BRAIN Initiative
Neuroethics Working Group Pre-Meeting for Continuing Trial Responsibilities Workshop

Perspectives from Insurance Providers and Research Administrators

February 28, 2022

Virtual Meeting

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Executive Summary

On February 28, 2022, the Neuroethics Working Group (NEWG) of the Brain Research Through Advancing Innovative Neurotechnologies (BRAIN) Initiative held a pre-meeting for a 2022 Continuing Trial Responsibilities Workshop. The workshop will focus on research-related care responsibilities for participants in clinical trials involving implantable neurological devices and will include perspectives from the National Institutes of Health (NIH), health insurers, device manufacturers, patients, caregivers, patient advocates, researchers, regulators, and bioethicists. Furthermore, the workshop topics will reflect the collective belief that key stakeholder groups involved in clinical trials hold a shared responsibility to facilitate post-trial care, yet how that care should be facilitated remains unclear.

During this series of pre-meetings, the National Institute for Neurological Disorders and Stroke (NINDS) will convene relevant stakeholders to gather information that will shape the Continuing Trial Responsibilities Workshop. This pre-meeting featured the perspectives of insurance providers and research administrators. Topics highlighted as relevant to this stakeholder group included (1) minimum post-trial care, (2) setting expectations for post-trial care, (3) factors that impact post-trial care and coverage, and (4) gaps in post-trial care.

Minimum Research-Related Care

From the perspective of insurance providers and research administrators, minimum post-trial care typically includes access to individuals who can help coordinate or support the transition from clinical trial care to private care, including social workers, nurses, and study coordinators. Post-trial care also requires access to data generated during the clinical trial for use in private care; these data should be provided to patients in a timely manner to ensure patients can inform their private physicians of the implanted device or drug and receive appropriate related care in the future. Post-trial care also involves providing patients with sufficient time to enable informed decision-making. For example, upon the completion of some trials, patients will be required to determine whether they wish to continue using a currently implanted device or upgrade to a newer device of greater interest to the sponsoring company; in some cases, sponsors require patients to make such decisions quickly, which is not appropriate or fair to patients.

Research organizations and insurers may be obligated to go beyond the minimum level of post-trial care depending on multiple factors, including the risk undertaken by the patient during the trial (particularly if that risk is considerably high), available alternative treatments/devices, and the safety of continuing or discontinuing use of the device/treatment. Post-trial care beyond the minimum can include continued access to an investigational device or drug provided in the study that is benefiting patients but has not yet received regulatory approval, or that the sponsor does not plan to pursue further following trial completion.

Setting Expectations for Research-Related Care

Expectations related to post-trial care must be established during recruitment and the informed consent process—long before a clinical trial is completed. For some clinical trials, the informed consent process involves providing patients with financial information about cost coverage throughout the clinical trial and after study participation is completed. Research organizations and insurers recognize that setting expectations regarding the financial cost of study participation would be aided by providing patients with a maximum out-of-pocket cost so that patients know the highest possible financial burden before agreeing to participate.

Expectations for post-trial care may differ for drug versus device trials. Communicating expectations for device-focused trials may be easier simply because researchers are devoting time to a smaller patient population. However, forecasting the possible needs of a patient with a device (such as a battery replacement or need for device removal) can be more difficult than forecasting the needs of a patient in a drug trial. Additionally, stopping a drug regimen is easier to visualize and discuss with patients (i.e., when the patient runs out of drug supply, they will no longer take the drug) than expectations related to keeping or removing a device from a patient (i.e., after a trial ends, patients may still need additional surgery). Communicating expectations is further complicated by the lack of clarity regarding who is responsible for covering the costs of necessary maintenance or upkeep long after a device was implanted.

Factors that Impact Research-Related Care and Coverage

Determining how to provide post-trial care while ensuring the patient pays the least possible out-of-pocket costs can be difficult and likely requires case-by-care review. Clinical trial teams must consider the level of support provided by manufacturers or research institutions, the patient's insurance plan (or lack thereof), and the willingness of the research organization to cover specific costs, particularly those associated with device maintenance.

Other factors that can impact post-trial care include type of sponsor (e.g., federal or commercial) and level of approval achieved or sought (e.g., full FDA approval). Compared to commercially funded trials, studies funded by NIH must follow additional policies that can influence how academic institutions cover specific post-trial care costs. Some entities, including the Centers for Medicare and Medicaid, will provide cost coverage for investigational devices, whereas others may not. Patients will likely have their costs of care covered by research organizations and clinical trial teams when an implanted device is being prepared for regulatory approval. Clinical trial teams will also provide cost coverage when the implanted device is being studied through follow-up time points and long-term data are needed to assess the device's efficacy and safety. If a device is deprioritized by the sponsor company or research organization, patients may be left without support from the sponsor.

Gaps in Research-Related Care

Most research organizations and insurers agree that maintaining coordination of care is critical for study participants leaving a clinical trial. However, in most cases, access to supportive resources (e.g., social workers or study coordinators) may be limited to the period directly

following clinical trial involvement rather than extending throughout the patient's lifetime, leaving them without long-term support to coordinate care and navigate insurance issues. Solutions must be identified to ensure that no gaps in care coordination and support are experienced by the patient. One solution would be to employ patient advocate coordinators who serve as liaisons between the clinical trial team and patients throughout the patients' lives to ensure that care is properly coordinated, new findings from clinical trial analyses are shared with patients, and patients can always obtain support for their implanted devices.

The clinical trial research field would benefit from the development of a maximum out-of-pocket cost threshold for clinical trial participation. While this threshold may vary for different trials, developing such a standard that can be tailored to various trial situations would help patients visualize the financial costs of entering a trial before committing.