Primer: Ethics of Unsolicited Clinical Trial Recruitment via Electronic Health Records (EHRs)

Clinical trials are essential for advancing medical knowledge and improving patient care, yet they often struggle to recruit enough suitable participants. Electronic Health Records (EHRs) offer a powerful way to identify people who may be eligible for studies and to contact them efficiently. Despite the potential benefits, many institutions hesitate to use EHRs for this purpose unless patients have consented in advance. Concerns about privacy, data protection, and respect for autonomy have created uncertainty about what is ethically permissible. This primer explains the key ethical issues and summarises a recent Singapore PDPC decision relevant to clinical trial recruitment.

Ethical Foundations

Three long-standing principles guide the ethics of research: respect for persons, beneficence, and justice. These are useful lenses for understanding when using EHRs for recruitment is appropriate.

Respect for persons is largely about autonomy and control over personal information. In unsolicited recruitment, however, the autonomy interest is comparatively limited. The use of health information is only for identifying potential eligibility. Individuals remain entirely free to ignore or decline an invitation, and their clinical care is unaffected. Nevertheless, some individuals feel strongly about having a say in any use of their health data, even for benign or socially beneficial purposes.

Beneficence and non-maleficence highlight both the potential value and the risks of EHR-based recruitment. The societal benefits are substantial: faster recruitment allows trials to generate results more quickly, helping both current and future patients. Individuals may also personally benefit, as trials can offer access to new or promising treatments. The risks—such as inadvertent disclosure of sensitive information, misunderstanding of one's medical condition, or simple annoyance—can be kept very low with appropriate safeguards, limited data access, and careful communication.

Justice enters the picture through concerns about fair access and equitable recruitment. EHR-based identification can help ensure that studies reach a wider and more representative range of potential participants. At the same time, oversight is needed to prevent over-contacting certain groups or excluding others because of how EHR systems are structured.

Is Prior Consent Needed for EHR-Based Identification?

Whether prior consent is ethically required for identifying potential trial participants through EHRs is contested. Supporters of permitting EHR-based screening without advance consent argue that the intrusion into autonomy is small, since individuals are merely invited—not enrolled—into research. They retain full control, and the potential benefits to society and to patients themselves can be significant. With strong data protection and careful procedures, the

risks of misuse or harm are minimal, and receiving an unsolicited research invitation is often less intrusive than the commercial messages people routinely receive.

Those who favour requiring prior consent emphasise that individuals may reasonably expect control over any use of their health information. Being contacted about a study could inadvertently reveal something about a person's medical condition, particularly in sensitive areas such as mental health, HIV status, or genetics. If patients do not realise their records may be used this way, unsolicited contact may undermine trust. There is also the possibility—especially for patients with rare or serious conditions—of feeling burdened by repeated invitations if safeguards are insufficient.

A pragmatic middle ground is increasingly adopted in many settings: allowing EHR-based identification but with strong limits, transparency, and options for patients to opt out. This approach recognises both the value of enabling research and the importance of respecting individual expectations and maintaining public trust.

Case Example: The IMH–PDPC Decision (2025)

A recent case from Singapore's Personal Data Protection Commission (PDPC) sheds light on how personal data may be used for research recruitment. Although it did not involve EHR-based searches, it helps clarify the legal and ethical boundaries.[1]

In 2024, the Institute of Mental Health (IMH) research team identified a patient as a potential participant by obtaining names and appointment times of suitable patients from the attending doctor and using internal systems to locate the individual. The patient complained that his medical information had been disclosed without consent. The PDPC found no disclosure to third parties—both the doctor and research officer were IMH employees—but concluded that IMH had indeed used personal data (including age and relevant medical profile) for recruitment purposes.

Crucially, the PDPC determined that implied consent was present. IMH had prominently displayed notices since 2014 stating that personal data might be used to invite patients to participate in research. The complainant had attended the clinic regularly and was considered reasonably informed. By continuing to seek care, he was deemed to have impliedly consented to this use of his data. Nevertheless, the PDPC criticised IMH's reliance on "deemed consent by notification," because the organisation had not told patients clearly how they could opt out. IMH later tightened its procedures so that clinical teams now introduce the possibility of research participation before research officers approach patients.

This decision illustrates that, at least in Singapore, internal use of patient data for recruitment may be permissible under implied consent, but organisations must be transparent, provide meaningful notice, and offer patients a clear means to express refusal.

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[1] See: https://www.pdpc.gov.sg/all-commissions-decisions/2025/07/no-breach-of-the-consent-obligation-by-institute-of-mental-health

Bringing the Ethics and the Case Together

The IMH decision reinforces key points relevant to EHR-based recruitment. Legally and ethically, using patient data to identify possible research participants can be acceptable when patients have been adequately notified and have reasonable opportunities to opt out. At the same time, trust must be protected: organisations should communicate clearly, restrict use of sensitive data, and ensure that invitations to participate are respectful and voluntary.

EHR-based recruitment should therefore be accompanied by safeguards such as prominent notice, data minimisation, careful staff training, transparent explanations to patients, and independent review of recruitment plans. With these protections, the practice can support high-quality research without compromising patient dignity or trust