Should participants in clinical trials be able to withdraw from passive follow-up?

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BACKGROUND
The right for a participant to freely withdraw from research procedures is generally unquestioned, derived from the principle of Respect for Persons. But is it reasonable to place some limits on this right? Consider the following hypothetical case:

CASE EXAMPLE
A study coordinator on a large, multicenter trial calls a participant for follow-up visit scheduling. The participant states she discontinued study medication ‘some time ago’ because it made her feel poorly, leading to hospitalization. When further questioned about these possible side effects, she expresses frustration with having been in the trial and says she no longer wants to participate. When asked about continued access to her medical records for follow-up of study outcomes, the participant refuses any further contact with the investigators or information to be collected about her for the trial.

ETHICAL TENSION
The participant’s decision is well within her rights and seems to have effects limited to her own privacy. However, we argue that this decision can also have impacts on other trial participants and the public at large, creating tension between Respect for Persons and Beneficence.

BALANCING RESPECT FOR PERSONS AND BENEFICENCE

Respect for Persons
- Trust
- Privacy
- Respect

Beneficence
- Population safety
- Actionable knowledge
- Participant safety

REAL WORLD EXAMPLE:
- Possible missed trial safety signals: Rimonabant was not approved in the US because of concern for attrition bias resulting in psychological risks. After the drug’s approval in Europe, it was later withdrawn from market due to observed increased suicide risk.
- Possible adverse drug reaction: The participant’s comments suggest she experienced an adverse drug reaction, which needs to be fully evaluated for her safety and the safety of other participants remaining on the trial.

LIMITATIONS
Our argument assumes:
- A study intervention with potential toxicity
- The information needed to accurately assess safety and efficacy can be collected passively from medical records
- The number of subjects without full follow-up is sufficient to threaten the validity of trial results

DISCLOSURES
WHC and MPB are contracted employee of CPC Clinical Research, a university-affiliated Academic Research Organization that receives research grants from various industry sponsors to design and conduct clinical trials.