Protocol Number: H21005
Funding Agency: Internal
Review Type: Exempt, Category 2
Title: Public Perceptions of Fake News, Allegations of Fake News, and Embarrassing Video Content
Number of Subjects: N/A

February 9, 2021

Daniel S. Schiff
GT Public Policy
schiff@gatech.edu

Dear Dr. Schiff:

The Institutional Review Board (IRB) has carefully considered the referenced protocol. Your approval is effective as of **February 9, 2021**. The proposed procedures and affiliated documents are exempt from further review by the Georgia Tech Institutional Review Board.

Minimal risk research qualified for exemption status under 45 CFR 46 104d.category 2.

Thank you for allowing us the opportunity to review your plans. If any complaints or other evidence of risk should occur, or if there is a significant change in the plans, the IRB must be notified.

For your reference, detailed PI responsibilities are included following this letter. If you have any questions concerning this approval or regulations governing human subject activities, please contact me at 404.385.2175.

Sincerely,

Kelly Winn

Kelly Winn, MS, CIP, RAC
Director of HRPP & Regulatory Affairs
Office of Research Integrity Assurance
Georgia Institute of Technology

cc: Barbara Henry, IRB Chair

Principal Investigator Responsibilities

Investigators who involve human subjects in their research have several specific responsibilities, some institutional, some regulatory, as indicated below:

A. Investigator Responsibilities Required by Georgia Institute of Technology Institutional Review Board

All investigators at Georgia Tech must comply with these Policies & Procedures when conducting research involving human subjects.

Investigators must:

1. Obtain approval from the Georgia Tech Institutional Review Board before undertaking research with human subjects.
2. Receive a written letter of approval from the Office of Research Integrity Assurance to document that IRB review occurred and approval was given. (Such letters of approval are frequently required by the funding sponsor and by publishers prior to publication in refereed journals).
3. Conduct every aspect of the project as approved by the Georgia Tech IRB.
4. Seek IRB review and approval by prior to revising the protocol. (The only exception to this policy is in situations where changes in protocol are required to eliminate apparent, immediate hazards to subjects).
5. Promptly report any unanticipated problems involving risks to subjects or others.
6. Assume full responsibility for selecting subjects in strict accordance with the inclusion/exclusion criteria outlined in the application materials.
7. Use only IRB-approved consent language. Approved consent documents are date-stamped by Office of Research Integrity Assurance. While there is no federal requirement that consent documents must be date-stamped, the specific approved language must be used in the consent process.
8. Comply with the applicable DHHS and FDA regulations, including the investigator responsibilities specified by both agencies.

B. Investigator Responsibilities Required by DHHS Regulations at §45CFR46

1. IRB Review and Approval

Investigators are responsible for obtaining IRB approval before beginning any human subjects research (§45CFR46.109(a) and (d)). Investigators are responsible for providing the IRB with sufficient information and related materials about the research (e.g., grant applications, research protocols, sample consent documents) so that the IRB can fulfill its regulatory obligations, including making the required determinations under §45CFR46.111 and, if applicable, subparts B, C and D. Investigators should follow institutional policies and procedures for IRB review that are required by HHS regulations at §45CFR46.103.

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB. Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary:

2. Informed Consent

Investigators are responsible for obtaining and documenting the informed consent of research subjects or their legally authorized representatives, unless the IRB approves a waiver of informed consent, or a waiver of documentation of informed consent, respectively (§45CFR46.116, §45CFR46.117). Investigators must give a copy of the informed consent document to each research subject (or the subject's legally authorized representative), and keep the signed original or a copy of it for their records (§45CFR46.117(a); §45CFR46.115(b)). When the documentation requirement is waived, the IRB may require investigators to provide subjects with a written statement regarding the research (§45CFR46.117(c)(2)).

3. Amendments

Investigators are responsible for obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects (§45CFR46.108(a)(3)(iii)). If investigators wish to modify an ongoing IRB approved research study, they must submit a request to the IRB and receive IRB approval before implementing the proposed modification, unless the change is designed to eliminate an apparent immediate hazard to subjects (§45CFR46.103(b)(4)). If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes promptly to the IRB. The HHS protection of human subjects regulations allow for expedited review and approval of requests for minor changes in previously approved studies (§45CFR46.110(b)(1)).

4. Amendments that Render Exempt Research Nonexempt

Investigators should consult with the appropriate institutional authority whenever questions arise about whether planned changes to an exempt study [defined at §45CFR46.104(d)] might make that study nonexempt human subjects research. The designated entity at Georgia Tech for making a determination of exemption is the Institutional Review Board. If a determination of exemption is made by an authorized member of the IRB, the Office of Research Integrity Assurance will issue a letter of exemption. *Investigators at Georgia Tech do not have the authority to make an independent determination that human subjects research is exempt.*

5. Progress Reports and Continuing Review

Continuing review of minimal risk research is not required, unless otherwise determined by the IRB (§45CFR46.109(f)(1)). If research is determined and justified to require continuing review, investigators are responsible for ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution's OHRP-approved Federalwide assurance (§45CFR46.108(a)(3), (45CFR46.109(e).

Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review prior to the expiration date of the current IRB approval. Investigators are responsible for submitting all required materials and information for the IRB to meet its regulatory obligations, and should follow the institutional policies and procedures for continuing IRB review of research that are required by HHS regulations at §45CFR46.109(e) and referenced in the institution's OHRP-approved Federalwide assurance.

If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study (§45CFR46.103(a)), except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB (§45CFR46.108(a)(4)). When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or

analyzing identifiable private information about human subjects (§45CFR46.103(a)). Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

6. Records the Investigator Must Keep

The HHS protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research (§45CFR46.115(b)).

Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research [§45CFR46.115(b)] that *must be retained by investigators for at least three years after completion of the research*, unless the IRB waived the requirement for informed consent or for documentation of informed consent (§45CFR46.117).

Investigators must retain the records in hardcopy, electronic or other media form accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (§45CFR46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the institution's Policies & Procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at §45CFR46.115(b). Other regulations or policies may apply to the retention of records, including study data.

7. Additional DHHS Regulatory Requirements

In certain circumstances, investigators are responsible for meeting the following additional regulatory requirements:

- providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others §45CFR46.108(a)(4);
- providing to the IRB prompt reports of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB (§45CFR46.108(a)(4));

C. Conflict of Interest

A conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to the Institute, such that an independent observer might reasonably question whether the individual's professional actions or decisions are influenced by considerations of personal gain, financial or otherwise. A conflict of interest depends on the situation, and not on the character or actions of the individual.

Conflicts of interest are common and practically unavoidable in a modern research university. At the Georgia Institute of Technology, conflicts of interest can arise out of the fact that a mission of the Institute is to promote public good by fostering the transfer of knowledge gained through Institute research and scholarship to the private sector. Two important means of accomplishing this mission include faculty consulting and the commercialization of technologies derived from faculty research. It is appropriate that faculty be rewarded for their participation in these activities through consulting fees and sharing in royalties resulting from the commercialization of their work. These rewards may be misunderstood or misconstrued and must therefore be carefully managed and appropriately disclosed.

Investigators who have a substantial financial interest in the outcome of the research, and those whose family members have a substantial financial interest in the outcome of the research, must, during the consent process,

disclose the conflict to potential subjects. This includes providing a written disclosure on the consent form to explain and document the disclosure.

An appropriately managed conflict that is fully disclosed to participants does not always negatively affect recruitment. Appropriately managed conflicts are registered with the Georgia Tech Research Corporation Office of Conflict of Interest Management, and approved plans for management are to be on record with that office. Questions should be forwarded to the Office of Research Integrity Assurance.

There will be cases in which the Georgia Institute of Technology has a financial interest in the research project, and in those cases, disclosure must likewise be made and documented during the consent process.

Finally, no investigator who is a member of the reviewing IRB participates in the review of any study on which he has a potential conflict of interest or is named on the research team.

To contact the Conflict of Interest Office for more information, please visit http://coi.research.gatech.edu/