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IMPACT OF COVID-19 PANDEMIC ON THE CONDUCT OF SURGICAL RESEARCH

The COVID-19 pandemic has resulted is significant disruptions in the conduct of basic and clinical research around the world. Social distancing policies have led to closure of basic science laboratories, with the exception of labs focused on COVID-19 clinical testing or research. Lab personnel have been required to interrupt experiments, store cells and biological samples, and cull experimental animals. Many labs have continued to hold meetings virtually and have increasingly focused on data analysis and manuscript preparation while awaiting the ability to resume experiments.

While there has not been any interruptions in NIH and other federal funding agencies, some research foundations have cancelled their annual grant programs, while others have pledged support towards COVID-19 projects. The NIH has extended submission deadlines for new grant applications, and funded labs have been offered flexibility regarding expenditure of funds, extension of budget periods and post-award reporting requirements. Funded investigators can apply for administrative supplements to existing NIH grants if and when financially impacted by the COVID-19 crisis [1]. New grant application cycles for federal funding in the US have not been affected, but funding priorities may be altered in response to the global call for COVID-19 research.

Starting in March, many academic institutions started mobilizing funding to stimulate basic, translational and clinical research on COVID-19. The large influx of protocol submissions for prospective studies ranging from COVID registries, tissue collection, and experimental therapies rapidly flooded IRBs committees. In order to prioritize expedited review and approval of COVID-19 projects, and to speed-up enrollment, institutions most affected by the pandemic were instructed to put non-COVID research protocols on hold; investigators were requested to interrupt all research activities. Investigators at these institutions were also notified that their research staff would be redeployed to assist with COVID-19 protocols. Exceptions have included cancer protocols at some but not the majority of institutions, while others have had to temporarily halt accrual of new subjects and demonstrate minimal research support for ongoing data collection in order to be allowed to proceed on a case-by-case basis.

The impact of these policies has been most disruptive for institutional, multicenter and international interventional and therapeutic trials. Since March, randomized clinical trials as well and prospective trials have been placed on hold with respect to both enrollment and data collection at institutions most affected by the pandemic in the US, UK, Northern Italy and Spain. These delays will impact study initiation and completion, reporting of trial results, which in turn will holdup clinical implementation of major therapies.

Several important steps should be taken by principal and site investigators during this pandemic to minimize the impact of this crisis on capture of high-quality research data. Protocol amendments and/or addendums should be filed with local or central IRB's to permit extensions in study visit windows to assess clinical endpoints following study procedures. Taking into account restriction in outpatient visits and reluctance of patients to come to medical facilities, standard in-person visits for evaluation should be replaced with telehealth visits when possible (i.e. when focused physical examination and/or testing is not required). Study questionnaires can also be administered remotely, and consideration should be given to complete monitoring visits virtually rather than in-person.

As institutions resume research operations in the next several weeks to months, upon lifting of IRB restrictions on protocols, it will be equally important for investigators to adapt to this new and uncertain hypervigilant environment. Eligibility criteria for enrollment and study completion will need to incorporate COVID-19 testing at various timepoints along treatment, particularly in cancer patients receiving neoadjuvant and adjuvant treatment. Telehealth visits will continue to play an important role and should be used when possible for screening, consent, and follow-up visits. It is to be expected that enrollment in clinical trials may be profoundly impacted by the fear of rampant nosocomial COVID infection in medical facilities and hospitals. Strategies will need to be developed to reassure potential trial subjects that their risk of potential exposure will be minimized.

Finally, the impact of the COVID-19 crisis on funding of surgical trials, in particular, is of grave concern. In several European countries, national major funding bodies have suggested that the majority of their research funding will be allocated towards COVID-19 protocols for the next 2-3 years. This may not only impact renewal of ongoing projects, but also initiation of new projects in several areas of unmet need including surgery and cancer. Given the current environment, the global surgical community may be faced with having to find alternative mechanisms for funding of non-COVID-related research that relies almost exclusively on professional societies, industry, research foundations, and philanthropic sources.