1 PURPOSE
1.1 This procedure establishes the process for researchers who are not employees, students or agents of UC Davis to conduct human subject research at UC Davis.
1.2 The process begins when the IRB receives notice that an external researcher is planning to conduct human subject research at UC Davis.
1.3 The process ends when the IRB Director or Associate Director determines that the research is acceptable and can be done at UC Davis or unacceptable and cannot be done at UC Davis and the documents are filed in SharePoint.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 External Researchers are required to notify UC Davis IRB Administration of any plan to conduct research involving human subjects at UC Davis.
3.2 The Director or Associate Director of IRB Administration will determine if the research is acceptable.

4 RESPONSIBILITIES
4.1 External Researchers, are responsible for notifying the UC Davis IRB and submitting required documents for review.
4.2 The Director and Associate Director are responsible for making the determination and providing notification to the external researcher.

5 PROCEDURE
5.1 Requests from external researchers to conduct human subject research at UC Davis are forwarded to hs-education@ucdavis.edu. Requests must include:
   5.1.1 Protocol;
   5.1.2 Consent Document, if applicable;
   5.1.3 All documents subjects will receive or review; and
   5.1.4 Evidence of IRB approval or an exemption determination.
5.2 IRB Education staff forward requests and associated documents to the Director and the Associate Director.
5.3 The Director or Associate Director review the request and associated documents and determine whether the research is acceptable, the consent process is adequate and the external researcher’s IRB has either approved the research or determined the research to be exempt.
5.4 If the Director or Associate Director have concerns regarding the acceptability of the research in terms of subject matter or participants, Student Affairs or another applicable department may be contacted to discuss the proposed research.
5.5 If the Director or Associate Director determines the research to be acceptable, the IRB will notify the investigator and alert the potential research participants, if possible and appropriate.
5.6 If the Director or Associate Director determines the research is not acceptable, the IRB will notify the external researcher of the decision and provide an opportunity for revisions to the research to enhance its acceptability.
5.7 Copies of the correspondence, protocol, consent and other document and IRB approval or exemption determination will be maintained in a file in SharePoint labeled “External Researchers.”

6 MATERIALS – None

7 REFERENCES - None