Loss to Follow Up: Policy Development and Formal Guidelines

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Background

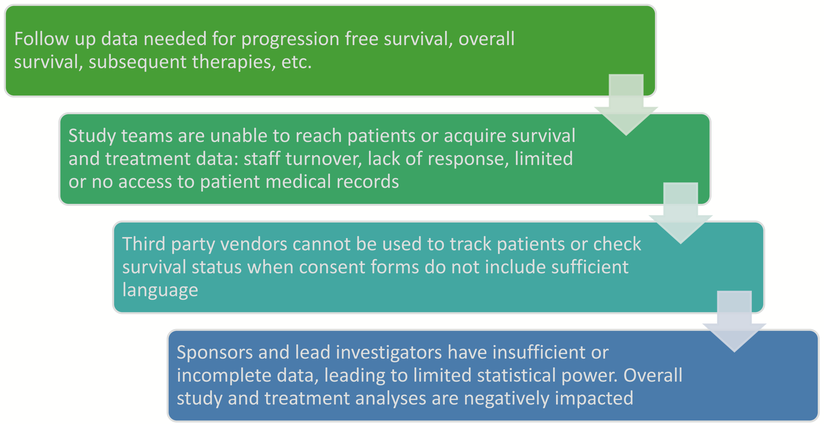
- Long-term and survival follow up, often over the course of five or more years, is an important source of data for endpoints in therapeutic trials
- It is challenging for staff to maintain contact with patients over time and to keep patients engaged in ongoing data collection efforts
- Patients who live further from the treatment site and who receive primary oncology care outside the study site or study site's network can be harder to retain during extended follow up periods
- Contacting patients indefinitely or without response could be seen as harassment by the patient or be challenging for staff
- Expectations were unclear for staff about frequency, method, and duration
- Sponsors may want or need to use third-party vendors to check public records and databases to determine if patients are alive and to collect details about the patient's death
- If consent forms do not include language about releasing identifiable information, sites are unable to provide this information to the vendors
- Without these data, endpoints are compromised and statistics may be underpowered or insufficient to provide conclusions

Consent and Data Sharing

- In consultation with Information Privacy and Security (IPS) officials, it was determined that the language for data sharing in the OHSU consent form template did not sufficiently cover sharing identifiable information with third-party vendors to be entered into public databases or web search
- Public web searches, such as Google, may retain search information and utilize it for internal purposes
- While language may be sufficient to share patient information with sponsor vendors, the entry of the information to other platforms is not clearly covered

Acknowledgements and Thanks

Brandi Fleck - OHSU IRB, Assistant Manager
Nikki Lee – OHSU Information Privacy and Security, Associate Chief Privacy Officer
Christina Burgin – OHSU Knight Clinical Research Quality Administration, Assistant Director
OHSU Knight Clinical Research Managers and Leaders
Early Policy Development and Input- Molly Thomas, Shashi Mendis, Diane Ventura



Solution and Methods

- Follow up requirements and timelines were developed referencing existing guidelines and best practices
- Emphasis was placed on patients: ensuring communication frequency and variety created highest likelihood for patient response
- A concern had been that attempting to contact patients indefinitely, as some protocols require survival follow up until death, could either make patients feel harassed or could be traumatic for family members after a patient has died, if they are unable or unwilling to respond to unknown calls regarding the deceased
- The policy focused on creating a path forward to reasonably limit staff effort expenses and patient impact while also meeting data collection and protocol requirements
- Disease program managers, assistant directors, and leaders provided input on the policy
- Language developed with IPS was integrated into the consent form template and can now be used for all future studies and in revised consent forms and provided for reconsent

References
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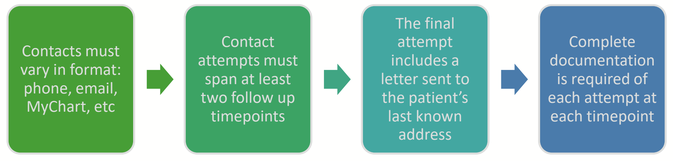
Key Policy Details

- There must be three contact attempts made at any given follow up timepoint
- Attempts must span at least two timepoints
- After two missed timepoints, a third-party vendor may be used, as long as the consent form includes sufficient language
- The final attempt to a patient will be a certified letter sent to their last known address
- Letters, including the final attempt, must utilize IRB approved language and templates.
- For cooperative and national trials, such as NCTN studies, contact attempts must be ongoing for two years before a patient can be considered lost to follow up
- Timepoints where contacts are appropriately attempted and documented but the patient does not respond will not generate protocol deviations for missing data.



Future Impacts

- Studies with patients currently in long term follow up or survival may not have the revised consent form language integrated or may not be able to reconsent patients to the new language
- Improvements to follow up and data collection will be ongoing as more patients are covered by the new language
- The policy clearly defines processes for contact attempts, which had previously been unstructured and potentially inconsistent across programs