

Board Action Date: 08/04/2022	Work Order Number: 1-1571037-1
Sponsor: Altus Assessments	Protocol Approval Expires: 08/04/2023
Sponsor Protocol Number: Amended Sponsor Protocol Number:	Continuing Review Frequency: No CR Required
IRB Tracking Number: 20224078	
Protocol Title: Determining the impact of the Altus Suite(c) assessments on the process of selecting ophthalmology residents	

THE FOLLOWING ITEMS ARE APPROVED:

Altus Attitudinal Survey #34926148.0
Protocol (07-18-2022)

Please note the following information about this review:

Under the revised common rule (effective 1-21-2019), continuing review by the Board of the above referenced research is not required; however, the IRB will maintain our records and continue responsibility for exercising administrative and regulatory oversight of this research. The IRB will automatically charge an Ongoing Oversight fee for this administrative effort unless we are notified the research is closing. To avoid unnecessary fees due to closure, a closure form must be submitted for each site 30 days prior to expiration.

The Board found that this research meets the requirements for a waiver of consent under 45 CFR 46.116(f)[2018 Requirements] 45 CFR 46.116(d) [Pre-2018 Requirements]

WCG IRB requires an "Initial Review Submission Form" and additional review materials be submitted for each investigative site seeking approval to conduct this research. The form and list of required documents can be found at www.WCGIRB.com. WCG IRB will begin reviewing investigator submissions upon written notice from you that the approved documents are acceptable. Please note that investigator submissions will not be reviewed until such notice is received by WCG IRB. If you have not provided us a list of the applicable investigators, please provide us with that information. To give approval to review investigator submissions, contact WCG IRB Client Services at clientservices@wcgirb.com.

ALL WCG IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization submitting shall promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

If this study includes data monitoring committee/data safety monitoring board, please note that the reports of all meetings of this committee should be submitted to the IRB even if the outcome of the meeting results in no changes to the study.

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT this IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.



Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using WCG IRB to provide oversight for your research project.

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