THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

Human Subjects Protection Program

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Date:	March 06, 2019
Principal Investigator:	Zuleima Cota
Protocol Number:	1902366508
Protocol Title:	Author's in the driver's seat: fast, consistent, computable phenotype data and ontology production
Determination:	Approved
Expiration Date:	March 04, 2024

Documents Reviewed Concurrently:

Data Collection Tools: *6 Questionnaires 2-23-19.docx*
HSPP Forms/Correspondence: *3 Application_2-5_v2018_6_02-23-19.pdf*
HSPP Forms/Correspondence: *4 appendix_waiver_v201_2-15-19.pdf*
HSPP Forms/Correspondence: *4 Dept. IRB Scientific Reviewer Approval 1-31-19.pdf*
HSPP Forms/Correspondence: *5 list_of_research_personnel_2-3_v2018_2-23-19.pdf*
HSPP Forms/Correspondence: *Advisor Sig.msg*
Informed Consent/PHI Forms: *1 Informed Consent_02-23-19.docx*
Informed Consent/PHI Forms: *1 Informed Consent_02-23-19.pdf*
Other Approvals and Authorizations: *COI Certification Complete for 1902366508.msg*
Recruitment Material: *2 Recruitment Invitation_02-23-19.docx*

Regulatory Determinations/Comments:

- The project is not federally funded or supported and has been deemed to be no more than minimal risk.
- The project listed is required to update the HSPP on the status of the research in 5 years. A reminder notice will be sent 60 days prior to the expiration noted to submit a 'Project Update' form.
- Waiver of Documentation of Informed Consent (45 CFR 46.117(c)(1)): As documented in the file, the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality; the research involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

This project has been reviewed and approved by an IRB Chair or designee.

- The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

- All research procedures should be conducted according to the approved protocol and the policies and guidance of the IRB.
- The Principal Investigator should notify the IRB immediately of any proposed changes that affect the protocol and report any unanticipated problems involving risks to participants or others. Please refer to Guidance Investigators Responsibility after IRB Approval, Reporting Local Information and Minimal Risk or Exempt Research.
- All documents referenced in this submission have been reviewed and approved. Documents are filed with the HSPP Office.