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Consenting to Heteronormativity: Sexual Assumptions in Biomedical Research

Marci D. Cottingham

University of Amsterdam
University of North Carolina at Chapel Hill

Jill A. Fisher

University of North Carolina at Chapel Hill

Abstract

The process of informed consent is fundamental to basic scientific research with human subjects. As one aspect of the scientific enterprise, clinical drug trials rely on informed consent documents to safeguard the ethical treatment of trial participants. This paper explores the role of heteronormative assumptions within this process, postulating the ways in which the biomedical texts that make up the informed consent process may render gay, lesbian, and non-binary gender-identifying participants discursively invisible. We argue that trial criteria and informed consent practices may reproduce a binary sex and gender

system in which ‘male’ and ‘female’ subjects are presumed to identify as heterosexual and engage in procreative sex. This binary is not one of equivalence as female subjects who are able to have children may be wholly excluded or excessively controlled in studies while male subjects are merely admonished to use medically sanctioned birth control methods. Furthermore, we claim that the assumption of procreative heterosexual behaviors may pervade the informed consent process and the mundane practices of biomedical research more broadly. Given that these assumptions have important implications for risk and inclusivity in clinical trials, in the last part of this paper we outline directions for future research on the reproduction of heteronormativity in scientific discourse and practice.

Keywords: heteronormativity, biomedical research, clinical trials, gender binary, scientific discourse.

1. Introduction

Human subjects are an integral part of research in the medical and social sciences.[1] In order to safeguard the ethical treatment of research participants, research ethics boards (REBs) require investigators to provide subjects with sufficient information about a study so they might make a knowledgeable decision as to whether or not they will participate. In particular, in clinical drug trials the process of informing participants typically requires an informed consent form, which describes the risks and benefits of participation and also overviews the criteria by which an individual may be included in the study. Moreover, this document serves as a basis for the dialogue between potential participants as study volunteers and clinical research staff. As a critical text to the research enterprise, the discourse within informed consent is a key site for understanding how clinical trials

[1] While it is now more common to use the term ‘participants’ in the social sciences, we use the term ‘human subjects’ interchangeably with ‘participants’ as this remains common terminology used in the biomedical field.

perform an array of social categories and meanings, including the normative assumptions of heterosexual social relations.

Looking specifically at the process of informed consent and the exclusionary criteria used by investigators in clinical trials, this paper details the ways in which heteronormativity — «the view that institutionalized heterosexuality constitutes the standard for legitimate and prescriptive socio-sexual arrangement» (Ingraham 1994, 204) — may frame human subjects as heterosexual beings engaged in procreative sexual practices. As we propose below, this framing may vary depending on one's status as 'male' versus 'female', with implications for the construction and reproduction of heteronormativity and a binary view of sex. Through this framing, women's sexuality appears deviant and GLBT subjects may be *discursively* excluded from clinical trials. Furthermore, non-procreative sexual practices, even those between men and women, may be ignored altogether, increasing potential risks to volunteers across the spectrum of sexual practices and identities. The prototypical human subject appears as hetero-identified, male-bodied, and sexually active despite the many ways in which actual subjects deviate from this norm. While the intersection of science and sexuality has included the empirical study of various sexual practices (Kinsey, Pomeroy, & Martin 1948), controversy surrounding a biological basis of gay and lesbian sexualities (Terry 1999), and the politics of drug development during the AIDS epidemic (Epstein 1996), little research has examined the mundane ways in which assumptions about sexuality are embedded in the scientific endeavor (Spanier & Horowitz 2011; Willey & Giordano 2011).

Addressing this gap, we overview how clinical drug trials are structured and the ways in which heteronormative assumptions may be embedded within this basic aspect of biomedical research. Heteronormativity refers to the «numerous ways in which heterosexual privilege is woven into the fabric of social life, pervasively and insidiously ordering everyday existence» (Jackson 2006, 108). Sexuality is dichotomously reduced to the categories of heterosexual and homosexual, with identities, feelings, and practices associated with the former deemed normative and natural. Operating at multiple levels — including social structure, discourse, and individual behavior — heteronormativity often

unknowingly serves «to distinguish male from female, to define what is sexual, to differentiate the normative from the deviant» (2006, 112). Like other forms of social classification (Bowker & Star 1999), individuals across the sexual hierarchy are constrained by its definitions and logics. Looking at heteronormativity within human subjects research, gay and lesbian participants may be ignored while only certain types of heterosex are legitimized. Gay, lesbian, and even asexual identities as well as non-procreative sexual behaviors are incomprehensible within the informed consent process in clinical trials. Turning our attention to the case of clinical drug trials, we propose a framework for seeing heterosexual assumptions within this basic feature of biomedical research. Before examining these assumptions in depth, we first overview clinical drug trials more generally as a key component of the biomedical establishment.

2. Clinical Drug Trials – Overview

In order for drugs to be approved for use in most industrialized countries, pharmaceutical companies must conduct research on non-human animal and human research subjects to demonstrate that their products are safe and efficacious.[2] Typically, clinical trials – those studies that use human participants – begin after data from non-human animal studies indicate that a product might be a promising treatment for a specific disease and is not likely to be dangerous for human consumption. Clinical trials are divided into four phases. Phase I trials are short-term studies that primarily enroll healthy volunteers designed to provide safety data by testing the tolerability of investigational drugs and provide data on therapeutic doses for subsequent trials. Phase II trials are small-scale studies using affected patients and are designed to collect additional safety information and preliminary efficacy data on investigational drugs. If these initial clinical trials suggest that investigational drugs are promising, pharmaceutical companies then invest in large-scale Phase III trials that compare the new product either to existing marketed drugs or a placebo. With results from all three of these clinical trial phases in hand, pharmaceutical companies can then seek

[2] For a detailed history of the regulation of prescription drugs in the United States, see Donohue (2006).

approval to market their product from the U.S. Food and Drug Administration (FDA) or comparable agencies in other countries. For those drugs that are approved for use, many continue to be tested in Phase IV clinical trials as a form of post-marketing surveillance that can generate additional data on the safety of these drugs as they are more broadly adopted for clinical use.

Biomedicine has a history of using white men as the primary subjects of research, from which results could then be extrapolated to other populations (Epstein 2009; Prescott 2007). At the same time, historical misuses of non-white populations, such as in the Tuskegee Syphilis Study and radiation experiments in the U.S., have drawn attention to the exploitative potential of human subjects research (Moreno 2001; Reverby 2009). As a corrective to these problems in biomedical research, the U.S. NIH Revitalization Act of 1993 mandated the systematic inclusion of women and minorities in all clinical trials sponsored by the National Institutes of Health (Epstein 2007).[3] In the same year, the U.S. FDA lifted a decades-long ban on the inclusion of women in clinical trials while continuing to limit the participation of pregnant women, marking a shift in the federal protection of fetuses from teratogenic effects of investigational drugs (Corrigan 2002; Lyerly, Little, & Faden 2008). At the same time, women continue to be seen as always potentially pregnant, and pharmaceutical companies often limit the inclusion of women to those who are surgically sterile or postmenopausal for their early-phase clinical trials (Fisher & Ronald 2010; Merton 1994). Given the higher rate of serious and life-threatening adverse drug reactions among women (Anderson 2008; Miller 2001), the inclusion of women in drug trials is not simply a political question about representation and access.

As part of the recruitment and enrollment process for clinical trials, research participants must provide their informed consent prior to receiving investigational drugs. Legal requirements for this process were codified in the U.S. in the early 1980s in order to protect human subjects' autonomy by providing prospective participants with adequate information to make informed decisions about their involvement in research (Faden & Beauchamp

[3] Canada has taken a similar regulatory approach to that of the U.S., but other countries like those that are part of the European Union and Japan have not passed any laws mandating the inclusion of women in biomedical research (Epstein 2007).

1986). Not only does this process include information about the risks and benefits of research, but it also tends to include the inclusion-exclusion criteria for the specific clinical trials and instructions on what activities are required or proscribed during participation. The inclusion-exclusion criteria are a critical mechanism by which researchers define who counts as having 'child-bearing potential' in clinical trials. For example, one study might allow the participation of women taking hormonal contraceptives, another might require women to have undergone surgical sterilization,[4] and a third might dictate that women need to be at least one-year postmenopausal. The instructional component of the informed consent document usually includes information about sexual activity. It is typical in drug studies for men to be informed that they are required to use a double-barrier method (for example, condom with spermicide) during the study and for at least 30 days after they receive the last dose of the investigational drug. Thus, the informed consent process is not only about the risks and benefits of consuming investigational drugs; it is also about the risks of sexual activity for study participants.

3. Heteronormativity in Clinical Trials

With this background on clinical trials, we propose a number of ways in which heteronormativity—presumptions about the sexuality and sexual practices of participants—may be perpetuated in the everyday conduct of biomedical research using human subjects. Feminist and poststructuralist theorists have highlighted the important role that biomedical science and, more specifically, biomedical discourse, plays in the creation of disease categories, patient types, and power relations within the medical establishment (Foucault 2003; Haraway 2004; Seear 2014). Extending this critique of biomedical discourse to the area of sexuality, biomedical texts can be seen as part of the «regulatory norms» that work «to materialize sexual difference in the service of the consolidation of the heterosexual

[4] Even the definition of 'sterilization' can differ among clinical trials. For example, some studies might accept women who have had non-surgical Essure whereas other might not even consider tubal ligation to make a woman non-childbearing and require instead hysterectomy for all female participants.

imperative» (Butler 2011, xii). In other words, the texts used within the practice of clinical trials may be a critical site where the gender/sex binary is affirmed and with it, heterosexuality is deemed normative. Following Butler, biomedical texts may perform «textual violence» against «the body's possibilities» (Butler 1990, 172) by naturalizing a gender binary that makes heterosexuality appear inevitable and the female body primarily, and problematically, pregnable.

Informed consent documents situate participants within a clear sex binary of 'female' versus 'male' subjects, as participants must choose one of these classifications as they confront the text. Necessary to their participation in trials, and with it the host of potential financial and therapeutic gains and losses, these texts act as gatekeepers that mold constituents as they pass through what appear as inconsequential bureaucratic hurdles. While the terms 'male' and 'female' subject alone affirm a view of sex as reducible to two, supposedly opposite yet compatible groups, these biomedical texts may also affirm a view of women's and men's sexuality as unquestionably (1) sexually active, (2) heterosexually identified, and (3) realized through sexual practices that lead to conception and reproduction. Even though this appears to be a parallel vision of women and men, there are double standards that structure the implications of a sexualized view of research participants. In this respect, below we detail the range of possible sites of entry for heteronormative assumptions to perpetuate, unacknowledged and unchallenged, within biomedical science. While each may be explored with a range of empirical methodologies, our preliminary propositions can serve as a guide to future work on the role of heteronormativity within clinical drug trials and biomedical research more generally.

3.1 The 'Female Subject' in Clinical Trials

In terms of women participants, assumptions about sexual identity, practices, and reproductive responsibilities frame the inclusion and participation of female trial participants in both subtle and obvious ways. This occurs as women are deemed eligible or ineligible for study participation and through the policing of their bodies upon inclusion. The female subject is constructed paternalistically as one who is always potentially

pregnant unless she is postmenopausal or surgically sterile. In this view, she is always engaged in heterosexual sexual activity and incapable of managing her own fertility. Thus, informed consent documents may assume that female subjects are of childbearing potential unless they have undergone surgical sterilization or menopause and are treated as though they are in need of special protection, including exclusion from drug trials. Reducing women to their reproductive capacity, this presumes that women participants identify as heterosexual and engage in procreative heterosexual sex.

While Lutz and Collins (1993) argue that art aestheticizes the female body and science dissects and desexualizes, the assumptions embedded in clinical drug trials appear to frame female-bodied participants as actively and irresponsibly heterosexual. Within this framework, it may be impossible — or at least not clinically relevant — for a woman to be abstinent, have a same-sex partner, be monogamous with a male partner who is surgically sterile, or any other configuration that makes the possibility of pregnancy effectively impossible. In this way, the language of informed consent conveys a profound clinical distrust of women. The odds of women conceiving while in a study trial are deemed to be of sufficient risk to the REBs, pharmaceutical companies, and researchers, that women who are able to have children may be wholly excluded from participating in a study.[5]

Regardless of sexual identity or practices, one potential implication of this exclusion of female-bodied individuals from certain trials is that their constrained choice may lead to their participation in other higher-risk studies. Studies involving a range of risky medical procedures may carry little risk to future offspring, but real and immediate risk to the individuals who participate in them. Barred from certain trials because of their status as potentially ‘child-bearing’, healthy volunteers motivated by financial incentives may have fewer options than those without the potential to ‘bear children’, namely those who are male-bodied, regardless of fertility status. What appears to be motivated by paternalistic concern for the unborn may inadvertently steer women toward studies that carry higher risk to themselves.

[5] The possibility of terminating an unplanned pregnancy that results during a clinical trial is yet another invisible part of the informed consent process that constructs women as helpless—and possibly hapless—when it comes to their fertility.

Regulatory efforts to include more women in clinical research emphasize the importance of their inclusion for scientific validity and their right to the therapeutic benefits of later stage trials (Berlin & Ellenberg 2009). However, once included in studies, fertile and even women who are effectively unable to have children may be subjected to a host of surveillance tactics. Medical records documenting a woman's status as surgically sterile may be requested prior to inclusion in a study. Clinic staff may collect additional urine and blood samples from female subjects over the course of their participation in a trial in an effort to vigilantly monitor their pregnancy status. Beyond assuming female subjects to be heterosexually-identified and actively engaged in procreative sex, these practices, couched in paternalism, further construct the female subject as always potentially pregnant and untrustworthy of her own sexual and reproductive behaviors. These practices reduce heterosexual women to their procreative potential and effectively erase lesbian, asexual, and abstinent women. Following Butler (2011), biomedical texts may perform the female subject as pregnable or non-pregnable (fertile or surgically sterile), regardless of her own volition, and render all other sexual and reproductive configurations as culturally illegible.

3.2 The 'Male Subject' in Clinical Trials

In terms of the male subject in clinical trials, reproductive status as fertile or infertile appears to bear little significance for their inclusion within trials. Men are primarily excluded from studies which pertain to women's «reproductive capacity and function» (Rogers & Ballantyne 2008, 536) and not as a result of a trial's potential risk to a man's future children. Study protocols may state that men are required to abstain from sex or use acceptable birth control measures. This again presumes that men both identify as heterosexual and engage in heterosexual sex. The participation of gay men or men who have sex with men (MSM)—in other words, men who may be sexually active, but not engaging in procreative sex—are inconceivable within this framing.

Unlike their female counterparts, however, men are not barred from participating in drug studies, even when they are regularly engaged in procreative sexual behavior. Instead, the informed consent process elicits their promise to prevent impregnating a woman for a set

period of time during and after a clinical trial. The implied ramification of breaking this promise is that the pharmaceutical company and researchers are not responsible for any problems that occur to a resulting fetus or child. In other words, the possibility of a fetus exposed to the risks of experimental drugs is tolerated when the exposure occurs through a male study participant but not tolerated when it occurs through a female study participant. This asymmetrical paternalism constructs the male subject as actively heterosexual as well as sufficiently responsible to take contraceptive precautions when engaging in procreative sex while participating in a clinical trial.

A concomitant assumption within the heteronormative framing of human subjects is the equation of sexuality with procreative sexual behavior. Non-procreative sexual practices are seemingly ignored in the informed consent process. This emphasis on procreative sex harkens back to early 20th century conflations of procreative sex with normality and all non-reproductive sex as abnormal and perverse (Katz 1995; Kimmel & Plante 2007). It also creates a disturbing degree of silence about any risks associated with intimate contact and the sharing of bodily fluids in non-procreate sex. Specifically, investigational drugs could be transmitted through bodily fluid to a research participant's partner, carrying with them unknown compounds that may increase health risks to others.

One example of a drug that transmits easily through physical contact and can create untoward effects is testosterone gel products (marketed in the U.S. as AndroGel, Axiron, and Testim). There is a growing biomedical literature on the potential of these drugs to cause the virilization of women and children, including through prenatal exposure (Kathiresan, Carr, & Attia 2011; Patel & Rivkees 2010). More importantly, there is now strong indication that men with heart disease who use these products are dramatically increasing their chance of heart attack and stroke (Vigen et al. 2013), but cardiovascular risks to partners with whom participants may transmit the product through intimate physical touch remains unknown. Another example of intimate partner exposure to drugs is with chemotherapy agents, which are present for at least 72 hours after treatment (Choy & Brannigan 2013; Pichini, Zuccaro, & Pacifici 1994). By privileging procreative sex, informed consent documents neglect to emphasize the myriad of other risks that may be

associated with research participants' sexual touch of partners – potentially affecting heterosexual and gay and lesbian identified participants. By presuming that all research participants engage in procreative heterosexual practices, biomedicine fails to grapple with the full range of possible risks that may be associated with non-procreative sex between research participants and their partners. Within this framing, a range of sexual practices are absent and the identities of gay and asexual men are rendered unintelligible. Furthermore, the bodies of subjects' sexual partners are ignored in the calculation of health risks involved in clinical trials.

3.3 Implications for GLBT Participants

Scholarship surrounding the inclusion of gay and lesbian individuals in biomedical research has primarily fixated on increasing the access of (primarily) gay men to experimental therapies for the treatment of HIV/AIDS (Loue & Pike 2007). HIV-positive women are often excluded from studies, either through the study protocols or through self-exclusion because the disease is associated with gay men (Ryan 1995). This focus on HIV/AIDS research, as well as the study of a 'scientific' basis for gay and lesbian sexuality, makes up the majority of the scholarship at the intersection of science and sexuality. Sexuality is viewed as relevant for biomedical research only when it investigates the biological or genetic causes of homosexuality or when an illness is perceived as a 'gay' disease. The extent to which heterosexual assumptions are embedded within biomedical discourse and practice, and the impact this might have on the GLBT population, has been relatively ignored.

While GLBT individuals are not overtly excluded from participation in clinical trials, we argue that they may be *discursively* excluded through a language of informed consent that makes their identities and sexual practices invisible. One mechanism by which this occurs is through prospective clinical trial participants' compelled adherence to the informed consent script. Regardless of whether or not prospective participants have sexual partners at all or have partners with whom procreative sex is possible, they must answer the questions about their sexual practices 'correctly' and promise to prevent pregnancy while they are

enrolled in a clinical trial. We see this as a biomedical ‘re-closeting’ of GLBT participants. In being forced to engage the consent process through this heteronormative framework, any potential risks or concerns that are unique to them are ignored or denied. This signals a fundamental limitation of the informed consent process when it lacks the flexibility for biomedical research to recognize the intention of inclusion-exclusion criteria and adapt them to the specific context of prospective participants.

Calls for the inclusion of particular subgroups of the population within clinical trials have only emphasized the need to improve upon the recruitment of women and racial/ethnic minorities. Steven Epstein (2007) analyzes this shift in biomedicine as the «inclusion-and-difference paradigm». This change in orientation to the recruitment of underrepresented groups rests on the cultural logic that excluded groups might be sufficiently biologically or physiologically distinct that the scientific findings of trials are compromised by their absence. Unfortunately, this new paradigm privileges the supposed objectivity of science over the narratives of social injustice associated with feminist critiques of science (Haraway 1988; Harding 1998). In this current context, the inclusion of GLBT volunteers as a sub-population is nonetheless ignored despite their cogency and strength as a political group (Armstrong 2002).

At this point it should be clear that we are not suggesting that the GLBT population does differ physiologically from those with other sexual identities, nor that their absence leads to radically different empirical findings. Rather we see the discursive exclusion of GLBT and asexual individuals and the cases in which women are physically excluded from study participation as indicative of a wider culture within biomedicine that continues to privilege and normalize the heterosexual, cis-gendered male while constituting all others as deviant at best, and culturally illegible at worst.

4. Future Research

The above propositions detailed the ways in which the informed consent process, a critical feature of basic scientific research involving human subjects, may presume sexual identity

and sexual practices. Below we discuss a number of fruitful avenues for future research in order to interrogate the role of heteronormativity within the informed consent process and biomedical research using human subjects more generally.

The first research need is a detailed analysis of informed consent documents in order to assess the scope of heteronormativity's influence on the process. We developed the above propositions from first-hand, but limited empirical knowledge of the range of documents that investigators use to appropriately inform potential subjects of the risks and benefits of studies. The types of studies, drugs, or procedures involved may influence how participants' sexual identity and practices are framed within the informed consent document. Content analysis of a range of informed consent documents and even published guidelines and textbooks would serve as a useful empirical starting point for assessing the role of heteronormativity in this scientific practice.

A second avenue of needed empirical research would center on the extent to which women continue to be excluded from participation in clinical trials and the heteronormative basis for such exclusions. Even the NIH mandate in the U.S. to include women only applies to government-funded research and primarily focuses on Phase III clinical trials. Arguments for increasing the number of women in clinical trials have primarily centered on the implications their absence has for the broad application of trial findings and developed therapies. Therefore, missing from this assessment is a critical look at the paternalistic and heteronormative assumptions implicit in the barring of women from trials that might pose undue risk to potential fetuses. Writing about the institutional efforts in the U.S. to increase women's inclusion in clinical trials, Merton notes that these efforts for inclusion continue to regard women as «add-ons, requiring special and different treatment than the male standard» (1994, 313). In critiquing these efforts, she faults the «gender identity of those conducting and funding clinical research» as men who are preoccupied with conditions that affect them most and who continue to «define and perceive the male as generically human and the female as a special sub-group» (1994, 313–314). We would extend this critique further to include attention to the sexual identities and practices that are assumed among trial participants and the role this plays in justifying the exclusion of women.

Future research on heteronormativity within clinical trials should also attend to the potential physical risks of non-procreative sex practices and if and how trials acknowledge this risk. In assuming that participants' sexual practices are exclusively procreative, informed consent documents may fail to fully cover a drug's potential risks to sexual partners. In fact, as the examples of virilization caused by testosterone treatments and the risks of chemotherapy agents suggest, the bodies of trial participants are not the only ones at-risk during a trial testing the unknown effects of an experimental drug. While participants may be admonished to abstain from sex, it is unclear what sexual practices are included in this sanction given the pervasive emphasis on procreative sex and the risk factors associated with impregnation during a drug trial. Participants may interpret these sanctions in a number of ways, potentially putting their partners at risk.

Finally, a fourth important area of needed research should focus on the experiences of gay and lesbian trial volunteers, with particular attention to their discursive exclusion, as well as the heteronormative policies and practices they confront during trials. Such policies may play an important role in participants' feelings of safety and inclusion in the scientific and medical domains. Sexual minorities should be meaningfully considered in all types of clinical trials rather than simply those that target HIV/AIDS. Similar to the inclusion of women in clinical trials, sexual minorities appear to be considered only as a special sub-group in contrast to the heterosexual standard. This differentiation reproduces the sexual hierarchy, privileging those who identify as heterosexual and disadvantaging or altogether ignoring those across the spectrum of sexuality.

5. Conclusions

The «domain of cultural intelligibility» (Butler 2011, xii) within biomedical research privileges, normalizes, assumes, and erases eligible and ineligible bodies for clinical trial participation. Furthermore, through the purportedly scientific and objective inclusion and exclusion criteria for clinical trials, the informed consent process inflexibly constructs the appropriate trial participant. In proposing a number of ways in which biomedical research

involving human subjects perpetuates heteronormativity, we have traced what is conceptually present and absent in this domain. As a result, biomedical texts appear to construct the male and female subject in binary, but asymmetrical ways. Rather than see sexual and gender identities on a continuum between what is considered normal and what is deemed abnormal, we follow Butler's work to propose a continuum between that which is deemed normative and that which is absent altogether – the culturally unintelligible. In the treatment of the male and female subject as implicitly heterosexual, binary sex categories are normalized, while bodies and identities outside of those categories are unrecognizable. This erasure of identities and practices is problematic for the inclusion of non-binary genders, sexes, and sexual identities as well as for the risks associated with non-procreative sexual practices. A full empirical understanding of clinical trials as heteronormative practices is in order, and we propose a number of streams of future research that might contribute to an understanding of the deeply political nature of whose bodies and sexual practices count as legitimate in clinical research. These include attending to the production of biomedical discourse through the texts of informed consent and trial regulation, rationales for excluding women from clinical trials, the risks of non-procreative sexual practices between participants and partners, and the experiences of GLBT participants within clinical trials.

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