



Monday Morning Practice Pearls #62

What does it mean for a research participant to be lost to follow-up?

Lost to follow-up refers to a clinical research participant who at one point in time was actively participating in a clinical research study, but has become lost (i.e., being unreachable) at the point of follow-up (short-term or long-term) in the study. Another way to think of a participant who is lost to follow-up is a failure to find the research participant.

How important is lost to follow-up?

Participants that are lost to follow-up can compromise the study's validity as study data points cannot be collected. Along with premature discontinuation of treatment, lost to follow-up may leave uncertainty about the true efficacy and safety of an intervention leading to a lack of confidence in the results of a study.

My protocol doesn't specify what is considered lost to follow-up – what should I do?

There is no evidence on when a participant should be deemed lost to follow-up or guidance on what should be done before a participant can be declared lost to follow-up. If your protocol does not specify what needs to happen before deeming a participant lost to follow-up, below are some guidelines:

- Make at least three (3) contact attempts using the research participant's preferred method of contact (via phone, email, or a combination of both) with documentation of contact attempts in CRIS.
- For greater than minimal risk studies, send a letter through a trackable delivery service (e.g., FedEx, UPS). If the participant does not respond, the shipping receipt should be filed in the individual's research record with a copy of the letter sent.
- If no responses are received, the patient should be documented as lost to follow-up, and taken off study.

REMINDER:

- Reach out to the local provider(s) listed in CRIS for assistance.
- If your study has both treatment and long-term follow-up, make sure that if a participant requests to stop their active treatment before the protocol specific timepoint (i.e., withdraws consent), remember to reinforce that there is still follow-up that will be needed. In this situation the participant may be very willing to remain on the study for this follow-up, so don't assume they are voluntarily withdrawing their consent from the entire study.