IRB ID #: 202004501

To: Amy Pearlman

From: IRB-01 DHHS Registration # IRB00000099,
Univ of Iowa, DHHS Federalwide Assurance # FWA00003007

Re: Effect of COVID-19 on mental health, training, and career planning of undergraduate pre-medical students, medical students, and medical and surgical residents.

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 07/28/20

Next IRB Approval Due Before: N/A

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
New Project	Full Board:	Children
Continuing Review	Meeting Date:	Prisoners
Biennial Review	Expedited	Pregnant Women, Fetuses, Neonates
Modification		
	Exempt	

Source of Support:

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

The following documents have been submitted for the above review and approval:

Subject Data Collection Instruments	MedicalTraineeSurvey_EffectOfC.pdf
Assurance Document	202004501_assurance-document.pdf
Exempt Information Sheet	exempt-information-sheet (2).rtf
Recruitment: Advertisements	Master Ads Doc.docx

This approval has been electronically signed by IRB Chair:
Brian Bishop, CIP, MA

07/28/20 1037

As Principal Investigator, you are responsible for ensuring this project is conducted in compliance with all applicable federal, state, and local laws and regulations, institutional policies, and requirements of the IRB, which include, but are not limited to, the following:

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. The research is approved to be conducted as described in the HawkIRB application. The addition or omission of study activities is not permitted without prior IRB review and approval. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. The IRB has approved all recruitment strategies described in the application. It is not necessary to use all of thesestrategies, but no additional recruitment strategies may be used without IRB approval.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. This includes data identified with a study ID# for which a link exists between the ID# and subject identifying information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards tosubjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB. Reports from the investigator to the IRB must be submitted via HawkIRB within ten working days of the event or within 10 working days of the PI becoming aware of the event.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be

maintained fora period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application. For research that involves Protected Health Information(PHI) under HIPAA, the research records must be kept for a period of six (6) years folling the close of the research project.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.