

American College of Emergency Physicians (ACEP) and the Society for Academic Emergency Medicine (SAEM) Joint Statement on Research During the COVID-19 Pandemic

As with environmental disasters and other crisis events, pandemics often present challenges within and beyond the clinical environment. Pandemics significantly impact medical research through decreased effort available for research due to necessary clinical duties, quarantined staff, disrupted research infrastructure and protocols, closed sites, limited travel, and confounding introduced by infection of trial subjects, as well as changes in the standard practices within the healthcare system. Given the uncertain duration of this pandemic, researchers should be prepared to introduce modifications to the conduct of research that will aid in the safe conduct and efficient completion of emergency medicine research in the current practice environment.

Emergency medicine is on the front line of pandemics, and emergency medicine investigators are uniquely positioned to study undifferentiated patients with symptoms consistent with COVID-19, patients diagnosed with COVID-19, and other related domains. In the spirit of disseminating best practices, and to provide a consensus on the conduct of emergency medicine research, the American College of Emergency Physicians (ACEP) and the Society for Academic Emergency Medicine (SAEM) together make the following recommendations:

Investigators should:

- Continue to adhere, to the greatest extent possible, to the principles of scientific and methodological rigor for new and existing projects
- Collaborate with other acute care researchers and professional societies to ensure the timely implementation of research supporting the efforts of frontline providers, including:
 - Rapid development and implementation of hypothesis-driven observational studies related to the COVID-19 pandemic, including diagnostic, therapeutic, and prognostic outcomes.
 - Rapid development and implementation of scientifically-sound and methodologically rigorous clinical trials related to COVID-19, with emphasis on quick turnaround and adaptive designs.
 - Development of a targeted COVID-19 research agenda that addresses issues such as timely identification and interventions, prioritization of study drugs/ intervention, coordination of study resources, and the use of central IRB review and approval of study protocols.
 - Development of research platforms, standard operating procedures, and consortiums to be deployed in the event of future pandemics, crises, or national emergencies.
- Consider social determinants of health, while engaging and involving the broader community in the implementation of any treatments or interventions
- Work closely with their institutional review board (IRB) and other regulatory bodies to facilitate rapid protocol review / revision / adaptation / contract review on COVID-19 related studies.
- Develop mechanisms to ensure that pre-existing clinical research protocols can be completed with as little disruption as possible to the plan outlined in the existing protocol.
- When feasible and appropriate, inform previously enrolled study participants of any changes to pre-existing research protocols that may result from the COVID-19 pandemic, including updated subject safety procedures, changes to study design or any other anticipated disruption of the management plan outlined in the original protocol.

- Consider use of Exception For Informed Consent (EFIC) and Waiver of Informed Consent (WIC) techniques where applicable to facilitate time-sensitive, potentially life-saving treatment; or when legally authorized representatives for critically ill patients are unable to provide consent or cannot be contacted in time due to infection control policy in place.
- Reduce potential infectious exposure for study team members and conserve personal protective equipment (PPE) by utilizing electronic, video or telephonic consenting / interviewing / monitoring techniques, minimizing in-person interactions between subjects and study team members, utilizing minimal specimen procurement and drug administration strategies and utilizing electronic and telehealth for follow-up monitoring.
- Current animal-based research not associated with the COVID-19 outbreak should be managed responsibly and humanely. As feasible, research should continue with appropriate social distancing in the laboratory setting as well as limiting workers to essential functions/experiments.

Departmental Research Administration should:

- When feasible and appropriate, support junior and early career researchers by creating alternative opportunities to large scale funded clinical trials (e.g., observation cohort studies, retrospective studies on collected data, open sharing of de-identified patient-level data, small pragmatic trials, involvement in data analysis and manuscript preparations, teaching and disseminating knowledge online).
- Provide resources and equipment for remote work to research staff if applicable.
- Develop strategies to keep research staff employed by either performing research activities (e.g., supporting COVID-19 research, working on existing research projects remotely), or being redeployed to clinical or clinical support roles.
- Facilitate interdisciplinary and interprofessional research opportunities that incorporate all aspects of emergency care (e.g., pre-hospital, emergency department, telehealth).

Grantors of research funding should:

- Consider deadline extension for grant applications, or provide assistance in obtaining no-cost extensions, in line with NIH practice.
- Support junior and early-career emergency medicine researchers by providing funding opportunities for funding of observational cohort studies, retrospective studies on collected data, small pragmatic trials, and other alternatives to large-scale prospective clinical trials.
- Centrally coordinates between sites and networks to capitalize on research efforts.

Institutional Offices supporting research should:

- Develop standing contingency plans that can be activated in times of pandemics, national emergencies, or other crisis events (e.g., remote functioning of the IRB, access and pathways to data, follow-up plan for previously enrolled patients, methods to safeguard subject privacy/confidentiality during remote operations, structured plan for halting and re-starting recruitment).
- Develop financial continuity plans for emergencies that enable investigators to maintain external funding support for work performed remotely or otherwise modified to be performed under changing clinical conditions.
- Work to expedite review and approval of research proposals relating to COVID-19, understanding the fast-moving pace of this pandemic.

- Centrally coordinates trials across networks to prevent duplication of efforts, maximize startup activity and leverage bandwidth across institutions.

Professional Organizations, including associations of healthcare workers and peer-reviewed journals that publish medical reports, should:

- Facilitate the efficient dissemination of knowledge gained. Examples include late-breaking submission for scientific conferences, virtual presentations, and fast-track peer-reviewed journal publications of COVID-19 related research.

Additional Resources:

- Council on Governmental Relations (COGR) - [Institutional and Agency Responses to COVID-19 and Additional Resources](#)
- National Institutes of Health (NIH) [COVID-19 guidance](#)

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