to recruit the participants?	
What, if any, pre-screen activities will be conducted?	
What is the total estimated time (months, years) to pre-screen participants?	
What is the amount of time, in weeks or months, expected or estimated for how long it will take before the first participant is attracted enough to enroll in the trial or study?	
How long will it take to create, gain consensus, and revise a recruitment strategy?	
How long will it take, using the recruitment strategy, to populate a Recruitment Plan?	
How long will it take to recruit, hire, and organize a team of people to dedicate themselves to implement the Recruitment Plan?	
How long will it take to train that team?	
How long might it take to write, and gain consensus on, the slogans, taglines, benefit statements, and other copy needed before purchasing ad space or radio ads or other placement?	

DOI 10.17605/OSF.IO/MW5YA

How long for preparation of images and graphics (for advertisements)?	
How long might it take for purchasing ad space or radio ads or other placement?	
Will the effectiveness of these messages or content, and the channels used, be tested in order to settle on a set of best approaches?	☐ Yes* ☐ No *If yes, how much additional time might that take?
How long will the engagement with stakeholders, such as clinicians with appropriate patients, or with families or tribal leaders, require?	
For the Launch phase, how long is that expected to take?	
How long will the Ongoing Recruiting phase take, when the trial or study has enrolled participants and treatment or sample collection or testing are being performed?	
At what % of participants enrolled will the timeline change to Final Recruiting phase?	
Is it expected that the team performing Final Recruiting will stay involved to a Post Trial phase?	☐ Yes* ☐ No

TIPS

This section requires no action but is intended as a resource to aid in recruitment planning. The following are strategies that have proven successful in enhancing study recruitment.

Tip	✓
Ensure the individual who is responsible for making the first contact is educated about the aim and process of the study. Ensure that individual possesses an attitude that is sensitive to the cultural values of the study population.	☐
Be sensitive to the values of potential participants. Culture may serve as a barrier to participating in research.	☐
Offer financial incentives to potential participants. These could include financial or other gifts, or free health or childcare.	☐
Tell people what they are receiving in a study (e.g., no-cost antenatal visits).	☐
Share quotes or testimonials from previous study participants.	☐
Use flexible hours for participation, assistance with transport and conducting visits at convenient locations for the participant.	☐
Conduct the assessment procedures at opportune times. These might be after the participant's work hours, on weekends and in places such as the participant's home or childcare center.	☐
Mention scarcity of study spots to fill (e.g., "only a limited number of spots remain on this study"), if such information is accurate and ethical.	☐
Show letters (signed by influential people) introducing the study.	☐

DOI 10.17605/OSF.IO/MW5YA

Phone (i.e., a telephone reminder) people who do not respond to other invitations to take part in a study.	☐
Utilize opt-out consent (vs active consent, i.e., “opt-in consent”), where appropriate.	☐
Create an easy-to-read consent form.	☐
Present ethics committees with (and obtain approval for) a ranked list of recruitment strategies that might be used depending on how recruitment is progressing. This may avoid delays before implementing additional strategies.	☐
Involve consultants from the communities where the participants will be recruited. Use them to identify approaches and strategies that match the needs and values of the potential participants.	☐
Consider using a questionnaire (within the invitation to participate) covering issues relevant to the study.	☐
Recruit at a church.	☐
Employ active methods of recruitment (e.g., telephone, face-to-face interactions) vs. passive methods (e.g., posters or brochures in clinic waiting rooms).	☐

TRACKING PERFORMANCE AND METRICS

Please answer the following questions, and when appropriate, add additional explanatory information.

Question	Response
What system will you be using for collecting recruitment data?	☐ a common open database Please specify: ☐ OpenClinica ☐ REDCap ☐ Other:
	☐ an MS Office tool Please specify: ☐ Microsoft Excel ☐ Microsoft Access ☐ Other:
	☐ a paper-based method Please describe:
	☐ Other (none of the above) Please describe:
What is the latest time by which to select the technology and identify a	

DOI 10.17605/OSF.IO/MW5YA

named team member to set up the system to track recruitment?	

Additional questions:

Question	Response
State who in your team are assigned recruitment goals.	
Will the recruitment goals be listed as or represented as number of enrollees?	☐ Yes ☐ No* *If no, please explain how goals are counted or defined:
Please list recruitment goals for each person or role type.	<table><tr><th>Role Type or Person</th><th>Goal</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table>
Is there a defined start time for counting recruitment?	☐ Yes* ☐ No *If yes, please define:
Is there a defined end time for counting recruitment?	☐ Yes* ☐ No *If yes, please define:

DOI 10.17605/OSF.IO/MW5YA

Will there be a projected or forecast recruitment goal, across the duration of the effort?	☐ Yes* ☐ No *If yes, please define:
If the process is already known, please describe how pre-screening counts, screening counts and enrollment counts will be recorded.	
When is it expected that decisions will be made on how pre-screening counts, screening counts and enrollment counts will be recorded?	
What is the name of the individual who will be responsible for ensuring pre-screening, screening and enrollment counts are properly calculated, with the data saved?	
If there are multiple sites for the study, will there be multiple individuals—perhaps one per site—responsible for inputting and storing the pre-screening, screening and enrollment data?	
Typical visual charts that track recruitment have "Time" at the bottom/on the X-axis. On the Y-axis, it shows a count of pre-screened, screened or enrolled participants. In this chart, will the bottom axis be broken into Months, Weeks, or Days?	☐ Months ☐ Weeks ☐ Days
How frequently will data be given to the technical person in order to report by Months, Weeks, or Days?	
How old will the data be in the reports? For example, will the reports show weekly recruitment totals for one year ago? Or will the reports show weekly recruitment totals including up to the week before? [usually this answer depends on how long it takes to collect all the data, store it, clean it if needed, and create the report]	
Will it be possible to track the number of participants enrolled through each recruitment channel (e.g., the number of subjects recruited	☐ Yes ☐ No

DOI 10.17605/OSF.IO/MW5YA

via Facebook or via a patient advocacy group)?	
How will the reason(s) a person declines study participation be tracked and how often will these data be reviewed in order to inform possible modifications to the recruitment strategy?	
How will a lag in enrollment be identified and quickly addressed (e.g., weekly teleconferences with sites, weekly study team meetings, frequent review of study-wide enrollment data)?	
How often will the study Sponsor be provided an update on target vs. actual recruitment data?	
How often will the study Funder be provided an update on target vs. actual recruitment data?	

From the Practitioner's Desk

"If you have two staff screening and recruiting participants at a research site and one of them is registering a higher acceptance rate and enrollment numbers, while the other staff is having a high decline rate and low enrollment numbers, it a good pointer to assess the recruitment skills of the latter. Not everyone is a good communicator even when they know the content so well."

-Elvis Ndansi, BSN, MSN, MPH

BEST PRACTICES

The following best practices have been compiled from the public domain (e.g., literature, web search) and are intended to provide a non-exhaustive review of key recruitment practices that could increase the success of the recruitment strategy.

Know the Study Population	
Get to know the study population: when designing a research study, considering the participant's point of view will help ensure the study does not put unnecessary burden on the participants.	☐

DOI 10.17605/OSF.IO/MW5YA

Minimize Participant Burden	
Properly understand participant needs and preferences before starting recruitment.	☐
Make it easy for potential participants to get information about the study (e.g., a study hotline that is free to call, dedicated webpage).	☐
Minimize any inconveniences (real or perceived) to the potential participants.	☐
Keep participants engaged.	☐
To ease participant burden, schedule follow-up visits to coincide with other visits and facilitate patients' preferences.	☐

Spend Adequate Time Pre-Screening/Screening Potential Participants	
It is important that participants feel they are part of the research, too. Creating a positive experience is an excellent way to gain referrals and promote study awareness.	☐
Spend adequate time with participants and answer any questions they have about the study.	☐
Support any difficulties of multicultural populations as participants. This can increase the participant pool.	☐
Ensure pre-screening efforts and assumptions are not preventing eligible and potentially interested participants from being offered study opportunities. Encourage Investigators and site staff to broadly offer study opportunities to all their eligible patients.	☐
Keep patient retention top of mind.	☐
To avoid difficulties with loss to follow-up, it is important to exclude participants from a study who are unlikely to comply with the requirements of the study.	☐

Compensate Participants Fairly and Timely	
Ensure participants are compensated appropriately in the study. Think about what is "reasonable" or "adequate" or "as deemed necessary."	☐
Ensure participant compensation is made in a timely manner.	☐

Utilize Recruitment Methods That Are Appropriate for the Study Population	
Use a wide variety of recruitment methods.	☐
Utilize digital recruitment campaigns when possible or appropriate.	☐
Use follow-up services (e.g., a follow-up phone call to a participant who initially expressed interest in the study).	☐
Contact participants who have already expressed interest in studies.	☐
Inform health care providers about the study.	☐
Connect with nonprofit partners and patient advocates.	☐
Screen participants for multiple trials at a time, if possible.	☐
Avoid medical jargon in recruitment materials and use everyday wording instead.	☐

DOI 10.17605/OSF.IO/MW5YA

Convey in the recruitment materials ‘what’s in it for me’. Some evidence showed a majority of participants interested in clinical trials were motivated by a personal benefit.	☐

Leverage Existing Relationships (or Invest in Building New Ones)	
Leverage trusted relationships to recruit and retain participants.	☐
Invest in building trust among historically underrepresented populations.	☐

Perform Thorough Site Feasibility and Training	
Ensure study sites undertake accurate study feasibility before accepting the trial.	☐
Conduct an internal kick-off meeting with the appropriate study teams/sites.	☐
Train Investigators and site staff on how to better communicate trial opportunities in terms of participant benefit.	☐
Set recruitment targets and provide incentives to maintain Investigator or site interest.	☐

From the Practitioner’s Desk

“Recruiting research participants requires some level of training that is tailored toward the type of participants to be recruited. Not everyone in the study team can play this role.”

-Elvis Ndansi, BSN, MSN, MPH

Spend Adequate Time Planning for and Tracking Recruitment	
When designing a study, special considerations must be made for the length and complexity of the trial from the participant and Investigator perspectives. Participants are unlikely to enroll in studies they find difficult to understand and that require multiple follow-ups. Likewise, Investigators typically avoid studies that are overly complex and require excessive hours spent on paperwork.	☐
Plan reasonable expectations of site enrollment.	☐
The Principal Investigator and/or Study Manager should review recruitment at participating sites regularly to address problems or praise top recruiting sites.	☐
It is important to have a trajectory graph of recruitment. If the recruitment rate deviates from the expected trajectory, the graph will allow the Investigator/Study Manager to pinpoint periods of slow recruitment.	☐
If recruitment is very low or slow, re-evaluate the inclusion and exclusion criteria to determine if it is too restrictive and can be modified without losing study integrity.	☐
Identify sites with consistently low recruitment and address the site-specific problems. Add new Investigators and sites if necessary.	☐
Make every effort to locate lost participants.	☐

DOI 10.17605/OSF.IO/MW5YA

DOI 10.17605/OSF.IO/MW5YA

References

Channels

Africa: Unleashing the potential of the new superpower in clinical trials. (2023, 20. March). https://www.pharmaceutical-technology.com/sponsored/africa-unleashing-the-potential-of-the-new-superpower-in-clinical-trials/

Allensworth-Davies, D. (2009. February). Aiming for the Right Sample Size. *Clinical Research Times*. https://wwwapp.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=233

Back to Basics: What is clinical trial recruitment? (2023, 1. May). https://www.medable.com/knowledge-center/guides-what-is-clinical-trial-recruitment

Cunningham-Erves, J., Joosten, Y., Kusnoor, S. V., Mayers, S. A., Ichimura, J., Dunkel, L., ... & Wilkins, C. H. (2023). A community-informed recruitment plan template to increase recruitment of racial and ethnic groups historically excluded and underrepresented in clinical research. *Contemporary clinical trials*, *125*, 107064.

Frank, G. (2004). *Current Challenges in Clinical Trial Patient Recruitment and Enrollment*. https://clinicaltrials.llu.edu/sites/clinicaltrials.llu.edu/files/docs/current-challenges-in-clinical-trial-patient-recruitment-and-enrollment.pdf

Garrison, D. (2021. April). *Strategies for Patient Recruitment: Promoting Equitable Inclusion of African Americans in Clinical Trials*. https://www.tech-res.com/TRIbune/Spring-2021/TRIbune-Spring-2021-Article2.aspx

Hull, S., Long, G. & Crowley, J. (2023). *Patient-Defined Recruitment: The Movement Advanced by the Pandemic*. https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/patient-defined-recruitment-the-movement-advanced-by-the-pandemic.pdf

IQVIA Patient Recruitment and Enablement. (2021). https://www.iqvia.com/-/media/iqvia/pdfs/library/fact-sheets/patient-recruitment-and-enablement.pdf

Kantor, E. (2023, 1. March). *5 common clinical trial patient recruitment challenges and solutions*. https://www.antidote.me/blog/5-common-clinical-trial-patient-recruitment-challenges-and-solutions

Karrasch, N. (n.d.). *A 4 Step Clinical Trial Recruitment Plan to Attain Your Sample Size*. Retrieved November 15, 2023, from https://trialfacts.com/articles/plan-clinical-trial-recruitment/

Kennedy, N., Nelson, S., Jerome, R. N., Edwards, T. L., Stroud, M., Wilkins, C. H. & Harris, P. A. (2022). Recruitment and retention for chronic pain clinical trials: a narrative review. *PAIN Reports*, *7*(4), e1007. https://doi.org/10.1097/pr9.0000000000001007

Kost, R. G., Corregano, L. M., Rainer, T. L., Melendez, C., & Coller, B. S. (2015). A data-rich recruitment core to support translational clinical research. *Clinical and Translational Science*, *8*(2), 91-99.

Kubicek, K. & Robles, M. (2016). *Tips and Tricks for Successful Research Recruitment: A Toolkit for a Community-Based Approach*. Southern California Clinical and Translational Science Institute. https://sc-ctsi.org/uploads/resources/recruitment_retention_toolkit.pdf

Langbaum, J. B., Zissimopoulos, J., Au, R., Bose, N., Edgar, C. J., Ehrenberg, E., Fillit, H., Hill, C. V., Hughes, L., Irizarry, M., Kremen, S., Lakdawalla, D., Lynn, N., Malzbender, K., Maruyama, T., Massett, H. A., Patel, D., Peneva, D., Reiman, E. M., … Aisen, P. S. (2023). Recommendations to address key recruitment challenges of Alzheimer's disease clinical trials. *Alzheimer's & Dementia*, *19*(2), 696–707. https://doi.org/10.1002/alz.12737

Maug, C. W. (n.d.). *Overcoming the challenges of clinical trial recruitment using big data technologies*. Retrieved November 15, 2023, from https://www.worldpharmatoday.com/articles/overcoming-the-challenges-of-clinical-trial-recruitment-using-big-data-technologies/

McDowell, A. (2022). *How to create a clinical trial recruitment plan [template]*. https://www.antidote.me/blog/how-to-create-a-clinical-trial-recruitment-plan-template

DOI 10.17605/OSF.IO/MW5YA

National Institute on Aging: Recruitment and Retention Tips. (n.d.).

Nawrat, A. (2020, 27. February). *What does the future hold for clinical trial recruitment?* https://www.pharmaceutical-technology.com/features/future-inefficiencies-of-clinical-trials/

Participant Recruitment Toolkit: Resources to help study teams recruit & retain participants. (n.d.). Michigan Institute for Clinical & Health Research. https://static1.squarespace.com/static/55ba3377e4b065cd994470b8/t/62a1096722612c2c67b07450/1654720871789/Participant+Recruitment+Toolkit+with+links_AS_622.pdf

Participant Recruitment, Retention and Adherence Plan Template. (n.d.). The University of Mississippi Medical Center. Retrieved November 15, 2023, from https://umc.edu/Research/Research-Offices/Clinical-Trials/files/11_Recruitment-Plan-template.pdf

Patient Recruitment for Clinical Trials in Africa. (n.d.). Retrieved November 15, 2023, from https://infiuss.com/patient-recruitment

Patient recruitment strategies for rare disease trials. (n.d.). Simbec-Orion. Retrieved November 15, 2023, from https://www.simbecorion.com/patient-recruitment-strategies-for-rare-disease-trials/

Perez, S. C., Folkesson, E., Anglaret, X., Beavogui, A.-H., Berbain, E., Camara, A.-M., Depoortere, E., Lefevre, A., Maes, P., Malme, K. N., Malvy, J.-M. D., Ombelet, S., Poelaert, G., Sissoko, D., Tounkara, A., Trbovic, P., Piguet, P. & Antierens, A. (2017). Challenges in preparing and implementing a clinical trial at field level in an Ebola emergency: A case study in Guinea, West Africa. *PLoS Neglected Tropical Diseases*, *11*(6), e0005545. https://doi.org/10.1371/journal.pntd.0005545

Recruitment and Retention Plan – Source Document: Coordinating Centers. (n.d.). Recruitment Innovation Center.

Recruitment Materials and Strategy. (n.d.). Retrieved November 15, 2023, from https://cctsi.cuanschutz.edu/resources/recruit

Recruitment of Participants for Clinical Trials. (2005).

Recruitment Playbook. (2023). https://web.archive.org/web/20230605124144/https://ctsi.pitt.edu/guides-tools/the-playbooks/recruitment-playbook/

Sandberg, J. (2014, 19. June). *4 Challenges of Clinical Trial Recruitment and How to Overcome Them*. https://orthospinenews.com/2014/06/19/4-challenges-of-clinical-trial-recruitment-and-how-to-overcome-them/

Sully, B. G. O., Julious, S. A. & Nicholl, J. (2013). A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials*, *14*(1), 166. https://doi.org/10.1186/1745-6215-14-166

Taani, M. H., Zabler, B., Fendrich, M. & Schiffman, R. (2020). Lessons learned for recruitment and retention of low-income African Americans. *Contemporary Clinical Trials Communications*, *17*, 100533. https://doi.org/10.1016/j.conctc.2020.100533

Trial Recruitment Plan. (n.d.). MacQuarie University. Retrieved November 15, 2023, from https://ctiq.com.au/wp-content/uploads/Clinical-Trial-Recruitment-plan-template-Dec-2019-V2.pdf

Vanderslott, S., Ryneveld, M. V., Marchant, M., Lees, S., Nolna, S. K. & Marsh, V. (2021). How can community engagement in health research be strengthened for infectious disease outbreaks in Sub-Saharan Africa? A scoping review of the literature. *BMC Public Health*, *21*(1), 633. https://doi.org/10.1186/s12889-021-10348-0

What Happens if Your Study Fails to Meet Recruitment Targets? (2023, 1. January). https://www.reliasmedia.com/articles/what-happens-if-your-study-fails-to-meet-recruitment-targets

Wilkins, C. H., Edwards, T. L., Stroud, M., Kennedy, N., Jerome, R. N., Lawrence, C. E., ... & Harris, P. A. (2021). The Recruitment Innovation Center: developing novel, person-centered strategies for clinical trial recruitment and retention. *Journal of Clinical and Translational Science*, *5*(1), e194.

DOI 10.17605/OSF.IO/MW5YA

Stakeholders

Clark, L. T., Watkins, L., Piña, I. L., Elmer, M., Akinboboye, O., Gorham, M., Jamerson, B., McCullough, C., Pierre, C., Polis, A. B., Puckrein, G. & Regnante, J. M. (2019). Increasing Diversity in Clinical Trials: Overcoming Critical Barriers. *Current Problems in Cardiology*, *44*(5), 148–172. https://doi.org/10.1016/j.cpcardiol.2018.11.002

Commission, N. B. A. (2001). *Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries* (Volume 2).

CTTI Recommendations: Planning for Successful Trial Recruitment. (2016). Clinical Trials Transformation Initiative. https://www.ctti-clinicaltrials.org/wp-content/uploads/2021/06/CTTI_Recruitment_Recs.pdf

Dabira, E. D., Fehr, A., Beloum, N., geertruyden, J.-P. V., Achan, J., Erhart, A., Martinez-Alvarez, M. & D'Alessandro, U. (2023). Perceptions and acceptability of the controlled human malaria infection (CHMI) model in The Gambia: a qualitative study. *Scientific Reports*, *13*(1), 8708. https://doi.org/10.1038/s41598-023-35752-x

Day, S., Blumberg, M., Vu, T., Zhao, Y., Rennie, S. & Tucker, J. D. (2018). Stakeholder engagement to inform HIV clinical trials: a systematic review of the evidence. *Journal of the International AIDS Society*, *21*(Suppl Suppl 7), e25174. https://doi.org/10.1002/jia2.25174

Dietrich, J. J., Munoz, J., Tshabalala, G., Makhale, L. M., Hornschuh, S., Rentas, F., Mulaudzi, M., Laher, F. & Andrasik, M. P. (2023). A qualitative study of stakeholder and researcher perspectives of community engagement practices for HIV vaccine clinical trials in South Africa. *Journal of Community Psychology*, *51*(3), 998–1015. https://doi.org/10.1002/jcop.22951

Ethical considerations in HIV preventive vaccine research (No. 978-92-9253-091–4). (2021). Joint United Nations Programme on HIV/AIDS and the World Health Organization. https://www.unaids.org/sites/default/files/media_asset/ethical-considerations-hiv-prevention-trials_en.pdf

Folayan, M. O., Brown, B., Haire, B., Babalola, C. P. & Ndembi, N. (2021). Considerations for stakeholder engagement and COVID-19 related clinical trials' conduct in sub-Saharan Africa. *Developing World Bioethics*, *21*(1), 44–50. https://doi.org/10.1111/dewb.12283

Graef, K. M., Okoye, I., Oti, N. O. O., Dent, J. & Odedina, F. T. (2020). Operational Strategies for Clinical Trials in Africa. *JCO Global Oncology*, *6*(6), JGO.19.00204. https://doi.org/10.1200/jgo.19.00204

Horowitz, C. R., Sabin, T., Ramos, M., Richardson, L. D., Hauser, D., Robinson, M. & Fei, K. (2019). Successful recruitment and retention of diverse participants in a genomics clinical trial: a good invitation to a great party. *Genetics in Medicine*, *21*(10), 2364–2370. https://doi.org/10.1038/s41436-019-0498-x

Huang, G. D., Bull, J., McKee, K. J., Mahon, E., Harper, B., Roberts, J. N. & Team, for the C. R. P. (2018). Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative. *Contemporary Clinical Trials*, *66*, 74–79. https://doi.org/10.1016/j.cct.2018.01.003

Mutebi, M., Scroggins, D., Simons, V., Oti, N. O. & Hammad, N. (2020). Engaging Patients for Clinical Trials in Africa: Patient-Centered Approaches. *JCO Global Oncology*, *6*(6), JGO.19.00190. https://doi.org/10.1200/jgo.19.00190

Recruitment and Retention Plan – Source Document: Site Feasibility and Planning. (n.d.). Recruitment Innovation Center. Retrieved November 15, 2023, from https://www.med.unc.edu/crso/wp-content/uploads/sites/1088/2021/08/Recruitment-and-Retention-Plan-Source-Document_SITE.pdf

Robinson, E. T., Baron, D., Heise, L. L., Moffett, J. & Harlan, S. V. (n.d.). *Communications Handbook for Clinical Trials*. Microbicides Media and Communications Initiative. https://www.fhi360.org/sites/default/files/media/documents/CommhandbkChapterOne.pdf

Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risks (By I. of Medicine). (2015). The National Academies Press.

DOI 10.17605/OSF.IO/MW5YA

Solarin, O., Mohammed, S. I., Ndlovu, N., Vanderpuye, V. & Olaiya, V. (2020). Partnerships and Collaborations: The Right Alliances for Clinical Trials in Africa. *JCO Global Oncology*, *6*(6), JGO.19.00194. https://doi.org/10.1200/jgo.19.00194

Spies, R., Siegfried, N., Myers, B. & Grobbelaar, S. S. (2021). Concept and development of an interactive tool for trial recruitment planning and management. *Trials*, *22*(1), 189. https://doi.org/10.1186/s13063-021-05112-z

Tjia, J., Clayton, M., Chiriboga, G., Staples, B., Puerto, G., Rappaport, L. & DeSanto-Madeya, S. (2021). Stakeholder-engaged process for refining the design of a clinical trial in home hospice. *BMC Medical Research Methodology*, *21*(1), 92. https://doi.org/10.1186/s12874-021-01275-0

Wilson, B., Wright, K., Taylor, R. & Higgs, E. (2021). Beyond recruitment: good participatory practice enhances the impact of research in a pandemic. *Nature Medicine*, *27*(3), 369–371. https://doi.org/10.1038/s41591-021-01271-3

Challenges

Stein, M. A., Shaffer, M., Echo-Hawk, A., Smith, J., Stapleton, A., & Melvin, A. (2015). Research START: a multimethod study of barriers and accelerators of recruiting research participants. Clinical and translational science, 8(6), 647-654.

Costs and Budget Considerations

Chaudhari, N., Ravi, R., Gogtay, N. J. & Thatte, U. M. (2020). Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspectives in Clinical Research*, *11*(2), 64–69. https://doi.org/10.4103/picr.picr_206_19

Lattie, E. G., Kaiser, S. M., Alam, N., Tomasino, K. N., Sargent, E., Rubanovich, C. K., Palac, H. L. & Mohr, D. C. (2018). A Practical Do-It-Yourself Recruitment Framework for Concurrent eHealth Clinical Trials: Identification of Efficient and Cost-Effective Methods for Decision Making (Part 2). *Journal of Medical Internet Research*, *20*(11), e11050. https://doi.org/10.2196/11050

Miller, H. N., Charleston, J., Wu, B., Gleason, K., White, K., Himmelfarb, C. R. D., Ford, D. E., Plante, T. B., Gelber, A. C., Appel, L. J., Miller, E. R. & Juraschek, S. P. (2021). Use of electronic recruitment methods in a clinical trial of adults with gout. *Clinical Trials*, *18*(1), 92–103. https://doi.org/10.1177/1740774520956969

Myers, B. A., Pillay, Y., Hornsby, W. G., Shubrook, J., Saha, C., Mather, K. J., Fitzpatrick, K. & Groot, M. de. (2019). Recruitment effort and costs from a multi-center randomized controlled trial for treating depression in type 2 diabetes. *Trials*, *20*(1), 621. https://doi.org/10.1186/s13063-019-3712-x

Patient-centered clinical trials improve recruitment and retention. (2023). https://www.biopharmadive.com/spons/patient-centered-clinical-trials-improve-recruitment-and-retention/647481/

Rasouly, H. M., Wynn, J., Marasa, M., Reingold, R., Chatterjee, D., Kapoor, S., Piva, S., Kil, B. H., Mu, X., Alvarez, M., Nestor, J., Mehl, K., Revah-Politi, A., Lippa, N., Ernst, M. E., Bier, L., Espinal, A., Haser, B., Sinha, A., … Chung, W. K. (2019). Evaluation of the cost and effectiveness of diverse recruitment methods for a genetic screening study. *Genetics in Medicine*, *21*(10), 2371–2380. https://doi.org/10.1038/s41436-019-0497-y

Reuter, K. (2020). Social Media for Clinical Trial Recruitment: How Real is the Potential? *EMJ Innovations*, 34–39. https://doi.org/10.33590/emjinnov/19-00121

Taylor, K., Properzi, F., Cruz, M. J., Ronte, H. & Haughey, J. (2020). *Intelligent clinical trials: Transforming through AI-enabled engagement*. Deloitte University EMEA CVBA. https://www2.deloitte.com/content/dam/insights/us/articles/22934_intelligent-clinical-trials/DI_Intelligent-clinical-trials.pdf

The role of print advertising in clinical trial recruitment: Lessons from a South African site. *Open Access Journal of Clinical Trials*, 83. https://doi.org/10.2147/oajct.s10027

DOI 10.17605/OSF.IO/MW5YA

Thornton, L., Batterham, P. J., Fassnacht, D. B., Kay-Lambkin, F., Calear, A. L. & Hunt, S. (2016). Recruiting for health, medical or psychosocial research using Facebook: Systematic review. *Internet Interventions*, *4*, 72–81. https://doi.org/10.1016/j.invent.2016.02.001

Ethics

Al, P., Hey, S., Weijer, C., Gillies, K., McCleary, N., Yee, M.-L., Inglis, J., Presseau, J. & Brehaut, J. (2023). Changing patient preferences toward better trial recruitment: an ethical analysis. *Trials*, *24*(1), 233. https://doi.org/10.1186/s13063-023-07258-4

Barnes, M. & Wallace, N. (2017). Laws and Ethics Affecting Clinical Trials in Africa. *Journal of Health Care Law and Policy*, *19*(2). https://core.ac.uk/download/pdf/128127845.pdf

BROWN, J. G. (2000). *Recruiting Human Subjects, Sample Guidelines for Practice*. https://oig.hhs.gov/oei/reports/oei-01-97-00196.pdf

Dha, N. (2022). *Regulations and Ethics of Clinical Trials*. https://www.news-medical.net/life-sciences/Regulations-and-Ethics-of-Clinical-Trials.aspx

Emanuel, E. J., Wendler, D., Killen, J. & Grady, C. (2004). What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *The Journal of Infectious Diseases*, *189*(5), 930–937. https://doi.org/10.1086/381709

Ethical Principles for Medical Research Involving Human Subjects. (2008). The World Medical Association, Inc. https://www.wma.net/wp-content/uploads/2018/07/DoH-Oct2008.pdf

Ethics in Clinical Research: Foundations and Current Issues. (n.d.). Retrieved November 15, 2023, from https://school.wakehealth.edu/education-and-training/graduate-programs/clinical-research-management-ms/features/ethics-in-clinical-research

Gelinas, L., Lynch, H. F., Bierer, B. E. & Cohen, I. G. (2017). When clinical trials compete: prioritising study recruitment. *Journal of Medical Ethics*, *43*(12), 803. https://doi.org/10.1136/medethics-2016-103680

Hunter, D. (2015). We could be heroes: ethical issues with the pre-recruitment of research participants. *Journal of Medical Ethics*, *41*(7), 557. https://doi.org/10.1136/medethics-2014-102639

LeBlanc, T. W., Lodato, J. E., Currow, D. C. & Abernethy, A. P. (2013). Overcoming Recruitment Challenges in Palliative Care Clinical Trials. *Journal of Oncology Practice*, *9*(6), 277–282. https://doi.org/10.1200/jop.2013.000996

Rennick-Egglestone, S. (2021). Principles for the production and dissemination of recruitment material for three clinical trials of an online intervention. *Trials*, *22*(1), 441. https://doi.org/10.1186/s13063-021-05412-4

Ryan, K. J., Brady, J. V., Cooke, R. E., Height, D. I., Jonsen, A. R., King, P., Lebacqz, K., Louisell, D. W., Seldin, D. W. & Stellar, E. (1979). *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Department of Health, Education, and Welfare. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xrespect

Soofi, H. (2022). Ethical aspects of facilitating the recruitment of people with dementia for clinical trials: A call for further debate. *British Journal of Clinical Pharmacology*, *88*(1), 22–26. https://doi.org/10.1111/bcp.14968

Wilson, S., Draper, H. & Ives, J. (2008). Ethical issues regarding recruitment to research studies within the primary care consultation. *Family Practice*, *25*(6), 456–461. https://doi.org/10.1093/fampra/cmn076

Zimmermann, B. M., Willem, T., Bredthauer, C. J. & Buyx, A. (2022). Ethical Issues in Social Media Recruitment for Clinical Studies: Ethical Analysis and Framework. *Journal of Medical Internet Research*, *24*(5), e31231. https://doi.org/10.2196/31231

DOI 10.17605/OSF.IO/MW5YA

Timeline

Chang, A. (2016). *Tips for preparing a clinical research recruitment budget*. https://recruit.ucsf.edu/blog/tips-preparing-clinical-research-recruitment-budget

Chaudhari, N., Ravi, R., Gogtay, N. J. & Thatte, U. M. (2020). Recruitment and retention of the participants in clinical trials: Challenges and solutions. *Perspectives in Clinical Research*, *11*(2), 64–69. https://doi.org/10.4103/picr.picr_206_19

Denhoff, E. R., Milliren, C. E., Ferranti, S. D. de, Steltz, S. K. & Osganian, S. K. (2015). Factors Associated with Clinical Research Recruitment in a Pediatric Academic Medical Center—A Web-Based Survey. *PLoS ONE*, *10*(10), e0140768. https://doi.org/10.1371/journal.pone.0140768

Greene, E. O. & Shiely, F. (2022). Recording and reporting of recruitment strategies in trial protocols, registries, and publications was nonexistent. *Journal of Clinical Epidemiology*, *152*, 248–256. https://doi.org/10.1016/j.jclinepi.2022.10.014

Jiang, X. & Zink, R. C. (2016). *Predictive Modeling for Patient Recruitment in Multicenter Trials*. https://community.jmp.com/t5/Discovery-Summit-Europe-2016/Predictive-Modeling-for-Patient-Recruitment-in-Multicenter/ta-p/23479?attachment-id=730

Library, Cre. & Singletary, F. (2014). Planning for a Participant Recruitment Phase. *The Clinical Research Education Library*, *2*(1), 1. https://doi.org/10.1044/cred-sprs-tth-003

Patient Recruitment and Enrollment in Clinical Trials. (2022). https://www.advarra.com/resource-library/patient-recruitment-and-enrollment-in-clinical-trials/

Ruban, A., Prechtl, C. G., Glaysher, M. A., Chhina, N., Al-Najim, W., Miras, A. D., Smith, C., Goldstone, A. P., Patel, M., Moore, M., Ashrafian, H., Byrne, J. P. & Teare, J. P. (2019). Effectiveness of different recruitment strategies in an RCT of a surgical device: experience from the Endobarrier trial. *BMJ Open*, *9*(11), e032439. https://doi.org/10.1136/bmjopen-2019-032439

Zuccon, G., Sullivan, C., Vegt, V. D. & Pole, J. (n.d.). *An AI-based system for clinical trial recruitment from electronic health records*. Retrieved November 15, 2023, from https://ai.uq.edu.au/project/ai-based-system-clinical-trial-recruitment-electronic-health-records

Tips

Gul, R. B. & Ali, P. A. (2010). Clinical trials: the challenge of recruitment and retention of participants. *Journal of Clinical Nursing*, *19*(1-2), 227–233. https://doi.org/10.1111/j.1365-2702.2009.03041.x

Treweek, S., Lockhart, P., Pitkethly, M., Cook, J. A., Kjeldstrøm, M., Johansen, M., Taskila, T. K., Sullivan, F. M., Wilson, S., Jackson, C., Jones, R. & Mitchell, E. D. (2013). Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open*, *3*(2), e002360. https://doi.org/10.1136/bmjopen-2012-002360

Treweek, S., Pitkethly, M., Cook, J., Fraser, C., Mitchell, E., Sullivan, F., Jackson, C., Taskila, T. K. & Gardner, H. (2018). Strategies to improve recruitment to randomised trials. *Cochrane Database of Systematic Reviews*, *2018*(2), MR000013. https://doi.org/10.1002/14651858.mr000013.pub6

Best Practices

Clinical Trial Site Recruitment Guide. (2019). https://ctiq.com.au/wp-content/uploads/Clinical-Trial-Recruitment-Guide-Final.pdf

Karlsberg, S. & Zeanah, C. (2022). *Strategies to Close the Gap in Clinical Trial Recruitment*. https://www.appliedclinicaltrialsonline.com/view/strategies-to-close-the-gap-in-clinical-trial-recruitment

McDowell, A. (2022). *10 clinical trial recruitment strategies that work*. https://www.antidote.me/blog/10-clinical-trial-recruitment-strategies-that-work

DOI 10.17605/OSF.IO/MW5YA

Mehaffey, L. (2021). *5 best recruitment strategies for clinical trials*. https://www.ringcentral.com/us/en/blog/5-best-recruitment-strategies-for-clinical-trials/

Schmitt, I. (2023). *5 Key Strategies for Clinical Trial Patient Recruitment*. https://www.proximacro.com/news/5-key-strategies-for-clinical-trial-patient-recruitment

Thoma, A., Farrokhyar, F., McKnight, L. & Bhandari, M. (2010). Practical tips for surgical research: how to optimize patient recruitment. *Canadian Journal of Surgery. Journal Canadien de Chirurgie*, *53*(3), 205–210.

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