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## Clinical Trials That Explicitly Exclude Gay and Lesbian Patients

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### To the Editor

We recently encountered proposed studies that explicitly excluded persons in same-sex relationships. We therefore decided to gather data on clinical trials to see whether this phenomenon is common.

We performed exploratory searches of the ClinicalTrials.gov database<sup>1</sup> to identify categories of studies from which lesbians and gay men were likely to be explicitly excluded. The ClinicalTrials.gov database contains detailed information on more than 80,000 clinical trials sponsored by the National Institutes of Health, other governmental agencies, and private industry. We sought explicit inclusion and exclusion criteria that would restrict trials to heterosexual patients, such as study requirements that participants be in heterosexual relationships. We included only studies with sites in the United States. All searches were conducted from November 4 through November 11, 2009.

We found that when we performed searches using the terms “couples,” “erectile dysfunction,” and “hypoactive” (related to hypoactive sexual disorder), we identified 243 studies, of which 37 (15%) had explicit exclusionary language (Table 1). In these 243 studies, the results of Fisher’s exact tests indicated that industry-sponsored trials, multiregion trials (according to census definitions), and phase 3 trials were the most likely to exclude lesbians and gay men ( $P<0.05$ ). Other variables, such as the year the study opened, whether the study is open to those over 65 years of age, and whether the study accepts healthy volunteers, were not associated with exclusionary criteria.

To ensure that we did not miss a general pattern of exclusionary language, we also examined eligibility criteria in 1019 studies that we identified by using the search term “asthma.” Exploratory searches indicated that such studies did not have high rates of exclusionary language, and indeed, no asthma trials were found to exclude lesbians and gay men. However, we incidentally found a clinical trial of attention deficit–hyper-activity disorder that required that participants be “in a reciprocal relationship with a person of the opposite sex.”

Our results indicate that exclusion of lesbians and gay men from clinical trials in the United States is not uncommon, particularly in studies with sexual function as an end point. It is likely that most gay and lesbian patients are unaware that their sexual orientation is being used as a screening factor for participation in clinical trials. Researchers should be held to careful scientific reasoning when they develop exclusion criteria that are based on sexual orientation.

## Acknowledgments

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## References

1. [ClinicalTrials.gov](http://www.clinicaltrials.gov/) database. [Accessed February 25, 2010]. at <http://www.clinicaltrials.gov/>

**Table 1**

Examination of 243 Studies for Exclusion Criteria That Are Based on Sexual Orientation.

Variable	Studies from Which Lesbians and Gay Men Were Not Excluded (N = 206)	Studies from Which Lesbians and Gay Men Were Excluded (N = 37)	P Value
	<i>number</i>		
Search term used			0.006
“Couples”	118	11	
“Erectile dysfunction”	58	19	
“Hypoactive”	30	7	
Location of study sites			<0.001
Midwest	32	2	
Northeast	50	3	
South	63	7	
West	19	1	
Multiregion	42	24	
Accepts healthy volunteers*			0.33
Yes	61	8	
No	141	29	
Initial phase of trial			<0.001
Phase 1	22	1	
Phase 2	30	5	
Phase 3	30	22	
Phase 4	34	4	
Other	90	5	
Funding source			<0.001
Industry alone	41	26	
National Institutes of Health alone	36	5	
Hybrid or other	129	6	
Year study opened*			0.12
Before 2000	10	2	
2000–2004	25	9	
2005 and later	167	26	
Maximum age accepted			1.00
Under 65 yr	53	9	
65 yr or older	153	28	

\* Data were missing from four studies from which lesbians and gay men were not excluded.