

Washington, DC 20548

August 10, 2020

441 G St. N.W.

The Honorable Elizabeth Warren United States Senate

Dear Senator Warren:

Thank you for your letter, jointly signed by Ranking Member Bernard Sanders, Senate Committee on the Budget and Senator Sherrod Brown, requesting that the Government Accountability Office review issues involving the operation of commercial Institutional Review Boards (IRBs), the private, for-profit entities that approve drug research and other studies involving human subjects.

GAO accepts your request as work that is within the scope of its authority. Consistent with GAO Congressional Protocols, given broad congressional interest in these issues, and upon agreement with your staff, we will allow other congressional committees of jurisdiction and interested members of Congress to become co-requesters of this work.

At the current time we anticipate that staff with the required skills will be available to initiate an engagement in about six months. Your request has been assigned to Ms. A. Nicole Clowers, Managing Director, Health Care. Closer to the time GAO can start this engagement, Ms. Clowers or a member of her team will contact your office to confirm that this request continues to be your priority for us. As applicable, we will also be in contact with the cognizant Inspector General's office to ensure that we are not duplicating efforts. If an issue arises during this coordination, we will consult with you regarding its resolution.

If you have any questions, please contact Ms. Clowers at 202-512-4010 or clowersa@gao.gov, or Mr. David Lewis, Assistant Director, Congressional Relations, on my staff at 202-512-7176 or lewisd@gao.gov.

Sincerely yours,

Will' - Brown

Orice Williams Brown Managing Director Congressional Relations

Ref: CCAR 20-0731