The Rise of `Recruitmentology': Clinical Research, Racial Knowledge, and the Politics of Inclusion and Difference

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ABSTRACT Recent debates concerning the biomedical meaning and significance of race have paid relatively little attention to the practical implications of new policies in the US mandating the inclusion of racial and ethnic minorities (along with other ‘underrepresented groups’) as research subjects in clinical studies. I argue that pressures to enroll underrepresented groups have stimulated the development in the US of an auxiliary science I term ‘recruitmentology’: an empirical body of studies scientifically evaluating the efficacy of various social, cultural, psychological, technological, and economic means of convincing people (especially members of ‘hard-to-recruit populations’) that they want to become, and remain, human subjects. Via the filtering of social scientific frameworks into the clinical research domain, recruitmentology has promoted hybrid ways of thinking about race – awkward encounters in which depictions of race as a bounded, quasi-biological medical and administrative category sit uneasily alongside an interest in understanding racial identities and communities as sociocultural phenomena. I analyze how recruitmentologists, in addressing the mandate to recruit racially diverse subject populations, conceptualize race while simultaneously grappling with problems of trust, collective memory, and participation. I also examine how the increasingly transnational character of biomedical research is intensifying the exploitative dimensions of recruitment while further transforming the racialized character of human experimentation. This analysis highlights the tensions underlying projects to eliminate health disparities by race.

Keywords biopolitics, clinical trials, difference, inclusion, race, recruitment, trust

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Clinical Research, Racial Knowledge, and the Politics of Inclusion and Difference

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In recent years, scholars in the field of science studies and elsewhere have increased their efforts to understand the ongoing remaking of race via diverse biomedical and bioscientific processes (Marks, 1995; Haraway, 1997: ch. 6; Graves, 2001; Lee et al., 2001; Reardon, 2001, 2005; Root, 2001; Sankar & Cho, 2002; Cooper et al., 2003; Duster, 2003, 2005; Nelson, 2003; Templeton, 2003; Wailoo, 2003; Fausto-Sterling, 2004; Kahn, 2004; Shields et al., 2005; Shim, 2005; Montoya, 2007). Scholarly concern has been prompted not only by scientific and technological
developments, but also, in countries such as the US, by increased awareness of ‘racial disparities’ in health outcomes (Williams & Collins, 1995; Smedley et al., 2003; LaVeist, 2005; Geiger, 2006). However, this important body of scholarship has paid relatively little attention to the implications of new policies in the US that are training the attention of researchers and pharmaceutical companies ever more closely on the goal of studying racial and ethnic minority groups. My own research has centered on understanding the various causes and consequences of new biopolitical imperatives for researching the medical effects of bodily difference and social identity in the US. Elsewhere I describe the formation, over the last 20 years, of a distinctive fusion of biomedical and governmental goals, terminology, and procedures that I call the ‘inclusion-and-difference paradigm’ (Epstein, 2006, 2007). The name is meant to reference the dual mandate of a new approach to biomedical research policy in the US: the inclusion of members of various groups generally considered to have been underrepresented previously as subjects in clinical studies; and the measurement, within those studies, of differences (by sex, race, ethnicity, and age) with regard to treatment effects, disease progression, or biological processes.

In this paper, I examine one concrete arena of scientific work that is being transformed, in large measure by the new imperatives of inclusion: the on-the-ground practices of finding and recruiting research subjects to participate in biomedical studies. Recruitment, once considered merely a chore, is now emerging as an applied science, one that both presupposes and generates knowledge about the characteristics of medically underserved communities. The implications of such developments for the science of race are complex: novel and contradictory understandings of the medical significance of race are being forged in the crucible of the practical work of recruitment. On one hand, the new bureaucratic mandates reinforce essentialist definitions of races as discrete groupings (operationalized via census categories) that differ from one another in presumptively biological ways. On the other hand, the very goal of recruiting has – at least some of the time – prompted clinical researchers to conceive of the targets of their efforts in a different way – as collective actors with distinctive and knowable sociocultural properties that must be apprehended by the researcher if recruitment is to be successful.

I begin by briefly considering some of the practical and ethical challenges that underlie recruitment and retention, especially in light of new federal mandates. Then, I analyze how, in the US, the increased pressure to enroll participants has brought into being a new science – one that hasn’t named itself, but that might be called ‘recruitmentology’. Practitioners of recruitmentology seek to produce and disseminate knowledge about how to successfully recruit and retain participants – particularly, how to understand and reach out to so-called ‘hard-to-recruit’ populations. Increasingly, recruitmentologists are developing an empirical body of studies scientifically evaluating the efficacy of various social, cultural, psychological, technological, and economic means of convincing people (again, especially
members of ‘hard-to-recruit populations’) that they want to become, and remain, human subjects. That is, whereas the science of clinical trials evaluates the efficacy of therapies or regimens, the auxiliary science of recruitmentology evaluates the efficacy of techniques necessary to get bodies into a trial in the first place, and to keep them there throughout the life of the experiment. This paper provides an initial investigation of the terrain of recruitmentology, with an emphasis on the emergence of a field of questions and problems.

Many recruitmentologists argue that the effectiveness of their efforts depends on addressing collective memories of racism and abuse of research subjects (such as in the Tuskegee syphilis study [Reverby, 2000]); they emphasize the highly charged politics of trust and mistrust that characterize relations between researchers and many of the communities from which they hope to recruit, particularly communities of color. Yet I argue that the recruitmentological desire to engage in a substantive way with an interlocutor militates against a formalist methodology that seeks to reduce recruitment to a series of empirically testable techniques. This tension – between recruitment as a problem of social relations and recruitment as a project of social engineering – finds its corollary in the tension over the meaning of race itself: while recruitmentology perhaps opens up a new conceptual space within clinical research for thinking about racial and ethnic minorities as collective social actors – as communities, embedded in fields of power relations – it by no means abandons a more essentialist understanding of races as discrete categorical groups with distinctive biomedical properties.

In explicating these tensions, I also consider the practical solutions to the problem of trust that some recruitmentologists have devised, including new models of participatory research that emphasize a more politicized understanding of race relations. Finally, I examine the increasingly transnational character of biomedical research and the ways in which globalization intensifies the dilemmas surrounding recruitment and retention while heightening the risks of biomedical exploitation of a racialized global underclass. I conclude by highlighting the complex implications of the new imperative to recruit ‘underrepresented groups’ for ongoing debates about race, science, and disease. I also consider the extent to which this imperative appears actually to benefit those studied or advance the goal of reducing health disparities in the US.6

The Body Hunt

Through the influence of actor network theory, it has become commonplace in science and technology studies to assert that successful scientific work is crucially dependent on ‘enrollment’: scientists build facts and extend the reach of their claims by enlisting people and objects behind their banner and assigning to them distinct roles in the knowledge production process (Callon, 1986; Latour, 1987). But while ‘enrollment’, in this sense, is a term used by those who study scientists to describe practices that those actors perhaps more typically understand in other ways, sometimes enrollment is
precisely what scientists themselves take as their mission. Enrolling (or ‘recruiting’, or ‘accruing’) research subjects is a sine qua non for biomedical investigators in both academic and commercial settings who simply cannot perform the experiments that are their bread and butter unless they can convince living, breathing human beings to become research material and offer up their bodies to medical manipulation and scrutiny. Similarly, the ‘retention’ of participants during the months or years over which a clinical trial may continue (and the willingness of those participants, along the way, to ‘comply with’ or ‘adhere to’ all the conditions of the experimental protocol) is critical for the generation of scientifically valid conclusions. Thus researchers testing pharmaceutical drugs need to ‘configure’ the activities of the research subject (Oudshoorn, 2003) as a first step toward eventually ‘configuring the user’ (Woolgar, 1991) – shaping the behavior of the downstream consumer of the product. Research teams therefore need to do more than make a good first impression on research subjects, as important as that may be: they need to do the hard work of maintaining a long-term relationship.

Yet especially with the overall expansion of clinical research in recent years, one of the most daunting tasks to confront researchers is the practical challenge of finding appropriate individuals to participate in clinical trials. In the US, this challenge has been further complicated by a series of laws, guidelines, and policies designed to diversify the clinical research process. In 1993, the US Congress passed the National Institutes of Health Revitalization Act, one section of which required both that women and ‘members of minority groups’ be included as research subjects in National Institutes of Health (NIH)-funded studies and that NIH-funded clinical trials be ‘designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial’ (National Institutes of Health Revitalization Act, 1993). That same year, the Food and Drug Administration (FDA) removed a restriction on the participation of women in many clinical trials of new pharmaceutical products (Food and Drug Administration, 1993). In 1997 further Congressional action granted an extension of ‘exclusivity’ (the period of exclusive marketing rights) to drug manufacturers willing to go back and test approved medications in pediatric populations; and the following year the NIH also passed a policy mandating the inclusion of children in federally funded clinical research (Food and Drug Administration Modernization Act, 1997; National Institutes of Health, 1998). The FDA also has published a rule requiring labeling information on the geriatric use of drugs, as well as a rule requiring the tabulation of safety and efficacy data by demographic subgroup (Food and Drug Administration, 1997, 1998).

These along with a number of other regulations and policies oblige clinical researchers in the academy as well as in industry to think about recruitment diversity from the outset. Indeed, applicants for NIH funding are required to specify numerical targets, broken down by ‘sex/gender’,
race, and ethnicity, in a special form on their grant applications; if funded, investigators must update these projections with actual recruitment figures on their annual reports to the agency. Recently some of the NIH component institutes have begun to add teeth to their enforcement of recruitment diversity. For example, in 2005 the National Institute of Mental Health adopted a new policy requiring researchers to specify recruitment ‘milestones’ in advance, with attention given ‘to recruitment plans for women and men, members of racial and ethnic minority groups, and to children’. If actual recruiting ever falls ‘significantly below the milestones’, then the investigator must correct the deficiency; ultimately, the agency reserves the right to ‘consider suspending, terminating or withholding support and in some instances, may choose to negotiate a phase-out of the award’. Of course, it is important to say that the approach of federal officials to the new inclusionary goals is proactive and not just punitive. Employees at US Department of Health and Human Services (DHHS) offices charged with promoting inclusive practices have devoted considerable attention to the issues of recruitment and retention – holding conferences on the topic and publishing and distributing ‘how-to’ books (Office of Research on Women’s Health, 1995, 2003; National Institutes of Health, 1997, 2002) – and they work closely with applicants to help them develop appropriate recruitment strategies. Moreover, the DHHS has created and funded a number of specialized academic research networks in the hopes of better promoting outreach to various demographic groups, including the Resource Centers for Minority Aging Research, the Pediatric Pharmacology Research Units, and the National Centers of Excellence in Women’s Health.

It follows that for those concerned about reversing health disparities or – perhaps more immediately – complying with the formal requirements of new policies mandating the inclusion of underrepresented groups in biomedical research, the practicalities of recruitment and retention are truly ‘where the rubber meets the road’. The opening sentence of a paper on the recruitment of African Americans and Latinos for research on lung cancer observed: ‘The National Institutes of Health 1993 Revitalization Act mandates inclusion of minority groups in clinical research to address their historical underrepresentation’ (Cabral et al., 2003: 272). The authors’ arguments about recruitment techniques essentially followed from that premise. While not every researcher is as explicit about it, certainly the laws and policies that comprise the inclusion-and-difference paradigm are a consistent point of reference in the new literature on recruitment, and they are never too far from consciousness. Multiple rationales underlie the interest in figuring out how to recruit women, racial and ethnic minorities, children, the elderly, and other groups effectively, including the goals of reversing past practices of underrepresentation, eliminating health disparities, responding to distinctive health needs of specific medical constituencies, and marketing pharmaceutical products to distinct ‘niche markets’. But clearly at least part of the boom in interest in the recruiting of subjects reflects a practical concern with satisfying requirements imposed by Congress, the NIH, and the FDA: academic researchers and pharmaceutical
companies are under pressure not only to come up with the bodies, but to come up with the right mix of bodies.

Yet accomplishing this goal can be quite a challenge – a fact that points to an important irony at the heart of the inclusion-and-difference paradigm. Much of the rhetoric of reformers in the 1980s and 1990s about the unwarranted underrepresentation of various groups in biomedical research seemed almost to paint an image of a mass of medical ‘have-not’s’, pounding on the walls of research institutions, demanding to be let into the experimental domain (Epstein, 2007: ch. 3–4). But in fact only sometimes does the supply of willing bodies exceed research demand. In the late 1980s and early 1990s, for example, in the absence of approved therapies to fight HIV, people with AIDS and HIV infection often clamored for entry into clinical trials, insisting, in the process, on their right to serve as ‘guinea pigs’ (Epstein, 1996: 181–234). Inspired by their example, others have pressed for greater availability of public information about ongoing clinical trials – a mandate that, in the US, has been endorsed by Congress in the FDA Modernization Act of 1997, which requires the DHHS to maintain a publicly accessible database of all clinical trials ‘in a form that can be readily understood by members of the public’ (Dresser, 1999: 26).10 But even if an increasing number of highly motivated, potential research subjects find their own way to clinical trials, much more typically – and especially when experimenters seek to recruit members of racial minority groups – those responsible for the orchestration of large clinical trials find themselves engaged in a vexing and time-consuming body hunt.11

**Voting with Their Feet**

All scientists at times have difficulty obtaining research materials; all scientists confront recalcitrant materials that may not behave as the researcher would like or would expect, and they may exert considerable energy in getting those objects to perform properly so that the experiment may proceed (Clarke & Fujimura, 1992). But research materials that ‘talk back’ – or that can ‘vote with their feet’ – present scientists with unique challenges. Here human subjects emerge as ‘subjects’ in both senses of the word – at times subject to the will of the experimenter, at times endowed with subjectivity, agency, and a capacity to pursue their own interests (Epstein, 1997; see also Meldrum, 1994: 384–86; Clarke, 1995; Oudshoorn, 2003: 171–73). Therefore, in their engagement with potential participants, clinical researchers must grant recognition to an ‘other’, and must grapple with ethics, commitment, and responsibility.

Thus along with the many other hats that US biomedical researchers already wear – as grant-writers, administrators, and public advocates – they now don new ones as marketers and persuaders (Fishman, 2004). However, chasing after human subjects – and perhaps particularly subjects who come from ethnically diverse backgrounds – is a costly endeavor. It demands dedicated staff time not only on the part of researchers, but also from nurses functioning as clinical trial coordinators and other personnel
hired specifically to assist with outreach and recruitment efforts (Mueller, 1997). Producing and disseminating publicity and recruiting materials adds to the expense – altogether, more than $500 million is spent on mass media promotion annually – as does the screening of potential research participants. One paper published in 2001 about an estrogen replacement and atherosclerosis trial estimated the average cost of recruiting and screening each participant to be $2500 (Folmar et al., 2001: 23). In addition, delays associated with recruiting subjects can add significantly to the cost of a study. In 2001 it was estimated that 57% of clinical trials ran a month or more late in recruiting. For trials leading to drug licensing, such delays may reduce the time remaining for reaping a profit before patent protections expire.

But where some see a challenge, others perceive a business opportunity: as more and more aspects of clinical trials get outsourced to private companies, recruitment is sometimes being turned over to for-profit consultants who specialize in managing this task on behalf of drug companies, and who maintain extensive databases of potential participants, cross-referenced by demographic and medical characteristics (Fisher, 2005). Between 1992 and 2001, the number of study participants recruited by private companies grew from 7 million to 20 million (Mirowski & Van Horn, 2005: 506). Insiders refer to this development as the professionalization of recruitment, and they note the increasing reliance on ‘metrics-driven recruitment practice’ (Anderson, 2003: 16). In 2005, a small contract research organization named Anaclim, a minority-owned business based in Indianapolis, became the first such business launched specifically to recruit minority participants for clinical trials (Anonymous, 2005: 1).

The new expectations about the social identity of the participants – that some numbers of them should belong to a specified sex, race, ethnicity, or age group – inevitably and significantly complicate what often is already a considerable chore, typically in ways that add to the expense. At the same time, new financial incentives intensify the challenges by generating competitive pressures. For example, the extension of ‘exclusivity’ offered by Congress to drug companies that test products with children have set off what Robert Temple of the FDA’s Center for Drug Evaluation and Research has characterized as a recruiting ‘frenzy’, with companies competing for the available supply of child subjects. A Wall Street Journal article in 2002 quoted Temple’s ironic comment: ‘If you have a hypertensive kid, hold on to him. He’ll be in hot demand’ (quoted in Lesney, 2002: 19, 24).

Indeed, at least some experts have worried that researchers might now be overly motivated to recruit groups such as racial and ethnic minorities, with potentially pernicious results. For example, some have voiced concerns that the requirements associated with the inclusion-and-difference paradigm will promote research by those who simply have not taken the time to learn about the communities they hope to study, and that such efforts are likely to fail. Barbara Howard, the principal investigator of a Women’s Health Initiative (WHI) site in the Washington, DC, area that was quite successful in enrolling racial and ethnic minorities, complained
about how the new policies mandating inclusion ‘resulted in a flood of researchers ... who thought this [studying minorities] was a way to get money’ – researchers who then found themselves ‘falling flat’ because they had no idea how to recruit the subjects they claimed to want to study.¹⁶ A related concern, expressed by Otis Brawley, an oncology researcher and the former head of the National Cancer Institute’s Office of Special Populations Research, had more to do with the abridgement of rights to informed consent in the face of new demands to recruit racial and ethnic minorities. Brawley speculated about the tremendous pressure confronting a hypothetical ‘Dr John Smith’ to enroll people of color:

If this woman in his office is white, he gives her all the pros and cons of going into the trial .... But the black woman or the Hispanic woman, they get a very hard sell because he’s got to produce, and if he doesn’t produce he loses his grant.¹⁷

Few investigators or DHHS officials whom I interviewed felt that this practice of the ‘hard sell’ was especially common, and many of them suggested that either careful scrutiny by institutional review boards (IRBs) or resistance on the part of potential trial participants would militate against it. One might then rephrase the issue to suggest that investigators potentially face several cross-cutting pressures simultaneously. At the same time as they may confront the imperative to show recruitment results, they must also satisfy IRBs that they are not exploiting ‘vulnerable populations’, and they must respond to deep suspicions about participating in biomedical research that are prevalent within many racial and ethnic minority communities. Thus, ironically, the diverse kinds of people that academic researchers and pharmaceutical companies operating in the US are now expected to enroll in their studies include some, such as children, whom IRB members are most vigilant in protecting from risk, and others, such as African Americans, who may be highly distrustful of the medical research enterprise and little interested in placing their bodies and their lives in the hands of scientists. In such circumstances, those seeking to carry out clinical trials truly find themselves in a quandary.

‘Recruitmentology’ as a Hybrid Science

How exactly do researchers go about recruiting subjects for large clinical trials? The manifold methods testify to the absence of any single dominant strategy. Depending in part on whether the trial is a prevention study or a test of a therapy, whether it seeks to study healthy volunteers or ill people, and whether it addresses a common condition or a rare one – but also depending on the local culture of research or individual researchers’ idiosyncratic judgments about how best to proceed – subjects might be recruited through their primary care physicians; in hospitals or clinics; through newspaper, radio, and television advertising; through public notices, billboards, or signs posted on public transportation; through flyers, brochures, or doorknob literature
packets; through listings in searchable online databases; through direct mail, random-digit-dialing, or ‘cold calling’; through celebrity campaigns; or by means of various forms of community outreach at places such as health fairs, churches, and nursing homes.\(^{18}\)

Overall, interviews with investigators involved in large clinical studies of women, minorities, children, and the elderly revealed few consistent opinions about the efficacy of the various recruitment methods. Some researchers praised community outreach events for the kind of trust they can engender, while others spoke with a bit of resignation of having to embark on ‘dog-and-pony shows’\(^ {19}\). Some swore by direct mail and have spent upwards of $100,000 on it in a single study-year, while others pursuing very similar studies called it next to useless.

Given the uncertainty over effective techniques in a high-stakes environment, it is not surprising that researchers increasingly are interested in obtaining reliable, generalizable answers to the question of how best to enroll. Hence a steady stream of papers appearing in a wide range of biomedical journals – typically, spin-off papers from large, collaborative research projects, essentially framed as ‘lessons learned’ from a given study – have reported on experiences with diverse recruitment strategies. These publications, along with conferences, workshops, and reports, all have provided assistance to researchers hoping to nail down the right approaches. While some of the advice – for example, ‘that the study leaders develop an eye-catching logo and use colors and catch phrases consistently throughout all publications’ (Vozenilek, 1999: 1190–91) – has a generic quality to it and is borrowed from the worlds of marketing and advertising, other lessons are more context-specific and reflect attempts to situate clinical research projects within their social milieus.

Success stories play an important function within this body of literature, not only in suggesting specific approaches, but also in presenting concrete evidence that recruitment of ‘special populations’ is a do-able task. Studies such as the African-American Antiplatelet Stroke Prevention Study (AAASPS), the Dietary Approaches to Stop Hypertension Collaborative Research Group (DASH), and the Strong Heart Study are frequently pointed to as positive examples of recruitment of racial and ethnic minority group members. The WHI, which specifically designated ten of its 40 centers around the US as ‘minority centers’ charged with the goal of over-recruiting minorities, has been lauded for achieving an ethnic representation that is not too far from that of the US population as a whole (Rossouw & Hurd, 1999; Fouad et al., 2004).

Alongside this advice literature – what might be called ‘soft’ recruitmentology – a more rigorous, ‘hard’ recruitmentology also has taken shape that attempts a scientific analysis. ‘For many researchers recruitment is not always guided by empirically tested rules, but instead occurs in a “hit or miss” fashion,’ complained Virginia Nacif de Brey and Virginia González (1997: 64), explaining the motivation behind their example of more rigorous recruitmentology, a comparative study of the efficacy of methods used to recruit Hispanics in the San Francisco Bay Area. Sometimes ‘hard’
recruitmentologists attempt to synthesize and summarize the insights from multiple studies, along the lines of a ‘meta-analysis’. Others go a step further by setting out formally to compare different recruitment strategies, for example by building a prospective experimental design into a planned clinical trial (Folmar et al., 2001) or into a feasibility study conducted prior to undertaking a trial (Whelton et al., 1996).

The formalization of recruitment reflects an explicit attempt to transform the art of recruiting into a science. Yet, as an auxiliary to clinical research, recruitmentology lacks the institutional structure of an actual scientific specialty area. There are, to be sure, no credentials, professional societies, or specialized journals to institutionalize this domain of scientific investigation, and most of its practitioners to date are simply clinical researchers themselves. However, state agencies invested in promoting inclusion of underrepresented groups are providing a certain measure of institutional backing to recruitmentology, for example by holding conferences on the topic (Office of Research on Women’s Health, 2003); and some journals have devoted special issues to such research.20 Thus my designation of recruitmentology as a ‘science’ requires qualification; but the possibility clearly exists that, over time, this domain of research may acquire more of the formal characteristics of a specialty area.

While recruitmentological scholarship strives toward scientificity, the science that it develops is of an interestingly hybrid type. The rise of recruitmentology reminds us that even as biomedicine becomes increasingly scientific in so many respects – rationalizing its treatment algorithms, employing more sophisticated technologies, and turning its attention to the molecular and genetic levels – it also remains a ‘human science’ in Foucault’s (1979) terms, one that concerns itself with monitoring the bodies and souls of individuals. Not just in the clinical encounter, but in increasingly varied settings ‘from bench to bedside’, biomedical experts do their work by coordinating or coercing the activities of laypeople – something they cannot accomplish unless they have some understanding of how people function in society (cf. Cambrosio et al., 2006). Indeed, in the case of trial recruitment and retention, what the hybrid character of biomedicine as both a natural and a human science appears to call for is a knowledge infusion from the social sciences. As clinicians come to realize that they need to know something about cultures, communities, groups, networks, and individual psyches in order to carry out their experiments, they import concepts and frameworks from sociology, anthropology, psychology, and economics. Social scientific knowledge – in both its formal and folk variants – is deployed to help research teams advertise trials effectively, find appropriate subjects, forge alliances with the communities that subjects come from, and ensure their continued participation. In the process, the teams that conduct clinical trials generate cognitive maps (Gieryn, 1999) of what both the biological world and the social world look like – in Sheila Jasanoff’s (2004) terms, they ‘co-produce’ natural and social order.

Recruitmentology studies take several forms. One sub-genre of the literature seeks to determine the barriers that keep individuals from
volunteering. Sometimes recruitmentologists use formal methods, such as surveys, to acquire a clearer sense of the motivations for participation or the reasons for refusal (Gorelick et al., 1998). Others have tried to gauge attitudes toward research in specific communities. For example, at a conference on health research in communities of color, Anna Nápoles-Springer at the Center for Aging in Diverse Communities of the University of California, San Francisco, reported on focus groups conducted with older Latinos and African Americans, as well as results from a questionnaire mailed to key informants at 117 community-based organizations serving those groups. The themes that surfaced repeatedly were a distrust of researchers, a lack of information about medical research, a fear of experimentation, and a perceived lack of benefits.21

A second type of study in the recruitmentology genre engages in various sorts of analysis of, or introduces knowledge about, the cultures of specific groups that are targeted for recruitment. For example, some researchers have pointed to the kinds of confidentiality issues that may affect potential participants living in rural areas or small towns. Others have invoked the language of endangerment often used in reference to black men to characterize young African-American men as ‘an endangered research species’.23 Claims about cultural differences abound – for example, that culturally specific meanings attributed to blood can affect willingness to provide blood samples in clinical research; or that ‘the family orientation of Indian subjects’ may crucially affect researchers’ abilities to enroll American Indians and Alaska natives (Hodge et al., 2000). Many of these observations come from researchers with deep ties to the groups in question and appear likely to be useful to researchers. Arguably, however, their utility may be limited to the degree that these formulations involve claims about cultural differences – for example, about how ‘perceptions of time differ by culture’ (Wilcox et al., 2001: 282) – that appear to treat cultures as static and invariant wholes, consisting of knowable, essential properties. At other moments, however, investigators warn about a reliance on simple constructs of ethnicity, which may blind us to important differences within groups, such as those between first- and second-generation immigrants.25

A third variety of recruitmentology is suggestive of the ways in which researchers understand themselves to be situated within elaborate webs of social relations or networks. For example, stroke researcher Philip Gorelick, in a paper entitled ‘Establishing a Community Network for Recruitment of African Americans into a Clinical Trial’ (Gorelick et al., 1996), diagrammatically located his study in social space in relation to a host of other institutions, including churches and community groups, a community volunteer corps, and parent–teacher associations (PTAs), as well as the NIH and the National Stroke Association. When interviewed, Gorelick was explicit about the sort of activity he understood himself to be engaged in: ‘I tell people that this is a study about sociology. And most biomedical scientists don’t understand what I am talking about. But this whole process is sociological.’26 As practical sociologists, clinical researchers like Gorelick not only see themselves as enmeshed within networks, but also appreciate...
that they must venture out into unfamiliar social worlds, and that doing so requires novel methods. For example, Linda Larkey and coauthors (2002) have described their reliance on ‘embajadoras’ (ambassadors), the Latinas who, once enrolled in the Arizona site of the WHI, were specially trained and sent out to recruit fellow Latinas. (In these investigators’ randomized study, embajadoras proved to be more successful at recruitment than either a matched group of ‘untrained Hispanic women’ or ‘untrained Anglo controls’.)

Other recruitmentology studies – very much of the ‘hard’, quantitative variety – adopt the economists’ language of cost–benefit analysis. Such studies have compared the costs of different recruitment strategies to what they term the ‘yield’ (the ratio of enrolled participants to the total who had to be screened in order to find them). In one such study, linked to a diabetes prevention trial that quite successfully recruited a sample of more than 3800 participants of whom almost one-half were people of color, investigators found clear differences in how specific minority groups first learned about the trial. The African Americans in the study were much more likely than the white participants to have found out about it through direct mail, while community screening events provided the key recruitment route for the American Indians (DPP Research Group, 2002: 166–67; see also King et al., 1994; Cabral et al., 2003). To be sure, a reader of these various studies of participant ‘yield’ might wonder just how generalizable any of the findings might be – across groups, from one geographic area to another, between prevention trials and treatment trials, between early studies of safety and later studies of efficacy, and so on. What does come across, however, is the concerted effort not only to quantify the analysis of recruitment techniques but also to emphasize the economies of recruitment. 27

Despite their differences, these various types of recruitmentology reflect an overlapping set of presumptions about the kind of sociocultural object that is under investigation. Economic, psychological, anthropological, and sociological ways of knowing the ‘other’ are increasingly seen as pivotal for the conduct of clinical research in biomedicine: diverse epistemologies of the social are being yoked to the study of biological disease processes and pharmaceutical treatments through the new emphasis on recruitmentology. The result is a growing tendency to conceive of the target of recruiting as not (or not only) the individual human subject but the social subgroup to which that subject belongs. 28 Indeed, in some cases this shift to the collective has been formalized. Researchers studying Native Americans, for example, may be required to obtain not only consent from individual research subjects, but also permission from an IRB representing the tribe – a sort of collective consent. 29 Yet the conceptualization of the group is complex and, in some ways, internally contradictory.

On one hand, as these developments suggest, the group is imagined as a social actor, complete with interests, chosen representatives, and its own collective memory – an agent that must be engaged with and taken seriously. On the other hand, the imperatives of the inclusion-and-difference
paradigm promote a conception of the racial or ethnic group as, in essence, a census category on a form. When tabulating recruitment for the NIH or the FDA, clinical researchers and pharmaceutical companies in the US are obliged to report numbers of participants using these formal racial identifiers (American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White) and ethnic identifiers (Hispanic or Latino, and Not Hispanic or Latino) (National Institutes of Health, 2000; Food and Drug Administration, 2005; Epstein, 2007: ch. 7). The reductionism inherent in this way of conceiving of group identity is then compounded by the search for differences that is promoted by the inclusion-and-difference paradigm: researchers are enjoined to conduct subgroup comparisons by race to test whether treatments have different effects in different groups. The more such subgroup comparisons are conducted, the more apparent differences are uncovered; and while such differences typically are mean differences with substantial overlap between racial groups, they tend to be reported and treated as categorical differences between races. These categorical differences are then usually taken to reflect the underlying biology of race (Duster, 2003; Epstein, 2007: ch. 10). Thus, while the practical work of recruiting promotes a conception of the group as a social actor that can be engaged with as an interlocutor, the biopolitical framework within which that recruiting is embedded encourages a narrow conception of the group as a reified, more-or-less biological, category.

Engaging an Interlocutor: The Politics of Trust and Mistrust

This tension between two ways of conceiving of the group has its corollary in the tension between two ways of imagining the ‘translation’ (Callon, 1986) of the interests of racial and ethnic minority communities. At times, recruitmentologists understand themselves to be interpellating a social actor whose interests must be appealed to in a substantive way if recruitment is to be successful. For example, researchers may invoke collective beliefs held by ‘the African American community’ and may argue that ‘for increased participation in research studies to occur, community members must be a part of the process from the very beginning’ (Green et al., 2000: 83, 85). At other times, recruitment is conceived of in formal and technical terms as a matter of finding the right approaches and inducements to ensure compliance with the pre-given interests of the researchers. For example, researchers may interpret their ‘yield data’ to suggest that ‘materials designed for mass mailing can also carry endorsements to improve the response from members of a particular demographic group’ (Lewis et al., 1998: 474). While the contrast between the two approaches may sometimes blur in practice, at least in principle they suggest different intellectual and political frameworks: In the first case, recruitmentologists imagine themselves to be solving a problem in social relations; in the second, the project is one of social engineering.
The increasing formalization of recruitmentology may well incline researchers toward the latter – toward a view of the problem as fundamentally a technical one, to be solved through ingenuity and the appropriate mix of tactics. Yet it is unclear whether a purely formalistic and instrumentalist recruitmentology can succeed, if it forestalls attention to the profound and sometimes intractable issues that affect research with communities of color – issues that include trust, citizenship, collective memory, and the power relations between researchers and their research participants. The point is that the history of abuses of patients by researchers is well preserved in the collective memories of many social groups. For example, because of the notoriety of the ‘Study of Untreated Syphilis in the Negro Male’ (more commonly known as the Tuskegee Syphilis Study; Reverby, 2000) the question of trust in biomedical research is interwoven in complicated ways with the politics of racial justice in the US. Investigators conducting research with African Americans routinely report confronting suspicions of being used as ‘guinea pigs’ like in the Tuskegee study (Thomas & Quinn, 1991).

Indeed, a whole branch of recruitmentological scholarship has examined the social–psychological impact of Tuskegee (Corbie-Smith, 1999; Shavers et al., 2000, 2002; Corbie-Smith et al., 2002). In one survey mailed to residents of Detroit, about one-half of the African-American respondents reported that they had less trust in medical researchers as a result of Tuskegee compared with only 17% of the white respondents (Shavers et al., 2002: 252). Another study, a national telephone survey conducted by Giselle Corbie-Smith and coauthors, compared 500 African-American respondents with 500 respondents from the overall US population (including African Americans). The differences in responses were striking. Nearly 42% of the African Americans, but only 23% of the sample of the overall population, disagreed with the statement: ‘If your physician wanted you to participate in research, you trust that he or she would fully explain it to you.’ And while only 8% of the respondents from the overall population thought that a physician had ever given them a treatment as part of an experiment without their permission, fully one-quarter of African-American respondents believed that was so. Even after adjusting the data to take into account social class differences, the authors found that African Americans were significantly more suspicious of medical research (Corbie-Smith et al., 2002: 2460).

At the same time, experts on African-American health issues have consistently emphasized that mistrust of medical research long predated Tuskegee – as much as that study has come to epitomize such attitudes. According to the historian Vanessa Gamble (1997: 1773; see also Brandon et al., 2005), it is a mistake to place ‘emphasis on a single historical event to explain deeply entrenched and complex attitudes within the Black community’. As Corbie-Smith and coauthors noted, mistrust among African Americans ‘may be rooted in experiences extending back to slavery and continuing to the present day’ (Corbie-Smith et al., 2002: 2458). At a community forum, researcher Eliseo Pérez-Stable cited examples from the
historical record that are commonly invoked, including the use of slaves for medical experimentation in the antebellum South; the use of black cadavers for dissection purposes in the 19th century; legends about ‘night doctors’ in the post-bellum period, who were hired to kidnap blacks in the South for medical experiments; and more recent concerns about genocide that link Tuskegee together with forced sterilization, the HIV/AIDS epidemic, and drugs in black neighborhoods.\(^{31}\) Corbie-Smith recalled that issues as diverse as the use of Agent Orange in Vietnam and the claim that the CIA had deliberately promoted the sale of crack cocaine in black neighborhoods surfaced in discussions with African-American groups about their attitudes toward biomedicine.\(^{32}\) According to Julia Scott, the director of the National Black Women’s Health Project,

\[\text{it’s not just history. And people try to say, ‘well that was done, that was over, that wasn’t me’. But there are current medical, everyday medical and scientific practices that reinforce [that] we still are seen as guinea pigs ... that people will take a risk with ....} \(^{33}\]

It is also important to observe that African Americans are not the only group to confront medical researchers with profound mistrust. As Gina Moreno-John and coauthors (2004: 98S; see also Lex & Norris, 1994) have noted, for a number of racial and ethnic minority groups in the US, mistrust of research ‘is rooted in a general mistrust of mainstream society’, while the possibility of exploitative or unethical treatment remains a serious one. According to the authors:

\[\text{Unfortunately, detrimental research outcomes continue to occur. For example, in Los Angeles in 1989, African American and Latino infants received the experimental Edmonston–Zagreb vaccine from the Centers for Disease Control and Prevention to study whether it could prevent measles in infants. Their parents were not informed that it was not licensed in the United States and had potentially lethal effects .... Recently, members of one Native tribe were ostracized after their reservation was identified in a study on syphilis, and another received adverse credit ratings by lenders after they were identified in a study on alcoholism .... The confidentiality of these participants was violated despite requests by tribal leaders that researchers not identify the tribes .... Ethnic minorities have participated in studies where researchers did not obtain informed consent, changed the protocol without consulting participants, withheld information, or did not follow-up as planned, resulting in a lack of trust .... (Moreno-John et al., 2004: 101S)}\]

Thus while ‘Tuskegee’ often functions as a placeholder in discussions of resistance to participation in clinical research on the part of communities of color, the problem of mistrust cannot really be addressed without consideration of a much broader set of historical and political issues affecting a range of racial and minority groups in the US.

An important dimension of the problem of overcoming such distrust concerns attitudes toward research among primary-care physicians serving racial and ethnic minority communities. As Mary-Rose Mueller (2004) has
described more generally, practicing physicians very often function as crucial mediators between patients and clinical researchers, passing on information about ongoing trials and influencing the decisions of patients about whether to enroll. On the one hand, a patient may be willing to place greater trust in a personal physician than in some unknown researcher; on the other, physicians may be particularly inclined to refer patients to trials when they know and trust the investigators conducting them. Thus trust is critical at both linkage points in the chain connecting patients to researchers via the intermediary of physicians. The apparatus of the randomized clinical trial might properly be seen as a ‘technology of trust’ (to borrow a phrase of Nelly Oudshoorn’s [2003: 225–41]); and adequate trust relationships may be a central component of its proper functioning.34 To acknowledge this point is to understand why many recruitmentologists seek to go beyond the formal analysis of ‘yields’ and motivations to imagine the construction of new models of trust relationships.

**Power and Community**

An important subset of recruitmentological work has proposed that deficits of trust need to be met with sincere and concerted trust-building measures. At the most basic level, these include working through community gatekeepers, such as clergy and politicians, and employing bilingual or multilingual staff when working with linguistically diverse communities. Some also recommend what might be called ‘identity matching’ (that is, making sure that at least the front-line employees for the study, if not the principal investigators, are members of the group being studied), though, in fact, recruitmentology studies do not always confirm the efficacy of this practice (Cotton et al., 1993: 1327; Thompson et al., 1996: 864; Stark et al., 2002: 34). For research in African-American communities, the NIH also has touted the virtues of alliances between researchers in universities with predominantly white faculties and those situated in historically black institutions.35 Clinical researchers also have been advised to think more about the duration of their commitment: Do researchers disappear after the trial is over – what Victoria Cargill, a panelist at a conference on recruitment, characterized as ‘drive-by research’?36 Or do they make a concerted effort to bring the lessons and benefits of the research back to the community?

On one hand, there can be little doubt that the perceived need to promote trust as an avenue to recruitment of subjects has sometimes given rise to cynical half-measures. One young physician recounted a story about being invited to be a co-investigator on a study, only to conclude eventually that what the senior investigator really sought was a ‘black face’ to display at community forums for purposes of reassuring potential participants.37 Another troubling anecdote was related at a conference by Aníbal Sosa of the Latino Health Institute in Boston: when a researcher sought his help in recruiting Latinos for a study, Sosa asked him, ‘What’s the study about? What’s the study design?’ According to Sosa, the researcher replied, ‘I don’t have time to get into all that. I just need your help arranging a meeting with
your people.’ To which Sosa replied: ‘Well I need to know a bit more, before I put you in touch with “my people”’.

On the other hand, much of the literature on trust-building explicitly challenges such approaches by connecting the issue of trust directly to that of transforming the power imbalance between the researcher and the community under study. One extended discussion of the implementation of trust-building measures, by Gina Moreno-John and coauthors, is based on the work of three of the Resource Centers for Minority Aging Research funded by the NIH (one at the University of North Carolina, one at the University of Colorado Health Sciences Center, and one at the University of California, San Francisco). The authors described strategies such as collaborating closely with community leaders, including members of community-based organizations on advisory boards, providing technical assistance in grant-writing and event planning to those community-based organizations, attending community events, and maintaining contact with communities after research ends (Moreno-John et al., 2004: 104S). Perhaps most significantly, the authors advocated a ‘participatory approach to research’ involving ‘a reciprocal relationship, with a mutually beneficial exchange of expertise and resources’ (Moreno-John et al., 2004: 114S, 117S).

Along these lines, other recruitmentologists have called for the adoption of ‘participatory action research’, a model of scholarly investigation that seeks to abolish the power imbalance between experts and laypeople by promoting ‘community ownership’ of research, based on community-driven determinations of research priorities (Dancy et al., 2004; see also Corbie-Smith et al., 2004). The NIH also has expressed interest in ‘community-based participatory research’ (sufficiently institutionalized to merit an abbreviation, ‘CBPR’), which they define as ‘scientific inquiry conducted in communities and in partnership with researchers’; the agency has issued funding calls for such research in both 2004 and 2007. Participatory styles of research presume a certain amount of deference to the authority of community leaders. As Ilena Norton and Spero Manson have described in the case of work with American Indians, this may mean a willingness on the part of investigators to accept suggestions with regard to ‘study questions, implementation, presentation of the results, and publications’. And the authors warn: ‘Investigators who object to the review of results by nonscholars are unlikely to be allowed by tribal governments to undertake their research’ (Norton & Manson, 1996: 858).

Exhortations of the virtues of community participation at times simply beg the crucial definitional questions: What constitutes a community? Who gets called upon to serve as a community’s representative? Will participatory research necessarily result in an equalizing of power between researchers and the communities they study (Dickert & Sugarman, 2005; Reardon, 2005)? At times, the rubric of participatory research may simply offer investigators another tactic to get the ‘bodies’ that they seek for the research they already have determined to conduct. However, various reports suggest the potential benefits of participatory approaches for successful recruitment and retention. For example, at a conference on...
recruitment, Barbara Howard described a study on the genetics of coronary disease in Alaskan Natives being conducted in 15 remote Alaskan villages – places with ‘no street signs’. To recruit the 1200 participants, researchers sought the ‘continuous input’ of community members, including consultation with tribal leaders, involvement of community recruiters, and the presence of American Indian physicians as investigators and on the steering committee. Moreover, research conducted in a participatory vein may be well positioned to benefit from what Barbara Dancy and coauthors have called ‘stakeholders’ expertise’ – local knowledge about the ways of the community that outside researchers would be unlikely to possess. Dancy and coauthors provided a telling example that is relevant to the challenges of recruitment:

During our recruitment efforts, the community advisory board has helped us to become increasingly aware of territorial issues. For example, in some low-income communities, unspoken, yet clear demarcations within the community delineate gang turf. This demarcation can be a street; on one side of the street is one gang, and on the opposite side of the street is the opposing gang. Recruiting potential research participants to attend research activities that are located in an opposing gang’s territory would reflect the researcher’s insensitivity to the rules of the community. The likelihood of the recruitment efforts being successful would be nil. (Dancy et al., 2004: 237)

Recruiting Gone Global

As this paper has suggested, scholarship in the ‘recruitmentology’ vein ranges from the most technical considerations of strategy and tactics to the most overtly political analyses of power and inequality in a historical context. I have shown how at least some versions of recruitmentology propose to interpelate racial and ethnic minority communities as collective actors rather than treat them instrumentally as objects to be aligned; and I have related this debate to the tension between two ways of ‘knowing race’ – as a sociocultural phenomenon and as a biological and administrative category. Yet what is the likelihood that human subjects will be granted the kinds of participatory status that the more ‘political’ kinds of recruitmentology propose? Here it becomes crucial to note that nearly all such writing makes an assumption that is increasingly less likely to hold true – that the participants to be recruited by US-based researchers or pharmaceutical companies are themselves located within the territorial borders of the US.

From 1987, the FDA has allowed pharmaceutical companies to file applications for drug approvals based solely on data obtained abroad, and the percentage of patients being studied in foreign countries has climbed rapidly since then (Goodman et al., 2003: 13). An FDA study of the approval of ‘new molecular entities’ between 1995 and 1999 found that ‘up to 35 per cent’ of the trials included foreign sites, translating into about 1140 foreign clinical trials per year (Food and Drug Administration, 2004: 32471). Contract research organizations (CROs, the private consulting
companies that are among those to which drug companies increasingly out-source their recruitment) are especially inclined to move their operations offshore. In addition, many university-based researchers with federal funding from the NIH, such as academics involved in tests of AIDS vaccines and therapies, are conducting research in foreign settings, often in collaboration with local investigators.43

It should be clear that the foreign locales in question here are not usually places such as England, Germany, or France. They are countries such as India, Uganda, Thailand, China, and Indonesia – places where the costs of conducting research are much reduced, and where patients have the experimental virtue of being ‘pharmacologically naive’ (that is, lacking previous exposure to treatment). As Adriana Petryna (2006: 37) has described, “‘Treatment saturation’ is making Americans increasingly unusable from a drug-testing standpoint, as our pharmaceuticalized bodies produce too many drug-drug interactions providing less and less capacity to show drug effectiveness and making test results less statistically valid.’ Less wealthy countries not only provide unexposed bodies; in addition, as David Rothman has pointed out, they offer the ‘advantage’ of a comparative absence of ‘effective review boards, or, for that matter, highly inquisitive and demanding patients’ (Rothman, 2000: 63; see also Nundy & Gulhati, 2005: 1634). Websites for CROs advertise their specialized capacities to deliver research subjects in particular regions of the world; for example, a company called LatinTrials, featuring research in Mexico, Argentina, Brazil, Uruguay, and Chile, asks ‘Why Latin America?’, and provides a range of attractive answers: ‘strong enrollment rates’; ‘good patient compliance and retention’; ‘availability of treatment-naive patients’.44

Recently, much attention has focused on India – described by the Financial Times in 2003 as ‘A Test-bed for Western Drug Companies’ – where the world’s largest CRO, the US-based company Quintiles, began operation in 1997, and where as many as a dozen such companies were operating by 2003. Along with offering ‘an enormous pool’ of treatment-naive patients, India can provide well-trained, English-speaking researchers, nurses, and staff ‘at less than a third of Western wages’. According to the Financial Times, ‘some executives believe India could become as prominent in pharmaceuticals as it is in information technology’ (Marcelo, 2003: 24). However, as an editorial in the New England Journal of Medicine observed (under the title ‘A New Colonialism?’), the scramble to take advantage of the growing financial opportunities in India has led to a range of ‘ethically dubious’ practices:

[Sponsors of trials] have been known to offer financial inducements to participants – such as paying illiterate blue-collar workers more per month to participate in a trial than they earn at their jobs and enticing subjects by providing medication that is worth more than their annual salary. Widespread illiteracy makes it particularly easy to sidestep the standard methods of obtaining informed consent. Investigators frequently enroll patients in trials as if their participation were a necessary next step in their care. And no protocol we have ever seen has promised to continue to
India is a country with extraordinary health needs, where millions die of parasites and tropical diseases. But only a tiny fraction of the drugs tested there are intended to treat such conditions; and, in any case, ‘the sponsors do not guarantee that new drugs tested in India will be made available there at affordable prices’ (Nundy & Gulhati, 2005: 1635). Certainly some transnational medical research, for example on the efficacy of AIDS vaccines, may someday directly benefit the countries in which the research is being conducted. For the most part, however, the better-off inhabitants of rich Western countries will be reaping the benefits of the substantial and growing corpus of research now being conducted on the bodies of the global poor.

Clearly, the globalization of clinical research has significant implications for the story told here. As I have indicated, a subset of recruitmentological work has emphasized the importance of trust and respect toward, and a genuinely participatory role for, the people and communities under study, as a prerequisite of successful recruitment as well as ethical treatment. Even in the US, the risk is that such intentions may remain lofty rhetoric. But the outsourcing of research seems potentially to displace these goals altogether. Will the primary solution to the dilemmas of recruitment and retention prove to be simple exploitation of vulnerability on a global level – and the neocolonialist extraction of ‘biovalue’ from a racialized underclass? If so, then all of the programmatic statements and recruitmentological research supporting such worthy aims as trust enhancement, community empowerment, and participatory research will simply be for naught.

However, the globalization of research has also, at moments, prompted close attention to ethical and political questions as well as vigorous public discussion. Indeed, the implications of global inequality for medical research ignited a fiery controversy in 1997 that proved to be one of the most divisive bioethical debates in recent years. The focus was on NIH-funded studies, conducted in several African countries, of the use of antiviral drugs to interrupt vertical transmission of HIV (that is, transmission from mother to fetus or newborn). In the US, the drug azidothymidine (AZT) had already been shown to be quite effective in stopping transmission as much as three-quarters of the time, but the course of treatment was too expensive for most African countries to afford. Therefore, researchers sought to test cheaper alternatives, such as reduced doses or courses of administration of various antiviral drugs. The catch was that most of these studies were designed to demonstrate the efficacy of the less expensive therapy via comparison with a control group receiving a placebo. Whistle-blowing critics vehemently insisted that all participants in US-funded clinical trials were entitled to the present-day standard of care, regardless of where the trial took place (Lurie & Wolfe, 1997). Indeed, for Marcia Angell (1997), executive editor of the prestigious New England Journal of Medicine, the withholding of therapy from the control group when known therapies existed suggested that ‘we have not come very far from Tuskegee at all’.
This incendiary analogy was strenuously rejected by the NIH, which funded the research, as well as by the local research collaborators in African nations; and debate about the case and similar studies effectively split the bioethics establishment and led to a formal reconsideration of ethical standards (Stolberg, 1997: A10). Much attention was devoted to this episode by expert and public commentators, and a good deal of ink was spilled in discussing the appropriate response (Annas & Grodin, 1998; Fairchild & Bayer, 1999: 919–21; Levine, 1999; Rothman, 2000). But it remains unclear whether such cases will prompt a more extensive consideration of the human and social costs and benefits of the new global production of biomedical knowledge and commodities.

More generally, conflict surrounding the globalization of research points to the boundaries of my analysis, which has emphasized how a biopolitical framework that is somewhat particular to the US and is policed by its federal agencies has sparked new ways of ‘knowing race’. Within the bounds of that framework, the theory and practice of recruitmentology have promoted novel fusions of biological and cultural knowledge about the medically ‘other’; and policies mandating their inclusion and the measurement of cross-group differences have inclined many researchers to think anew about the characteristics of medically disadvantaged groups. This epistemic work is closely intertwined with a series of concurrent debates – about the new genetics, about health disparities, about racial profiling in medicine, and so on – though, again, in ways that often reflect the particularities of the US. How these developments will articulate with transnational research practices, or with the global politics of health inequality, is much more difficult to discern.

**Conclusion**

A growing and interdisciplinary body of scholarly work has brought critical scrutiny to the uses of racial categories in the biosciences (particularly in the domain of genetics) as well as the dangers of ‘racial profiling’ in the clinic. My emphasis here on the theory and practice of recruitment into clinical trials – and the emergence of an auxiliary science of recruitmentology – calls attention to a related domain of ordinary biomedical work within which notions of racial (and other forms of) identities and differences are being reworked. Moreover, by viewing these new recruitment imperatives in the US as the downstream consequences of policies mandating the inclusion of racial and ethnic minorities (among others) as subjects in clinical trials, I emphasize the web of connections linking the everyday work of clinical research to the broad-scale formulation of a biopolitical framework for administering bodies and populations (Epstein, 2007). The developments that I describe intersect with many other present-day instances of the bioscientific rethinking of race – yet, clearly, there is no ‘master plan’ guiding the articulation of a ‘new science of race’. Rather, as Michael Omi and Howard Winant (1986: 68) have emphasized, processes of racial
formation are a hodgepodge – ‘an unstable and “decentered” complex of social meanings constantly being transformed by political struggle’.

As an emergent auxiliary science, recruitmentology lacks the institutional structure of a true scientific specialty area. The knowledge base is also relatively underdeveloped: there is, as yet, relatively little clarity about the reliability of recruitmentological findings or their generalizability across kinds of clinical research (in prevention versus treatment trials, with different phases of clinical trials, with different diseases or health issues, or with different social groups as subjects). What is perhaps most evident about recruitmentology at this stage is its hybrid formation via the importation of social-scientific frameworks for understanding social subgroups or communities. While this infusion from the social sciences has encouraged a focus on race with reference to the sociocultural and sociohistorical properties of organized communities, other aspects of the inclusion-and-difference paradigm promote more conventional notions of race as discrete biological subgroups of a population that can be demarcated using formal administrative categories of the state. I have suggested that this uneasy duality in the approach to race also maps onto a tension in the approach to recruitment – between addressing an interlocutor whose trust must be gained, whose history and culture must be understood, and who must become a genuine participant in research; and engineering the cooperation of research subjects through the scientific prediction of tactics most likely to succeed with them. Finally, I have suggested that the increasing tendency to find research subjects in the global South – and hence the increased inequality in power between researcher and research subject – makes it less likely that the former approach will become dominant.

What are the broader implications of recruitmentology for racial and ethnic minority communities in the US? Who benefits from recruitmentology? In the larger project of which this paper is part, I develop a partial critique of the new policies mandating the inclusion of diverse groups in medical research and the measurement of differences across groups. For example, I argue that by suggesting that there are clear biological differences between social groups, the inclusion-and-difference paradigm reinforces the tendency to overemphasize biology when thinking about race and gender. This in turn has the consequence of detracting attention from the crucial goal of eliminating health disparities, most of which have sociopolitical causes (Epstein, 2007). In light of these concerns, one conceivably might question the virtues of perfecting recruitment techniques for racial and ethnic minorities.

But a cynical dismissal of recruitmentology would miss the point: one need not accept the ongoing reification of race in medicine and genetics in order to recognize the crucial need for clinical research that focuses properly on the health concerns of racial and ethnic minority communities while also protecting research participants from undue risk. Indeed, any critical or revisionist research program to redress health disparities that challenges the orthodox representation of race likewise confronts the recruitment imperative. Therefore, my goal here has not been to ‘deconstruct’ recruitmentology.
but rather to do two things: first, to consider the complex interplay between alternative ways of thinking about race within recruitmentology; and second, to examine how at least some recruitmentologists have come to focus attention on issues of trust, collective memory, and the power relations that structure clinical research. It would be too simple to suggest that any single ‘right way’ to perform clinical trials with racial and ethnic groups emerges out of the recruitmentological literature. But the debates occurring within it point to some of the dilemmas that will have to be addressed, if the goal of eliminating health disparities by race is to have a chance of success.

Notes
I am grateful to Joan Fujimura and Troy Duster for organizing this special issue. I also want to thank: Joan Fujimura, Jill Fisher, Martha Poon, and participants at a workshop on the social sciences organized by the UCSD Science Studies Program for important comments on earlier drafts; Stefan Timmermans for valuable feedback on related material; and Michael Lynch and four anonymous reviewers for critical comments and helpful suggestions.

1. There is nothing new about the fateful conjuncture of scientific investigation and racial meanings: as Troy Duster (2003: 258) has observed, ‘for more than two centuries, the intermingling of scientific and commonsense thinking about race has produced remarkable exchanges between scientists and laity about the salience of race as a stratifying practice ... and as a socially decontextualized, biologically accurate, and meaningful taxonomy’. But while the scientific (re)making of race has a long history, recent advances in genetics have reinvigorated debates once thought to have been settled definitively about the biological significance of racial categories. Much disagreement has been voiced recently, by scientists, clinicians, scholars, and politicians, about the implications of a scientific understanding of race for the everyday practice of medicine – for example, about the legitimacy and utility of so-called ‘racial profiling’ in the design of medical treatment (Schwartz, 2001; Root, 2003; Bloche, 2004; Kahn, 2004; Hacking, 2005; Epstein, 2007: ch. 10).

2. The categorical terms used in this paper are meant to represent the terms employed by the actors I studied, in all the ambiguity of everyday usage. On the history of the biomedical reliance on age, sex, and race categories, see also Hanson, 1997.

3. Political pressure leading to these changes reflected simultaneous concerns with social equity and with scientific generalizability: on one hand, advocates demanded that biomedical research institutions serve the entire population, particularly including those who they claimed had been under-studied; on the other hand, advocates insisted on the reality of group-specific medical differences (often understood to be rooted in the biology of research subjects) and warned against the presumption that findings derived from the study of any one sort of person (such as middle-aged white men) might automatically be extrapolated to other sorts of people (such as women, racial and ethnic minorities, children, and the elderly). Concretely, the inclusion-and-difference paradigm is manifested in a series of laws, policies, and guidelines adopted from the 1980s onward that encourage or require inclusionary research practices and/or the measurement of subgroups differences on the part of investigators funded by the NIH as well as pharmaceutical companies submitting applications for approval of their products to the FDA; in the creation of bureaucratic offices promoting and monitoring such approaches within those agencies and elsewhere within their parent agency, the US Department of Health and Human Services; and in consequent changes in the everyday work practices of people who conduct medical experiments on human subjects. I argue that the consolidation of the inclusion-and-difference paradigm holds a range of implications for practices of standardization and
classification in science and governance; the evolution of new modes of biopolitical citizenship; and the intersections between identity politics and processes of racial and gender formation (Epstein, 2003a,b, 2004, 2006, 2007, 2008).

4. Data for the larger project of which this paper is a part were obtained in accordance with a strategy to juxtapose perceptions and trace actions across multiple ‘social worlds’ (Clarke, 1990), including those of clinical researchers concerned with recruiting ‘underrepresented groups’, pharmaceutical companies, federal health officials promoting the health of ‘special populations’, politicians, and health advocacy organizations. Data have been obtained from 72 semi-structured, in-person interviews in and around Boston, New Haven, New York, Baltimore, Washington, Atlanta, Ann Arbor, Chicago, Denver, Boulder, San Francisco, Los Angeles, and San Diego. Those interviewed included: past and present NIH, FDA, and DHHS officials; clinical researchers; pharmacology researchers; biostatisticians; medical journal editors; drug company scientists; women’s health advocates and activists; bioethicists; members of Congress; Congressional aides; lawyers; representatives of pharmaceutical company trade associations; experts in public health; and social scientists. Additional primary data sources include documents and reports from the NIH, the FDA, the CDC, the DHHS, and the US Congress; archival materials from health advocacy organizations; materials from pharmaceutical companies and their trade organizations; papers, letters, editorials, and news reports published in medical, scientific, and public health journals; and articles, editorials, letters, and reports appearing in the mass media.

5. This emphasis on understanding the culture and community of research populations has its analogues elsewhere in modern medicine – for example, in the growing emphasis on the delivery of ‘culturally competent’ care. See, for example, the June 2003 special issue of *Academic Medicine*, which is devoted to the theme of cultural competence with particular attention to medical education.

6. In carrying out this analysis, my emphasis does not fall on the category of race exclusively – I think for good reason. The new policies and procedures of the inclusion-and-difference paradigm recognize several forms of identity and difference, principally including sex or gender, race and ethnicity, and age categories. In the operation of the paradigm, differences among forms of difference certainly matter – for example, the enforcement of racial and ethnic inclusion by federal health agencies depends crucially on the past history, within the government, of deploying an authorized set of official categories of racial and ethnic membership, borrowed from the US census (Epstein, 2006, 2007). But despite the variation in the ways that categorical identities are handled by federal agencies and by researchers, the simple fact that the same policies simultaneously encompass multiple forms of social difference and stratification justifies an analysis that likewise is appreciative of this diversity. Therefore my focus here will be on race-based research – but in relation to other dimensions of difference and inequality.

7. The NIH aggregates these numbers in a database and presents annual reports to Congress. The FDA also has been in the process of developing such a database (Epstein, 2007: ch. 8).


9. Interview with Wendy Baldwin, PhD, Deputy Director for Extramural Research, NIH (Bethesda, MD, 23 March 1998); interview with Vivian Pinn, MD, Director, Office of Research on Women’s Health, NIH (Bethesda, MD, 14 April 1999).

10. In its current form, this database can be found at <www.clinicaltrials.gov/>.

11. The ‘body hunt’ may also be especially difficult for prevention trials in comparison with treatment trials (see Rimer et al., 1996 as well as the comments by Otis Brawley in ‘Deadly Diseases and People of Color: Are Clinical Trials an Option?’ [1996], Food and Drug Administration, <www.fda.gov/oashi/patrep/howard.html>), or, more generally, when those to be recruited are healthy volunteers rather than ill patients in search of cures. However, as Jill Fisher (2005) has documented, when the financial...
incentives offered for enrollment are sufficient, some members of the healthy poor may prove more than willing to serve as ‘serial participants’ in Phase I trials, signing up for one such trial after another.


13. In the US the clock begins ticking on the 20-year duration of a patent for a pharmaceutical product with the initial filing with the FDA, well before drug approval.

14. Recruiting may be outsourced either to ‘contract research organizations’ (CROs) that perform many tasks related to the conduct of clinical trials, or to more specialized ‘central patient recruitment companies’ that focus on recruitment and retention. All this is just part of what Fisher (2005) describes as the general increasing tendency toward outsourcing in private-sector clinical research.

15. I am grateful to Jill Fisher for forwarding me this information.


17. Interview with Otis W. Brawley, MD, Director, Office of Special Populations Research, National Cancer Institute, NIH (Rockville, MD, 18 March 1998).

18. As Jill Fisher (2005) has observed, the increasingly pervasive public advertising for clinical trial participants mirrors the direct-to-consumer advertising of pharmaceutical products that is now ubiquitous in the US.

19. See, for example, the Spring 2000 issue of the Journal of Mental Health and Aging, which was devoted to ‘recruitment and retention in minority populations’. The journal Controlled Clinical Trials, which focuses on the methodology of clinical research, also has featured many recruitmentological contributions.

20. Of course, like all cost–benefit analyses, these ones potentially bracket potential ‘costs’ as well as ‘benefits’ that simply don’t lend themselves to expression in quantitative terms. See Porter (1995) and Espeland & Stevens (1998).

21. Interview with Spero Manson, MD, Department of Psychiatry, University of Colorado Health Sciences Center, Denver, CO, 29 June 1999. On such mechanisms of group consent and their complexities in another domain of research in the biosciences, see the important discussion in Reardon (2005: ch. 5). On the distinction in medical research between risks to the individual and collective risks to the group, see also Foster & Sharp (2000: 93–95).

22. Reporting is supposed to represent research subjects’ own self-classifications according to these categories. Beginning in 2000, in response to a growing emphasis on
‘multiracialism’ in US society and a corresponding change in census practices, participants may be counted as belonging to more than one racial category (National Institutes of Health, 2000).

31. Author’s field notes, ‘Health Research in Communities of Color’.
32. Interview with Giselle Corbie-Smith, MD, Emory University (Atlanta, GA, 29 March 1998).
33. Interview with Julia R. Scott, RN, President, National Black Women’s Health Project (Washington, DC, 19 March 1998).
34. On the centrality of trust relationships to the maintenance of moral order in modern science, see Shapin (1994).
35. Interview with John Kusek, MD, National Institute of Diabetes and Digestive and Kidney Diseases, NIH (Bethesda, MD, 23 March 1998); interview with Claude Lenfant, MD, Director of the National Heart, Lung, and Blood Institute, NIH (Bethesda, MD, 14 April 1999).
36. Author’s field notes, ‘Science Meets Reality’ workshop.
37. Personal communication, 1999.
39. More generally, on the use of participatory action research in the domain of health, see Khanlou & Peter (2005).
41. Author’s field notes, ‘Science Meets Reality’ workshop.
42. Many such discussions of the potential virtues of stakeholder expertise in clinical research are directly or indirectly indebted to the role played by AIDS treatment activists beginning in the late 1980s (Epstein, 1996).
43. The recruitment of participants from outside the US for NIH-funded studies raises fascinating questions about how racial and ethnic identities are reported by investigators on NIH forms, given the NIH’s reliance on US census categories. I discuss these issues in Epstein (2007: ch. 7).
45. Of course, neither does the presence of clinical research in wealthy countries such as the US guarantee that products, once marketed, will be available to former participants in trials.
46. Such opportunism harks back to past moments in the history of medical research when humans typically became research subjects as a consequence of highly unequal power relations. I review this history in Epstein (2007: ch. 2); see also Schiebinger (2004).
47. Aspects of the regulatory framework of the inclusion-and-difference paradigm are present in other countries, especially including Canada but also some European countries, and to some degree the paradigm may gradually be diffusing transnationally. However, the resistance to official categorization by race in some countries makes it unlikely that this approach to research will become dominant everywhere. I discuss these issues in Epstein, 2007: ch. 12.

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