Determination of Human Subject Research

Colorado State University
Research Integrity & Compliance Review Office, Institutional Review Board

If there is any question as to whether your project is human subject research, please submit this form to the IRB; complete all sections and email to: RICRO_IRB@mail.colostate.edu

Principal Investigator:
Phone:
Email:

Alt. Contact:
Department: Phone:
Email:

Project title:

Purpose of the project: provide a 3-5 sentence lay-language description.

Project Procedures: describe all project procedures, include the source of data or specimens and circumstances under which they were/will be collected.

Is this activity RESEARCH?
Research: A systematic investigation designed to develop or contribute to generalizable knowledge.

Do you consider this project to meet the definition of research? Yes [ ] no [ ]
If “no” explain why:

Does this research involve HUMAN SUBJECTS?

Does your project include obtaining data or specimens about a living individual through intervention or interaction or by collecting personal identifying information about the individual? yes [ ] no [ ]

Does your project involve the use of existing data or specimens? yes [ ] no [ ]
If “yes” answer the following:

• Do the data or specimens contain identifiable private information (i.e. the identity of the subject is or may be readily ascertained or can be associated with the information?) yes [ ] no [ ]

• Are the data or specimens coded such that a link exists that could allow the data or specimens to be identified? yes [ ] no [ ]
   If ‘yes’, is there an agreement prohibiting the PI and their staff access to the key to the code? yes [ ] no [ ]

• Were the data or specimens originally collected for this project? yes [ ] no [ ]

• Were the data or specimens originally collected during standard yes [ ] no [ ]
Were the data or specimens originally collected for research purposes under an IRB approved protocol? ................................................................. yes □ no □

Is this FDA-regulated research? ................................................................. yes □ no □

Does your project include testing the safety and efficacy of a drug or device in a living individual? ................................................................. yes □ no □

Does your project include an In Vitro Diagnostic Device? ................................. yes □ no □

Other Considerations:

Does your project involve human embryonic stem cells (hESC), adult human stem cells, pluripotent cells or somatic nuclear transplantation? ................................................................. yes □ no □

Does your project involve the use of fetal tissue? ................................................................. yes □ no □

External Funding:

Is your project supported by external funding? ................................................................. yes □ no □

If ‘yes’: provide a copy of the grant application, contract, agreement, etc. for this project with this form. Funding is provided from the USDA through a cooperative agreement.

Thank you for your complete application.

The IRB will send you a Notice of Determination of Human Subject Research or will contact you if more information is needed.