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Columbia University’s Personalized IRB Liaison Service: Evaluation over its initial 2.5 years

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OBJECTIVES/SPECIFIC AIMS: National concerns about IRB-related research delays have led to re-assessment of IRB review processes at institutional levels. We sought to address whether a dedicated IRB Liaison Service at the Irving Institute’s central location could provide additional useful staff support to the investigator community for interactions with the IRB at various levels of protocol submission. METHODS/STUDY POPULATION: We evaluated the results of a user satisfaction survey and performed a focused in-depth analysis of Liaison Service impact. An online tracking and satisfaction survey was implemented for researchers to complete following each consultation. The goal was to gauge the uses, user types and usefulness of the Service, and to follow-up with researchers who might have additional questions. Data was gathered about users of the Service and their affiliations, and the topics and questions that were discussed. A terse summary was drafted to categorize each consultation that was conducted during office hour sessions. Additionally, surveys were emailed to researchers to gauge their experience with the Service and their overall satisfaction. Users completed the survey either in person at the end of the consultation, or by email request sent immediately following each in-person consultation. The impact of the IRB Liaison Service on IRB protocol approval times was analyzed for a random sub-sample of protocols for which consultations were provided. Consultations for studies with an associated IRB protocol number (i.e., at least initially submitted) from May 2015-June 2017 had been assigned a number in an Excel file. Using a randomization formula, a subset of 90 protocols was identified for further analysis. Protocols that did not result in an IRB submission and duplicate entries were removed. The final dataset consisted of 67 protocols. Those protocols were assessed by type of review process (expedited versus full board review), by status (new submission, first return, second return, etc.), and by which of the seven IRB committees completed the review. Consultations for each protocol included in this subset were reviewed using the notes about that consultation. IRB records in Columbia’s online research oversight system, Rascal, were also reviewed to assess the timing of and issues raised in subsequent IRB review. Factors examined included whether the protocol was approved at next submission and if not, whether questions raised in subsequent IRB returns were related to the topics discussed in the consultation. RESULTS/ANTICIPATED RESULTS: Since its inception in January 2015 through June 2017 (2.5 years), a total of 501 in-person consultations have been performed, usually 25-30 per month. Users were primarily study coordinators and investigators. Most requests concerned new protocol development, policy questions or assistance in addressing IRB comments from submitted protocols. Survey response rate was 43%. Results of 215 completed satisfaction surveys were 100% positive. Of 67 unique protocols analyzed for outcomes of the consultation, 73% were subsequently approved within 14 days. DISCUSSION/SIGNIFICANCE OF IMPACT: Overall, we