

Providing Research Participants Completed Study Findings: A (Slightly) Different Perspective

Maurie Markman, M.D.

Basic Concepts

- Patients have a **right** to be informed of completed study results
- Researchers have an **absolute obligation** to inform patients of study results (during and following completion of a trial) that may impact their current and/or future health
- But, patients do not have an obligation to be provided study results that do not impact their current and/or future health

Why is this even an issue?

- Study results that will not in any conceivable manner impact the health (current or future) of a research subject *may actually have a negative emotional impact* (e.g., increase anxiety related to concern for the potential risk of cancer recurrence, when there is no evidence that it will be possible to favorably alter or impact that risk)

Example

- ***Patient A*** with metastatic *Cancer B* receives **Regimen C** on a phase 3 randomized trial.
- ***Patient A*** is doing well, but the study results reveal that ***Regimen C*** has statistically-significant shorter time to disease progression (PFS) and reduced overall survival compared to treatment on ***Regimen D***, the ‘other’ study arm.
- There is no evidence that any *second-line treatment program* will improve this situation **if Cancer B ultimately recurs.**

Informed Consent Proposal

- Research participants are entitled to be provided a summary of study findings, when they are available
- Research participants will always be informed of study finding (during or after the completion of a study) that may have a direct impact on decisions regarding the current or future management of their condition

Informed Consent Proposal

- Research participants may decide to receive information regarding study findings, when available, that the researchers believe have no known impact on how their condition will be treated either now or in the future.

Informed Consent Proposal

- Before research participants decide to receive information that does not influence their subsequent treatment directly, *it is important for them to understand that the study results relate to the entire population of patients who entered the trial, and not to a specific individual.* Furthermore, the findings are expressed as the “chance” (or probability) that something may happen, and not a prediction that it will happen at a particular time or to a particular individual

Informed Consent Proposal

- For patients with *serious medical conditions*, before research participants decide to receive information that does not influence their subsequent treatment directly, it is important for them to understand the information may not present an overall favorable picture of the specific treatment employed in the trial or, in a randomized study, the regimen the individual received.

Informed Consent Proposal

- *Under the conditions noted, when there are no known alternative treatment options available for the individual that may alter the overall unfavorable outlook for the *group of patients who participated in the trial*, research participants will need to decide whether they would want to be provided this information.*

- Markman M. Providing research participants with findings from completed cancer-related clinical trials: Not quite as simple as it sounds. *Cancer* 2006; 106:1421-1424.