

# Written informed consent and selection bias in observational studies using medical records: systematic review

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**STUDY QUESTION** Does informed consent for medical record use introduce selection bias? Are there differences in key demographic variables between participants and non-participants in prospective observational studies requiring informed consent for medical records access? What are the consent rates in these studies?

**SUMMARY ANSWER** Significant differences between participants and non-participants may threaten the validity of results from observational studies requiring consent for use of medical records. To ensure that privacy legislation does not unduly bias observational studies using medical records, research ethics boards must consider carefully the need for mandatory consent.

## Selection criteria for studies

We searched Embase (1980 to week 13, 2008), Medline (1966 to week 3, March, 2008), and the *Cochrane Library* (issue 1, 2008) for English language studies. We sought all studies reporting characteristics of participants and non-participants approached for informed consent to use their medical records for prospective observational studies or registries. We included studies reporting at least one of the following characteristics: age, sex, race, education, income, or health status.

## Primary outcome

Comparisons between participants and non-participants by age, sex, race, education, income, or health status.

## Main results and role of chance

Of 1650 citations, 17 unique studies met our inclusion criteria and had analysable data. Our inter-rater reliability for included studies was 0.84 (95% CI 0.83 to 0.86). Of 161 604 eligible patients in the 17 studies, 108 033 (66.9% (95% CI 66.6% to 67.1%)) provided active consent for use of their medical records. Consent rates for eligible participants varied across the studies (36.6% to 92.9%). By characteristic, we identified 16 studies reporting age, 14 reporting sex, seven reporting income, and six reporting race, education, or health status. Across all outcomes, differences between participants and non-participants occurred, but there was a lack of consistency in the direction and size of effect.

## Bias, confounding, and other reasons for caution

Our review was limited by the published reports—including lack of clarity about the sample size and reporting standards for screening and consent procedures. Not all studies reported data on our outcomes of interest; authors may not have collected data on these outcomes or chose to report only significant differences between enrolled

## SUGGESTED STRATEGIES TO MINIMISE BIAS FROM INFORMED CONSENT

Request a waiver of consent from research ethics boards with explicit procedures to protect patient confidentiality

If a waiver is not possible then:

Collect a minimum dataset of key prognostic variables on all eligible people identified through screening

Complete a preliminary analysis comparing participants and non-participants on key prognostic variables at predetermined times

Revise the strategy for recruitment as necessary

Educate clinicians, researchers, and research ethics boards on conditions under which studies can proceed without individual consent

Standardise reporting of methods used to seek informed consent

Increase awareness by clinicians and researchers of the potential for selection bias from informed consent and implications for interpretation of result

and non-enrolled patients. Because these observational studies were not specifically designed to study differences in consent between participants and non-participants, we may have observed statistically significant differences across our outcomes of interest simply due to chance.

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