



IRB 360 NEWSLETTER

Connecting Research with Ethics

Over-Recruitment of people past the IRB-approved target number can put additional human subjects through unnecessary research interventions and burdens. It exposes them to potential research-related harms and risks, which include the loss/leakage of confidential personal information.

To maintain public trust, researchers must exercise due diligence with regards to recruitment numbers.

Over-Recruitment & IRB Non-Compliance

Recruiting subjects beyond the approved 'maximum recruitment number' (max. no.) without IRB approval constitutes as 'Non-Compliance', and requires the submission of an [Incident Report Form](#) to the IRB. Depending on the severity of the non-compliance, a warning letter might be issued to the Principal Investigator (PI).

As responsible researchers, there is a need to track recruitment numbers in a timely manner, and halt recruitment once the max. no. has been reached. If you intend to recruit beyond the max. no., **an amendment must first be submitted to increase the target**, prior to additional recruitment.



Determining the Maximum Recruitment Number

Subjects who have **dropped out or withdrawn from a study count towards** the actual number of subjects enrolled (*e.g. 10 subjects were enrolled, but 4 had eventually withdrawn; the total no. enrolled is still 10*). When deciding on the max. no. for recruitment, you should make provisions to account for potential study drop-outs/withdrawals.

Here are some scenarios of Over-Recruitment based on actual 'Non-Compliances' reported to the IRB

Scenario 1

A study's online survey received a higher-than-expected response rate, and the responses collected met the maximum recruitment no. in a very short period.

The PI proceeded to close the survey, but *those who had already started the survey before the closure could still submit their responses* even after the survey had been closed. The PI went on to use the survey data from these over-recruited individuals.

Survey platforms like Qualtrics have a "[Quotas](#)" function to ensure that researchers gather only the exact amount of data required for their study. The PI should have [set a quota limit](#), and enabled the [settings upon meeting the set quota](#) to end the survey prematurely; and not record/delete the extra responses.

The PI should also have been **pro-active in tracking the response numbers**, and **not use the 'extra' data as no amendment had been approved to increase the recruitment target**.

While the PI had accounted for potential dropouts, s/he should have closely monitored the attrition rate and recruitment numbers.

Since **study withdrawals/dropout/collection of partial or incomplete data count towards the final enrolment figure**, upon discovering that the actual attrition was higher than expected, the PI should have filed an amendment to increase the maximum recruitment target.

Scenario 2

The PI estimated a 10% attrition rate, and factoring this in the sample size calculation, a recruitment target of 220 subjects was approved by the IRB.

But the actual attrition rate was more than 10%; to meet the sample size target, the PI recruited more people resulting in a final enrolment of 275 subjects.

Scenario 3

The experiment required the research data to be representative of the study population's demographics (*e.g. race, age, gender*). When the max. recruitment target was met, the *data set was found to be not representative*, and the *experiment was re-conducted several times until the data was representative*. The final enrolment number was 500% of the approved max. recruitment target.

The PI should have: monitored the enrolled subjects' demographics to ensure the collected data set matched the study population's profile; and requested an amendment to increase the recruitment target before re-conducting the experiment.

If the study is an online survey, platforms like Qualtrics and Prolific offer options to setup a [demographics quota](#) or [prescreening filters](#) to obtain a representative data set.

ANNOUNCEMENT

If you are unable to access ERMP because **'Your account is not valid or Access denied'** submit the online [User Access Request Form](#) using your NTU/NIE email to request for an account/access.



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