University of Michigan
IRB Authorization Agreement
U-M as the IRB of Record for an External FWA-holding Institution

Name of Reviewing Institution Providing IRB Review (IRB of Record)

Name of Designated Institution:	University of Michigan – IRB-HSBS
FWA#:	000004969
IRB Registration #:	00000245, 00000246, 00000248

Name of Relying Institution

Name of Relying Institution:	James Madison University
FWA#:	00007339
IRB Registration #:	00004226

The Officials signing below agree that ***Relying Institution*** and IRB will rely on IRB-HSBS for review and continuing oversight of its human subjects research described below.

☒ **This agreement is limited to the following specific protocol(s):**

eResearch Study Number:	HUM00186024
Title of Study:	Political Elite Survey 2020
Principal Investigator:	Alexander Furnas
Sponsor or Funding Agency:	Tides Advocacy Foundation
Principal Investigator at Relying Institution:	Timothy LaPira
IRB Number at Relying Institution:	# 21-2184

☐ **This agreement applies to the following category of research projects:**

By signing this agreement, both institutions have agreed that IRB-HSBS will serve as the IRB of Record for the Relying Institution's participation in the above-referenced study and are agreeing to uphold their institutional responsibilities as outlined in this document. The Relying Institution remains responsible for ensuring compliance with IRB-HSBS's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official at University of Michigan:

Lois Brako

Signature

11.4.2020
Date

Lois Brako, Ph.D.
Print Full Name

Assistant Vice President for Research – Regulatory and Compliance Oversight
Institutional Title

Signature of Signatory Official at the Relying Institution:

Anthony L Tongen
Signature

11/6/20
Date

Anthony Tongen, Ph.D.
Print Full Name

Vice Provost, Research and Scholarship
Institutional Title

Division of Responsibilities

Responsibilities of the reviewing IRB (IRB-HSBS):

1) Maintain a Federalwide Assurance (FWA) with OHRP and the registration of its IRBs;

2) Maintain a Board membership that satisfies the requirements of 45 CFR 46 and provides special expertise as needed from Board members or consultants to adequately assess all aspects of the study;

3) Make available to the local institution upon request IRB-HSBS Standard Operating Procedures;

4) Perform initial reviews, continuing reviews, reviews of protocol amendments, reviews unanticipated problem and incidents of serious and/or continuing non-compliance, and reviews of any other documents as needed consistent with applicable regulations and with IRB-HSBS SOPs;

5) Maintain and make accessible to the IRB at the Relying Institution, the IRB-HSBS application, communications with the Principal Investigator, approvals and disapprovals, approved consents, and other study documentation. Upon request, the IRB-HSBS will provide copies of minutes of IRB meetings relevant to the protocol;

6) Provide Relying Institution with approved informed consent template(s), if relevant to the Relying Institution's role in the research. Modifications will be subject to approval by IRB-HSBS;

7) Provide immediate notification to the IRB at the Relying Institution in the event of a suspension or restriction of IRB-HSBS's authorization to review studies; and

8) Notify the Relying Institution of any IRB-HSBS policy decisions or regulatory matters that might affect the institution's reliance on IRB-HSBS reviews or performance of the research at the local institution.

Responsibilities of the relying IRB and local institution (Relying Institution):

1) Maintain a Federalwide Assurance (FWA);

2) Maintain a human subjects protection program, as required by the DHHS OHRP;

3) Provide IRB-HSBS with the name and address of a local contact person who has the authority to communicate for the IRB at the Relying Institution (e.g., the local IRB administrator). Provide this information to the relying site PI and study team;

4) Notify IRB-HSBS immediately if there is ever a suspension or restriction of the IRB at the Relying Institution's authorization to review studies;

5) Ensure that the investigators and study staff at the Relying Institution are appropriately qualified and meet the institution's standards for eligibility to conduct research;

6) Promptly notify IRB-HSBS if there is an unanticipated problem, a serious and/or continuing non-compliance determination, suspension or restriction of the investigator at the Relying Institution;

7) Ensure the safe and appropriate performance of the research at the Relying Institution according the IRB-HSBS approved protocol. This includes, but is not limited to: monitoring study compliance; reviewing major protocol violations, and any unanticipated problems involving risk to subjects or others that occur at the institution; ensuring a mechanism exists by which complaints about the research can be made by local study participants or others. Any actions taken as a result of problems identified in these areas should be reported to IRB-HSBS and the study's Principal Investigator. IRB-HSBS will collaborate with the Relying Institution regarding external reporting to regulatory agencies, as appropriate;

8) Require the PI at the Relying Institution to maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations; and

9) Require the PI at the Relying Institution to maintain compliance with state or local laws, regulations, policies, or ancillary review processes relevant to the research and related to the protection of human subjects (e.g., conflicts of interest, child abuse reporting, HIPAA Authorization/Privacy Board review, etc.).

Attachment A

Description of ALL Engaged Research Activities to be Conducted by Relying Institution

Accessing identifiable data