FOURTH ROUND OF UPDATES TO THE FDA GUIDANCE FOR CLINICAL TRIAL RESEARCHERS AMID COVID-19 PANDEMIC

September 23, 2020

THE U.S. FOOD AND DRUG ADMINISTRATION ("FDA") AGAIN SUPPLEMENTS ITS MARCH 18 GUIDANCE ENTITLED "CONDUCT OF CLINICAL TRIALS OF MEDICAL PRODUCTS DURING COVID-19 PUBLIC HEALTH EMERGENCY"

The FDA has added content to the question-and-answer appendix in its clinical trial guidance for industry, investigators, and institutional review boards. The updated guidance is posted here, and a brief summary of key provisions follows.

A CLINICAL TRIAL INVESTIGATOR MUST REVIEW ALL INVESTIGATIONAL NEW DRUG APPLICATION SAFETY REPORTS AND REPORT ALL SERIOUS AND UNEXPECTED ADVERSE EVENTS TO THE INSTITUTIONAL REVIEW BOARD (IRB)

The Agency has clarified that it is not acceptable for an investigator to review only certain IND safety reports. In order to fulfill his or her obligations to protect the safety of all trial participants (21 CFR 312.60), the investigator must not limit the review process to only safety reports that ultimately result in a change to the investigator brochure, informed consent, or protocol. Additionally, investigators must report all, and not just certain, "unanticipated problems involving risk to human subjects or others" to the IRB (21 CFR 312.66). Generally, any serious and unexpected adverse event that meets the criteria for safety reporting would likewise trigger the investigator's IRB reporting obligation.

CONCLUSION

Although the COVID-19 public health emergency continues to impact the conduct of clinical trials of medical products, including drugs, devices, and biological products in unprecedented ways, the FDA remains committed to the IND safety reporting process and its essential role in protecting the safety of trial participants. Investigators must fulfill their responsibilities to protect the safety of trial participants in a clinical investigation.

If you have any questions about these pharmacy measures, please contact a member of Hancock Daniel's Life Sciences team. For any other concerns arising from the pandemic, please contact a member of the firm's COVID-19 Task Force.