Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

The Informed Advantage: Consent Support Hotline

D. O'Neill, C. Jerome, J. McGraw, A. Dudley, A. Gorman, B. Scruggs

Sidney Kimmel Comprehensive Cancer Center at Jefferson

1. Background

Our cancer center recently achieved designation as a comprehensive cancer center, a milestone that necessitated a review of our existing research support infrastructure. In particular, we recognized the importance of aligning our informed consent processes with the best practices observed at other leading comprehensive cancer centers. A key gap was the lack of timely, centralized support for staff navigating complex informed consent situations, leading to procedural inconsistencies. To ensure consistent, high-quality, and ethical research practices, we implemented an informed consent hotline. This provided research staff with immediate, real-time access to expert consultation for complex consent scenarios, enabling efficient and compliant procedural application.

2. Goals

The Quality Assurance and Education (QAE) monitoring team aimed to implement an informed consent hotline to offer expert guidance on complex informed consent scenarios, including protocol-specific requirements, regulatory updates, and best practices documentation, to clinical research staff (physicians, coordinators, etc.) across all Jefferson research sites, with the goal of ensuring regulatory compliance and streamlining informed consent process.

3. Solutions and Methods

Following an initial announcement at an all-staff retreat in March 2024, the informed consent hotline was launched in April 2024. To ensure ongoing awareness, monthly reminders are provided at all-staff meetings, and informational flyers are prominently displayed in clinical and research areas. The hotline operates 7 days a week, from 7:00 AM to 7:00 PM, offering readily accessible support to research staff. To facilitate efficient and expert real-time guidance, the QAE team established a dedicated phone line and developed a comprehensive online resource library. This internal library provides QAE staff with quick access to up-to-date policies, procedures, and frequently asked questions, enabling them to address inquiries effectively. A structured rotational schedule among QAE team members ensures consistent, expert-level hotline coverage and minimizes response times for real-time support.

4. Outcomes

Since its April 2024 launch, the informed consent hotline has demonstrated measurable impact. There was a six-week adoption period before the first call was received. Since then, there has been 23 documented inquiries, predominantly addressing complex consent scenarios, specifically non-English speaking consent and re-consenting protocols. Call duration has decreased from an initial 20-minute average to a consistent 5-10 minutes, indicating increased efficiency. The hotline serves both central and regional research sites, with user feedback consistently positive. Procedural consistency is supported by the distribution of relevant guidance documents during and after calls. Notably, data collected from hotline interactions directly informed the revision and implementation of an updated remote consent policy. Furthermore, the need for escalation of complex consent questions to leadership has been significantly reduced, indicating the hotline's effectiveness in providing timely and authoritative guidance.

5. Learned and Future Directions

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Call volume analysis indicates a direct increase following monthly all-staff meeting reminders. Conversely, weekend utilization remains consistently low. To optimize service delivery, a survey will be conducted to assess staff satisfaction and determine optimal operational hours. This data will influence potential adjustments to the hotline's availability, ensuring alignment with staff needs. Future development will explore the integration of supplemental communication channels, such as email and/or text messaging, to enhance accessibility and efficiency.