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Family-Centered Consenting for Co-Enrollment

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To the Editor:

Collaboration across concurrent pediatric critical care research studies with overlapping inclusion criteria is imperative to maximize opportunities to improve outcomes for patients and their families as they traverse through critical illness and recovery. Limited access to patients is recognized as an obstacle to conducting effective pediatric critical care studies (1–3). Evidence suggests that co-enrollment is operationally feasible and most families are willing to enroll in multiple studies during their intensive care unit stay (4). A path to co-enrollment has been delineated by intensivist-scientists which advises consideration of potential scientific impact of multiple interventions on study results, safety implications, burden on research staff and families, and, if an interventional trial, possible interaction between therapies.

Critical care studies increasingly evaluate post-discharge outcomes using remote, survey-based methods. The recent multistakeholder-informed Pediatric Critical Care Core Outcomes and associated Measurement Sets (COS and COMS, respectively) delineate a set of instruments that comprehensively measure priority outcome domains (5, 6). Use of the COMS framework could decrease variability of measurements employed and support

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harmonization across pediatric critical care studies for co-enrollment and meta-analyses. Evaluating these outcomes is imperative to understand the implications of critical illness and interventions being tested, but collection of post-discharge data can burden families, particularly those co-enrolled in multiple studies with overlapping post-discharge assessment intervals. For example, a family could be asked to complete the same instrument for two investigative teams during a similar time interval. The ability to share survey data across studies could decrease the burden placed on families and demonstrate a cohesive approach to clinical research. To pursue this goal, following approval from each study's leadership and regulatory groups, it is necessary to obtain consent from the participant to coordinate and share data across studies. Importantly, in addition to consent from the participants, data sharing between study teams may also require administrative approvals (e.g., data use agreement). Herein, we propose a novel method to obtain consent from participants for data sharing across studies. This approach was approved by the letter authors' institutional review boards.

Modifiable consent document.

Because studies being conducted across each pediatric intensive care unit are ever-changing and overlapping study populations are not consistently predictable, delineation of potential co-enrolling studies in a pre-written consent document is infeasible. We propose including the following modifiable component in the consent form to allow data sharing across studies for which a patient is co-enrolled:

> Your child was previously enrolled in _____ study. Do you give permission for this study's team and the study team of the previously enrolled study to share your child's health information (e.g., survey responses)? It is not always possible to share information between studies but, when possible, it may reduce the need for you to submit the same information twice and help collect research information more quickly.

Including this statement in the consent form demonstrates respect for persons by offering participants a choice while also striving to minimize burden. This is particularly important in the context of overlapping study populations, which is common in pediatric critical care (2). While decreasing participant effort for survey completion is one application of this tool, it could also be considered for data sharing of study-specific laboratory results or case report forms. In addition to decreasing a study team's burden, sharing these data also minimizes burden on patients and families by decreasing the need for blood draws and minimizing the number of people with protected health information access. To increase our ability to conduct large, multicenter pediatric critical care studies, we must be deliberate and collaborative in our approach to study procedures to optimize the experience for the patients and families we serve.

Copyright Form Disclosure:

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