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# Equitable Participant Recruitment in U.S. Clinical Research: A Narrative Review and Multilevel Framework

**Olufisayo Ezekiel Ogunbayo**
Department of Hematology, Oncology, Springfield Clinic, Springfield, Illinois, United States

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Corresponding Author: **Olufisayo Ezekiel Ogunbayo**

**Abstract**

Persistent underrepresentation in U.S. clinical research can limit the applicability of evidence, constrain equitable access to research opportunities, and obscure clinically important variation in intervention effects and harms. This narrative review critically synthesizes contemporary evidence on equitable participant recruitment and proposes a multilevel framework linking institutional capacity, community trust and institutional trustworthiness, and participant engagement. PubMed and authoritative U.S. policy sources were searched through July 31, 2026, using concepts related to recruitment, enrollment, representation, underserved populations, community engagement, trust, site access, eligibility, participant burden, and decentralized research. Priority was given to U.S.-focused empirical studies, recent reviews, consensus reports, and federal guidance, supplemented by reference-list and related-article searching. The evidence supports a research-system model of recruitment equity. Institutional capacity shapes where studies are located, who is eligible and referred, and whether sites can provide language, navigation, scheduling, accessibility, and financial support. Community trust is more appropriately considered alongside institutional trustworthiness, including transparency, continuity, shared decision-making, and responsiveness to community priorities. Participant engagement depends on understandable communication, voluntary decision-making, and reduction of geographic, financial, caregiving, linguistic, disability-related, and digital burdens. Strategies are most credible when implemented as coordinated packages rather than isolated outreach tactics. The proposed framework positions accessibility, relevance, trustworthiness, shared power, burden reduction, and accountability as cross-cutting mechanisms linking institutional, community, and participant domains to equity-sensitive recruitment outcomes. The framework is evidence-informed but not yet validated and should be prospectively evaluated and refined with stakeholders.

**Keywords:** Clinical Research, Clinical Trials, Participant Recruitment, Research Equity, Community Engagement, Trustworthiness, Representation, United States

## 1. Introduction

Clinical research is central to the development of safe and effective interventions, yet the value of its findings depends partly on whether study populations are relevant to those who will ultimately use the resulting products and services. Inadequate representation can limit external validity, reduce confidence in subgroup-specific estimates of benefit and harm, and distribute access to research opportunities inequitably. In the United States, these concerns extend beyond race and ethnicity to age, sex, disability, socioeconomic position, language, insurance status, caregiving responsibilities, digital access, and rural or geographically underserved residence. Equitable recruitment should therefore not be equated with making every study mirror national census proportions. Instead, it requires a fair opportunity to learn about, access, and consider participation while enrolling populations appropriate to the scientific question, disease distribution, and intended treatment population (National Academies of Sciences, Engineering, and Medicine [NASEM], 2022; Schwartz *et al*., 2023) [13, 17].

Participation gaps remain visible across therapeutic areas despite longstanding federal attention. Analyses of trials supporting cancer and cardiovascular drug approvals have documented incomplete demographic reporting and underrepresentation of clinically relevant populations, particularly Black and Hispanic participants and older adults in some disease areas (Chen & Li, 2021; Loree *et al*., 2019) [5, 12]. A recent systematic review of therapeutic-product trials similarly found wide variation in how diversity was defined and measured, with only a minority of reviewed articles using an explicit reference standard (Chege *et*

*al*., 2024) [4]. These findings illustrate two related problems: representation may be inadequate, and the methods used to judge adequacy are often inconsistent.

Representation cannot be evaluated responsibly through a single national benchmark. Disease prevalence, exposure to risk, care-seeking patterns, trial eligibility, site catchment areas, and the population expected to use an intervention vary across studies. Comparison with census data may be informative in some contexts but misleading in others. A stronger approach specifies the target population prospectively, identifies which groups are scientifically and ethically important to include, and documents the recruitment pathway from identification and referral through screening, eligibility, consent, and enrollment (NASEM, 2022; Schwartz *et al*., 2023) [13, 17].

Recruitment inequities begin well before an individual decides whether to consent. Trial opportunities are unevenly distributed, and communities experiencing social or economic disadvantage may have fewer nearby research sites. Geographic concentration of high-volume centers can increase travel time, direct costs, unpaid work absence, and caregiving burden for rural residents and people living outside major research networks (Lee *et al*., 2024; Sekar *et al*., 2024) [11, 18]. Protocol-level choices may narrow access further through restrictive eligibility criteria, frequent in-person visits, complex screening procedures, limited language services, technology requirements, and rigid schedules. Recruitment outcomes therefore reflect institutional design and capacity as much as participant preference.

Community relationships form a second critical level. Historical and contemporary experiences of discrimination, exclusion, poor-quality care, and extractive research influence how communities evaluate research institutions. Describing the problem only as participant mistrust risks relocating responsibility from institutions to populations that have experienced legitimate reasons for caution. Sustained partnerships, bidirectional communication, shared decision-making, appropriate resourcing of community organizations, culturally and linguistically responsive communication, and return of findings can strengthen relevance and institutional trustworthiness (Cunningham-Erves *et al*., 2024; Odedina *et al*., 2024) [6, 15].

At the participant level, awareness and willingness are inseparable from practical accessibility. Transportation, work and caregiving obligations, out-of-pocket costs, visit frequency, disability accommodations, digital connectivity, and excessive data collection may make participation disproportionately difficult for people with fewer resources. Communication and education are important but are unlikely to overcome structural constraints unless accompanied by navigation, flexible scheduling, accessible sites, language support, reimbursement, and study designs that minimize avoidable demands (King *et al*., 2024; Law & Chatfield, 2026) [9, 10].

These interacting determinants help explain why isolated recruitment tactics often produce limited or temporary gains. Advertising cannot compensate for inaccessible sites; community outreach cannot resolve unnecessarily restrictive protocols; and numerical enrollment goals have limited value without adequate budgets, monitoring, and institutional accountability. Current U.S. policy increasingly recognizes this broader responsibility. The U.S. Food and Drug Administration (FDA) issued final guidance in December 2025 on enhancing participation through eligibility criteria, enrollment practices, and trial design, while its Diversity Action Plan guidance remained in draft form at the review cutoff and addressed enrollment goals and strategies for applicable studies (FDA, 2024, 2025) [19, 20]. The National Institutes of Health (NIH) revised its inclusion policy in 2025; the revised policy became effective on August 16, 2025, and maintains expectations for inclusion of women and members of racial and/or ethnic minority groups in NIH-supported clinical research (NIH, 2025) [14].

The literature on recruitment is extensive but fragmented by disease, population, setting, and level of analysis. Reviews frequently describe barriers or catalog individual strategies without fully explaining how institutional capacity, community trust, and participant engagement interact. This narrative review critically synthesizes contemporary U.S. evidence across these levels and proposes a multilevel framework for research practice, organizational planning, and policy. The central argument is that equitable recruitment is best treated as a research-system responsibility rather than a deficit among prospective participants.

## 2. Review Approach

A targeted narrative review was conducted to identify contemporary evidence and policy relevant to equitable participant recruitment in U.S. clinical research. A narrative approach was selected because the topic spans heterogeneous empirical studies, qualitative research, systematic and scoping reviews, consensus reports, policy guidance, and conceptual frameworks. The purpose was interpretive synthesis and framework development rather than exhaustive retrieval, prevalence estimation, or meta-analysis. The review was guided by the principles of clear justification, transparent literature searching, appropriate referencing, scientific reasoning, and balanced presentation described in the SANRA framework for narrative reviews (Baethge *et al*., 2019) [2].

PubMed and authoritative U.S. policy repositories were searched through July 31, 2026. Search concepts included combinations of clinical research, clinical trials, recruitment, enrollment, accrual, equity, diversity, representation, underrepresented populations, underserved populations, community engagement, trust, trustworthiness, institutional capacity, research sites, eligibility criteria, participant burden, social determinants of health, digital recruitment, decentralized trials, and United States. Federal and consensus sources were identified through the FDA, NIH, and National Academies websites. Reference-list and related-article searching of key reviews and consensus statements was used to locate additional empirical and conceptual sources.

Sources were selected purposively for direct relevance to recruitment equity, methodological or conceptual contribution, recency, and evidentiary quality. Priority was given to U.S.-focused empirical studies, systematic or scoping reviews, multisite or national analyses, consensus reports, and current federal guidance. Foundational studies were retained when they addressed enduring mechanisms not adequately covered by recent literature. Non-U.S. conceptual or methodological sources were used selectively when they addressed mechanisms plausibly relevant to U.S. research practice; they were not used as estimates of U.S.

prevalence or access. Evidence was organized deductively into institutional capacity, community trust and trustworthiness, and participant engagement, while allowing cross-cutting themes to emerge. Because this was not a systematic review, no PRISMA flow diagram, pooled effect estimate, independent duplicate screening, or formal risk-of-bias summary was produced. The review does not claim to identify every eligible publication.

The review addressed three organizing questions: how institutional design and capacity shape access to research; how community relationships and institutional trustworthiness affect recruitment; and how communication, material burden, and accessibility influence participant engagement. The framework was developed by linking recurring inputs and strategies to mechanisms and outcomes across these domains. Framework development was interpretive rather than a formal psychometric or causal-modeling exercise. The model should therefore be regarded as an evidence-informed conceptual framework rather than a validated instrument. No human participants or individual-level data were involved; institutional review board approval was not required.

## 3. Scientific and Ethical Rationale for Recruitment Equity

Recruitment equity is often justified through generalizability, but the scientific argument is more precise than a simple demand for demographic diversity. The relevance of participant composition depends on whether treatment effects, safety, implementation, or acceptability may vary across clinically important characteristics. Age, comorbidity, pregnancy status, disability, social context, concurrent medication use, and access to care can influence whether trial procedures and findings translate to routine practice. When clinically relevant populations are missing, uncertainty is transferred from the trial to clinicians and patients after approval or dissemination.

The ethical argument concerns both access and distribution. Clinical research can provide early access to promising interventions, additional monitoring, specialist expertise, and opportunities to influence future care. Unequal access to these opportunities may reproduce existing disparities even when the study itself is scientifically sound. At the same time, equitable recruitment does not mean pressuring individuals to enroll. Respect for autonomy requires that people can decline without penalty. The ethical aim is a fair opportunity to consider participation under conditions that do not impose preventable or disproportionately distributed burdens.

Numerical diversity is therefore necessary in many studies but insufficient as a complete measure of equity. A trial may report a demographically diverse final sample while relying on recruitment procedures that exclude people without transportation, broadband, paid leave, English fluency, or flexible caregiving arrangements. Conversely, a trial may not mirror national demographics yet still be appropriate if its enrollment reflects a clearly justified disease population and offers equitable access within that population. Transparent specification of the target population and recruitment pathway is essential to distinguish scientific relevance from symbolic reporting (Chege *et al*., 2024; Schwartz *et al*., 2023) [4, 17].

## 4. Institutional Capacity

### 4.1 Geographic Access and Site Infrastructure

Institutional capacity forms the structural foundation of recruitment. Before any outreach begins, organizations and sponsors decide where studies will open, which clinicians and health systems will participate, and what resources sites will receive. These decisions shape who has a realistic opportunity to be considered. Research concentrated in large academic centers may be efficient for sponsors but geographically misaligned with where many affected patients receive care. U.S. analyses of cancer-trial access have shown that travel time and proximity to major research centers vary with geography and socioeconomic context (Lee *et al*., 2024; Sekar *et al*., 2024) [11, 18].

Opening sites in underserved areas is not sufficient if those sites lack staffing, pharmacy capacity, laboratory support, contracting expertise, reliable reimbursement, or access to specialty services. Community sites may face disproportionate administrative demands relative to expected enrollment. Sponsors can unintentionally reinforce inequity when feasibility assessments prioritize past accrual volume without accounting for underinvestment, local disease burden, or the time required to build referral networks. Equitable site selection therefore requires both geographic analysis and capacity-building.

Potential solutions include satellite locations, mobile research units, partnerships with community health centers and safety-net systems, shared research infrastructure, and decentralized trial elements. These approaches can reduce travel and connect research to routine care, but they require role clarity, data-quality safeguards, training, and sustained funding. Community-based access should not mean transferring operational risk to under-resourced organizations without adequate support.

### 4.2 Protocol Design, Eligibility, and Operational Flexibility

Protocol design functions as a recruitment intervention. Eligibility criteria determine who can enter the screening pathway, while visit schedules, procedure intensity, washout requirements, and technology expectations determine who can remain practically eligible. Criteria inherited from earlier trials may exclude older adults, people with common comorbidities, those taking routine medications, pregnant or lactating individuals, and people with disabilities without a proportionate scientific or safety justification. Contemporary guidance and professional statements increasingly encourage broader, scientifically defensible eligibility criteria (FDA, 2025; Kelsey *et al*., 2022) [20, 8].

Operational flexibility is equally important. Evening or weekend visits, remote follow-up, local laboratory testing, home nursing, transportation assistance, and coordinated scheduling can reduce participation burden. Yet flexibility must be designed prospectively and budgeted. Adding accommodations after enrollment difficulties emerge often produces delays and inconsistent implementation. Protocol feasibility should therefore include an equity assessment that asks who may be excluded by each procedure, where the burden falls, and whether a less restrictive alternative could preserve scientific integrity.

Language exclusions are a common example of operational decisions becoming structural barriers. Translation,

interpretation, and multilingual staffing require time and funding, but failure to plan for them can exclude clinically relevant populations by default. Clinical research coordinators have identified language access, staff capacity, and study complexity as important barriers to recruiting underrepresented participants (Heffernan *et al*., 2023) [7]. Language planning should begin with protocol and budget development, not after recruitment problems arise.

### 4.3 Workforce, Referral Pathways, and Accountability

Recruitment depends on people and organizational culture. Research coordinators, clinicians, navigators, interpreters, data teams, and community-engagement personnel perform distinct functions. When recruitment is added to existing clinical workloads without protected time, potential participants may never hear about relevant studies. Clinicians may lack current trial information, be uncertain about eligibility, or avoid discussion because of time constraints. Assumptions about a patient's likely interest, understanding, transportation, or adherence may also affect who is referred. Qualitative studies of research staff have similarly identified workload, language access, study complexity, and implementation constraints as barriers to recruiting and retaining underrepresented participants (Heffernan *et al*., 2023; Yousafi *et al*., 2024) [7, 21].

A representative workforce can improve communication and contextual understanding, but demographic concordance alone does not guarantee equitable practice. Institutions need recurring training in inclusive communication, bias recognition, disability access, and community-engaged research, alongside systems that make equitable actions feasible. Multistakeholder recommendations emphasize that workforce diversity, organizational mission, and durable infrastructure should be developed together rather than treated as separate initiatives (Kelsey *et al*., 2022) [8].

Accountability requires measurement across the full recruitment pathway. Institutions should monitor who is identified, referred, approached, screened, excluded, consenting, and enrolled, with reasons for nonprogression where feasible and ethical. Final enrollment proportions cannot reveal whether inequity arose from site availability, clinician referral, eligibility criteria, screening procedures, participant refusal, or barriers after consent. Stage-specific denominators and a justified comparator population make recruitment data more actionable.

Technology may strengthen accountability through electronic health record-supported identification, referral alerts, dashboards, and centralized screening. However, automated tools can reproduce inequity if the underlying data are incomplete or if algorithms are deployed without evaluation across populations. Digital tools should augment, not replace, relationship-based recruitment and human review.

## 5. Community Trust and Institutional Trustworthiness

Trust is frequently described as a barrier to participation, particularly among communities historically excluded from or harmed by research. That description is incomplete unless it also examines institutional trustworthiness. Caution may be a rational response to discrimination, poor communication, extractive research practices, lack of transparency, or prior experiences in which institutions sought participation without sustaining relationships or returning findings. A research-system perspective therefore asks not only whether communities trust research, but also what institutions have done to earn and maintain trust.

Trustworthiness is demonstrated through consistency, transparency, ethical governance, responsiveness, and respect for community knowledge. It cannot be manufactured during a short recruitment campaign. Community engagement is most credible when it begins before protocol finalization, influences study procedures, and continues through interpretation and dissemination. The BEE framework emphasizes relationship building, shared goals and resources, equitable partnership formation, and bidirectional learning across the research process (Cunningham-Erves *et al*., 2024) [6].

Community organizations can identify locally meaningful research questions, acceptable communication channels, accessible sites, language needs, and burdens that academic teams may overlook. Faith communities, advocacy organizations, community health workers, local clinicians, and advisory boards can all contribute, but their roles should be defined and resourced. Asking community partners to deliver recruitment targets without decision-making authority or compensation reproduces the power imbalances that engagement is intended to address.

Community advisory boards are most useful when members can influence protocol design, recruitment materials, consent processes, participant support, and return of results. Symbolic consultation after major decisions have been made has limited value. Institutions should document how community input changed the study or explain transparently why a proposed change could not be adopted. Responsiveness is central to trustworthiness.

Trusted messengers may increase awareness and initial receptivity, but they cannot independently overcome inaccessible sites, restrictive eligibility, inadequate reimbursement, or poor consent processes. Community engagement should therefore be linked to institutional action. Reviews and practice recommendations consistently support early engagement, long-term partnership, culturally and linguistically responsive communication, and visible return of value to communities (Bodicoat *et al*., 2021; Odedina *et al*., 2024) [3, 15].

The return of findings is an important but often neglected element. Participants and communities may reasonably expect to learn what a study found and how their contribution mattered. Aggregate results should be communicated in accessible formats, and negative or inconclusive findings should not disappear. Continuing communication after enrollment ends can strengthen institutional credibility for future studies.

Trust also has an interpersonal dimension. Respectful, nonjudgmental communication from clinicians and research staff affects whether potential participants feel heard and safe asking questions. However, interpersonal skill cannot substitute for institutional reform. A warm conversation does not make an inaccessible protocol equitable, just as a diverse workforce does not compensate for absent community governance or financial support.

## 6. Participant Engagement and Accessibility

### 6.1 Awareness, Communication, and Informed Choice

Participant engagement begins with awareness but should not end with information delivery. People may be unfamiliar with clinical research, randomization, placebo use, research protections, or the difference between research and routine

care. Clear explanation is necessary, yet knowledge alone does not determine participation. Individuals may understand a study and still be unable to enroll because of time, cost, distance, caregiving, language, disability access, or digital requirements.

Communication should be understandable, culturally and linguistically responsive, and paced to support voluntary decision-making. Plain-language materials, visual aids, teach-back, interpreter access, and repeated opportunities for questions can improve comprehension. Potential participants may also wish to consult family members, clinicians, or trusted community figures. Supporting deliberation is different from maximizing acceptance; respectful refusal is an ethically appropriate outcome.

Recruitment materials should describe not only potential benefits but also uncertainty, risks, procedures, time commitment, costs, reimbursement, data use, and alternatives. Overly promotional language may increase initial interest while weakening trust once the actual burden becomes clear. Consistency between advertising, screening conversations, and consent documents is therefore important.

### 6.2 Material Burden and Participant Support

Participation burden is a major mechanism linking social disadvantage to recruitment inequity. Travel, parking, lodging, unpaid leave, childcare, eldercare, meal costs, device requirements, repeated questionnaires, and frequent procedures can make participation unrealistic even for highly motivated individuals. These burdens are not evenly distributed. A requirement that appears modest to a salaried participant with reliable transportation may be prohibitive for someone working hourly shifts, living far from the site, or managing multiple caregiving responsibilities (King *et al*., 2024; Law & Chatfield, 2026) [9, 10].

Compensation and reimbursement can reduce burden when they are adequate, timely, transparent, and easy to access. Reimbursement that arrives weeks after a visit does not help a participant who cannot pay upfront travel costs. Complex payment platforms or tax concerns may create new barriers. Study budgets should distinguish reimbursement of expenses from compensation for time and inconvenience and should consider the participant journey rather than a single visit.

Participant navigation is a recurring facilitator. Navigators can explain study logistics, coordinate appointments, arrange transportation, connect participants with language services, and communicate across clinical and research teams. Navigation is most effective when staff have the authority and resources to solve problems rather than merely provide information. Proactive recruitment may improve inclusion but can require additional support to sustain participation, as illustrated in longitudinal research using intensive digital data collection (Porticella *et al*., 2024) [16].

Accessibility includes disability accommodation. Recruitment materials, consent procedures, facilities, devices, and outcome assessments should be usable by people with sensory, cognitive, mobility, and communication disabilities. Excluding people because standard procedures are inaccessible can undermine both justice and scientific relevance. Universal design and supported decision-making should be considered early rather than as exceptional modifications.

### 6.3 Digital and Decentralized Recruitment

Digital recruitment and decentralized trial elements can reduce geographic and scheduling barriers through online outreach, electronic consent, telehealth visits, wearable devices, home delivery, and local data collection. They can also reach people who are not connected to major research centers. Current recommendations recognize the potential of decentralized designs to improve access while emphasizing that equity is not automatic (Aiyegbusi *et al*., 2024) [1].

Digital strategies may exclude people without broadband, compatible devices, private space, digital literacy, accessible interfaces, or confidence in data security. Algorithmic advertising may reach populations unevenly, and reliance on patient portals may miss people receiving fragmented care. Hybrid options, device provision, technical support, accessible design, and nondigital alternatives are needed to prevent one barrier from being replaced by another.

The appropriate question is therefore not whether research should be centralized or decentralized, but which combination of local, remote, and traditional procedures best fits the target population and scientific question. Equity assessment should include who benefits from each modality, who may be excluded, and what support is required.

## 7. A Multilevel Framework for Equitable Recruitment

The literature supports a multilevel framework in which institutional capacity, community trust and trustworthiness, and participant engagement are distinct but mutually dependent domains. Institutional capacity determines whether appropriate opportunities exist and whether research teams can support inclusive participation. Community trust links institutional conduct to the social context in which recruitment occurs. Participant engagement represents the point at which individuals encounter, interpret, and act on a research opportunity.

The framework identifies six cross-cutting mechanisms: accessibility, relevance, trustworthiness, shared power, burden reduction, and accountability. Accessibility includes geographic, financial, linguistic, physical, temporal, and digital feasibility. Relevance concerns whether the research question, target population, and recruitment approach make sense in relation to disease burden and community priorities. Trustworthiness reflects transparent and responsive institutional behavior. Shared power concerns meaningful influence over decisions. Burden reduction addresses avoidable demands and unequal participation costs. Accountability requires measurement, feedback, and action.

These mechanisms connect inputs and processes to equity-sensitive outcomes. Relevant outcomes include reach, screening, eligibility, enrollment, representativeness, recruitment timeliness, cost, and participant experience. No single outcome is sufficient. Rapid accrual can coexist with poor representativeness, while demographic diversity can coexist with unequal burden. Participant experience and the distribution of costs should therefore be evaluated alongside enrollment.

The framework also includes feedback loops. Recruitment data should inform changes to site selection, protocol design, staffing, community partnership, and participant support. Community feedback should influence future research priorities and operational decisions. Continuous improvement distinguishes durable recruitment capacity from one-time diversity campaigns.

The model is not a linear funnel in which institutions act, communities trust, and participants enroll. Each level influences the others. Community input can reshape institutional protocols; participant experience can alter community perceptions; and institutional investment can determine whether engagement recommendations are implemented. Fig 1 presents the framework as an organizing model for planning and evaluation. The vertical arrangement is heuristic rather than a fixed causal sequence, and the feedback loop represents iterative learning across domains.

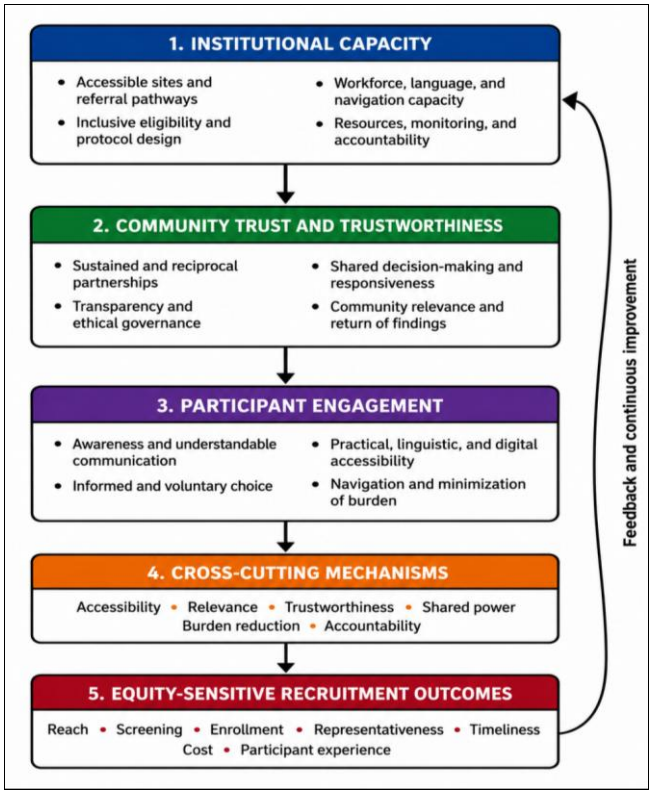


**Fig 1:** Multilevel framework for equitable participant recruitment

Institutional capacity, community trust and trustworthiness, and participant engagement operate through accessibility, relevance, trustworthiness, shared power, burden reduction, and accountability to influence reach, screening, eligibility, enrollment, representativeness, timeliness, cost, and participant experience. Arrows indicate analytic relationships rather than a fixed causal sequence; feedback supports continuous improvement.

## 8. Implications for Research Practice and Policy

Research institutions should treat equitable recruitment as core infrastructure rather than a project-specific add-on. Permanent capacity includes multilingual staff, navigation, accessible consent processes, community-engagement expertise, flexible scheduling, transportation and caregiving support, disability accommodation, and recruitment analytics. Institutional leaders should assign responsibility, fund the work, and review performance across studies rather than relying on individual investigators.

Investigators should begin recruitment planning during question and protocol development. The target population and comparator for representation should be justified prospectively. Eligibility criteria and procedures should be reviewed for differential exclusion, and community or participant input should be obtained while changes remain possible. Recruitment plans should explain not only how people will be contacted but also how barriers after contact will be addressed.

Sponsors and funders should align budgets and timelines with equity goals. Community partnership, translation, interpretation, navigation, transportation, decentralized options, and monitoring require resources. Sites serving underrepresented populations may need start-up support and longer lead time. Feasibility metrics should recognize local disease burden, community reach, and capacity-building potential rather than relying only on previous accrual.

Community partners should participate in governance, not only dissemination. Their roles may include shaping priorities, reviewing protocols, selecting communication channels, identifying burdens, interpreting findings, and planning return of results. Compensation and authorship or acknowledgment should reflect their contributions. Partnership agreements can clarify decision-making, data use, conflict resolution, and expectations after study completion.

Regulators and policymakers can reinforce these practices through clear expectations for inclusive design, appropriate eligibility, participant-centered operations, and transparent reporting. The FDA's final December 2025 guidance emphasizes broadening eligibility where scientifically appropriate and adopting enrollment practices and trial designs that support participation (FDA, 2025) [20]. The Diversity Action Plan guidance remained draft at the review cutoff and addresses enrollment goals and strategies for applicable studies; it should therefore be cited and interpreted as draft guidance rather than a finalized requirement (FDA, 2024) [19]. NIH's revised inclusion policy became effective on August 16, 2025, and continues federal expectations for inclusion of women and members of racial and/or ethnic minority groups in NIH-supported clinical research (NIH, 2025) [14].

Policy requirements are necessary but insufficient. Numerical targets can produce compliance-oriented behavior if they are disconnected from site investment, community partnership, and participant support. A multilevel framework can help translate policy into operational questions: Are appropriate sites available? Are eligibility criteria defensible? Are community relationships reciprocal? Are burdens identified and reduced? Are stage-specific recruitment data reviewed and acted upon?

Reporting standards also need improvement. Publications should specify the target population, recruitment setting, recruitment channels, denominators at each stage, reasons for exclusion or nonparticipation where feasible, accommodations offered, and the comparator used to judge representation. Negative or null recruitment interventions should be published to reduce repeated investment in unsupported strategies.

The central implementation lesson is that no single tactic is likely to resolve recruitment inequity. Evidence and consensus recommendations favor coordinated packages that combine accessible sites, inclusive protocols, clinician engagement, community partnership, multilingual communication, navigation, burden reduction, and accountability (Bodicoat *et al*., 2021; Kelsey *et al*., 2022; NASEM, 2022) [3, 8, 13]. The appropriate package will vary by population, disease, setting, and study design.

## 9. Research Gaps and Priorities

Much of the recruitment literature remains descriptive. Studies frequently identify barriers or report lessons learned without prospectively comparing strategies. Future evaluations should use pragmatic, embedded, or implementation designs to test coordinated recruitment packages across sites and populations. Outcomes should include reach, enrollment, representativeness, time, cost, fidelity, participant experience, and unintended consequences.

Standardized stage-specific reporting is a priority. Without denominators for identification, referral, approach, screening, eligibility, consent, and enrollment, it is difficult to locate inequity in the recruitment pathway. Research should also test alternative reference standards for representation, including disease prevalence, treatment populations, site catchment areas, and populations most likely to use the intervention.

Evidence is particularly needed from rural settings, federally qualified health centers, safety-net institutions, tribal health systems, smaller research sites, and populations experiencing intersecting barriers. Disability, limited English proficiency, caregiving, housing instability, immigration concerns, and digital exclusion should not be treated as secondary characteristics. Intersectional analyses may reveal barriers that are obscured when race, age, geography, or income are examined separately.

Economic evaluation is also limited. Equitable recruitment may require greater upfront investment but produce scientific, operational, and social value through improved generalizability, faster resolution of access problems, and stronger community infrastructure. Studies should report the cost of strategies and distinguish short-term project expenses from durable capacity-building.

The proposed framework requires structured refinement with participants, community representatives, coordinators, clinicians, investigators, site leaders, sponsors, funders, and regulators. Subsequent work should develop measurable indicators for each mechanism and test whether framework-guided planning improves recruitment and participant experience without compromising voluntariness or scientific integrity.

## 10. Strengths and Limitations

This review integrates institutional, community, and participant-level evidence within a single U.S.-focused model. It combines empirical research, recent reviews, consensus recommendations, and current federal guidance, while avoiding explanations of underrepresentation that rely solely on participant attitudes. The framework translates a broad literature into mechanisms and operational questions that can support planning, implementation, and evaluation.

The review also has important limitations. It was narrative rather than systematic; source identification and selection were purposive, and the bibliographic search relied primarily on PubMed with supplementary reference-list, related-article, and policy searching. No exhaustive multi-database search, duplicate screening, or formal risk-of-bias assessment was performed. Relevant studies may therefore have been missed, and the synthesis reflects interpretive judgment. Much of the available evidence is observational, qualitative, disease-specific, or based on expert consensus, limiting causal conclusions about recruitment strategies. Terminology and benchmarks for representation also remain inconsistent across the literature.

Finally, the framework has not been prospectively validated and should not be presented as a predictive instrument. Its domains may require adaptation for pediatric, emergency, rare-disease, pragmatic, behavioral, and decentralized research. Some cited conceptual sources were developed outside the United States and were used for transferable mechanisms rather than U.S.-specific estimates. These limitations reinforce the need for transparent application, stakeholder refinement, and empirical evaluation.

## 11. Conclusion

Equitable participant recruitment in U.S. clinical research cannot be achieved through outreach or education alone. Recruitment is shaped by the interaction of institutional capacity, community trust and institutional trustworthiness, and participant engagement. Institutions determine whether studies are available, appropriately designed, adequately staffed, linguistically and physically accessible, and supported by fair referral and eligibility processes. Communities evaluate whether research relationships are transparent, reciprocal, and responsive. Participants make decisions under practical conditions shaped by time, cost, caregiving, transportation, language, disability access, technology, and perceived relevance.

The proposed framework positions accessibility, relevance, trustworthiness, shared power, burden reduction, and accountability as mechanisms linking these domains to recruitment outcomes. It emphasizes evaluation across the full pathway from identification and referral through screening, eligibility, consent, and enrollment, rather than reliance on final demographic composition alone. Stage-specific measurement can help identify where inequity enters the recruitment pathway and which organizational response is needed.

For investigators, sponsors, institutions, community partners, and policymakers, the central implication is that underrepresentation should be treated as a research-system challenge. Sustainable improvement requires redesigning the conditions under which participation is offered, investing in durable community and site capacity, reducing avoidable burden, and measuring whether recruitment is both scientifically appropriate and practically equitable. Prospective testing is required before the framework can be considered validated.

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