



United States Critical Illness and Injury Trials Group

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The United States Critical Illness and Injury Trials (USCIIT) Group is an inclusive, grassroots “network of networks” with the dual missions of fostering investigator-initiated hypothesis testing and developing recommendations for strategic plans at a national level. The USCIIT Group’s transformational approach enlists multidisciplinary investigative teams across institutions, critical illness and injury professional organizations, federal agencies that fund clinical and translational research, and industry partners. The USCIIT Group is endorsed by all major critical illness and injury professional organizations spanning the specialties of anesthesiology, emergency medicine, internal medicine, neurology, nursing, pediatrics, pharmacy and nutrition, surgery and trauma, and respiratory and physical therapy. Recent successes provide the opportunity to significantly increase the dialogue necessary to advance clinical and translational research on behalf of our community. More than 200 investigators are now involved across > 30 academic and community hospitals. Collectively, USCIIT Group investigators have enrolled > 10,000 patients from academic and community hospitals in studies during the last 3 years. To keep our readership “ahead of the curve,” this article provides a vision for critical illness and injury research based on (1) programmatic organization of large-scale, multicentered collaborative studies and (2) annual strategic planning at a national scale across disciplines and stakeholders.

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Abbreviations: CCSC = Critical Care Societies Collaborative; CTSA = Clinical and Translational Science Award; LIPS = Lung Injury Prevention Study; NCAT = National Center for Advancing Translational Science; NIH = National Institutes of Health; OECR = Office of Emergency Care Research; PROOF = Program for Prevention of Organ Failures; USCIIT = United States Critical Illness and Injury Trials

The United States Critical Illness and Injury Trials (USCIIT) Group created clinical research infrastructure to reduce the barriers to investigation for the critical illness and injury communities in the United States.¹

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As an inclusive, grassroots “network of networks,” the USCIIT Group’s dual missions are to foster investigator-initiated hypothesis testing and to develop recommendations for strategic plans at a national level.² The USCIIT Group was funded in 2008 by a National Institutes of Health (NIH) (National Institute of General Medical Science) meeting grant (U13) with four aims³:

1. Establish an inclusive, nationwide network of experts to review published data, vet hypotheses, write clinical protocols, and generate pilot data that facilitate implementation of large clinical trials.

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2. Promote interactions and synergy across established research programs, both academic and nonacademic, to improve the robustness of clinical trials and test hypotheses in a US population.
3. Provide a venue to discuss education and training in the science of clinical trial design, conduct, analysis, and reporting for critically ill or injured patients.
4. Ensure patient protection and privacy by addressing the ethical, legal, and social implications of research in the specialized circumstance of critical illness or injury.

To these ends, the USCIIT Group provides a biweekly teleconference venue for investigator and NIH interinstitute communications; engages in a multisociety task force for annual research strategic planning; catalyzes Health and Human Services interagency dialogue for endorsement of transforming initiatives; seeks to coordinate research training nationally as a Clinical and Translational Science Award (CTSA) Thematic Special Interest Group; and fosters innovative, multidisciplinary, multicenter studies that typically start as investigator-driven clinical proposals. Typically, hypotheses are tested by multidisciplinary teams that openly solicit input and encourage collaboration among investigators with similar interests across institutions. The USCIIT Group is governed by a steering committee of investigators and by an organizing committee composed primarily of Health and Human Services staff. The USCIIT Group involves > 200 investigators across > 30 academic and community hospitals. Collectively, USCIIT Group investigators have enrolled > 10,000 patients from academic and community hospitals in studies during the last 3 years.^{4,5}

Significance

The USCIIT Group is endorsed by all major critical illness and injury professional organizations spanning the specialties of anesthesiology, emergency medicine, internal medicine, neurology, nursing, pediatrics, pharmacy and nutrition, surgery and trauma, and respiratory and physical therapy. The transformative nature of the USCIIT Group and its unique role in the United States have been recognized.⁶ The group plays an important role, as there is no federal agency or national organization in the United States that facilitates critical illness and injury research or strategic planning across specialties and the human developmental continuum. The USCIIT Group Thematic Special Interest Group also provides a new opportunity to leverage the huge investment in infrastructure across 60 academic sites (nodes) in the CTSA network. Finally, the USCIIT Group provides a network for the new

era of health services and comparative effectiveness research, as described recently by the leadership of the NIH, the Agency for Healthcare Research and Quality, and the new Patient-Centered Outcomes Research Institute.^{7,8} A spectrum of important deliverables is expected, including, but not limited to, the following:

- Create of a “network of networks” for critical illness and injury research for rapid data sharing, analysis, and reporting, leveraging the existing research infrastructure across 60 sites in the CTSA network.
- Efficiently conduct (in terms of recruitment and funding spent) multicentered studies, the results of which lead to optimized outcomes and reduce unwanted practice variance.
- Coordinate peer review for research protocol generation and presentation of consensus policies, procedures, results, and recommendations.
- Harmonize institutional review board submissions, working with national organizations such as the Public Health Ethical Research Review Board.
- Organize research education and training across the 60 sites supported by the NIH CTSA.
- Facilitate communication and create infrastructure to promote national emergency preparedness.
- Establish biobanks linked to robust clinical databases that can be used to identify biomarkers and genetic variation associated with outcome.

Finally, to address its missions globally, the USCIIT Group participates in the International Form of Acute Care Trialists (InFACT), a collaborative network of investigator-led research groups.⁹

VISION

The USCIIT Group’s collaborative approach enlists multidisciplinary investigative teams across institutions, critical illness and injury professional organizations, federal agencies that fund clinical and translational research, and industry partners. Recent successes provide the opportunity to significantly increase the dialogue necessary to advance clinical and translational research on behalf of our community. Operationally, this will depend upon leveraging resources available through the new CTSA Thematic Special Interest Group (NIH National Center for Advancing Translational Science; NCATS) and improved coordination of strategic planning with the Critical Care Societies Collaborative (American Association of Critical Care Nurses, American College of Chest Physicians, American Thoracic Society, and Society of Critical Care Medicine).

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