

STAR Process for Evaluating Human Subjects Research Applications

1. Human Subjects application and supporting materials are submitted to PIR via electronic form found on STAR Webpage <https://www.pima.edu/administration/star/index.html> or sent to the applicant by email.
 - a) If an applicant does not follow the procedure/ instructions as described on the STAR website, it is necessary to have additional communication with her or him to provide the requisite information regarding the HSR process and what is needed to submit an application. This may involve both verbal and email communications.
 - b) Additional communication is also sometimes necessary to answer questions regarding the HSR process.
 - c) Note: The HSR application needs to be updated to reflect the changes to the SPG, Regulation, and User Guide.
2. Once an application is submitted and determined to be complete by the project lead, the project lead evaluates the individual components involved in the application: the researcher's credentials, rationale for the research, scholarly context, research design, informed consent forms, the subject population, risk to benefit ratio(s), PCC resources needed to perform research, previously approved IRB materials (if submitted), and complete research proposals (if submitted). If the application or materials need to be completed, amended or corrected, the project lead communicates this to the applicant, and work with her/him until all documents are on the best of their shape and content.
3. Once an application and related materials are reviewed by the project lead, the 2nd reviewer reviews the materials and gives her/his comments and opinion on the decision to the project lead. The project lead and the 2nd reviewer agree on the recommendation (Approved/Non-approved/Exempt/Non-applicable to HSR) and prepare corresponding decision letter for the Assistant Vice Chancellor of STAR.

Note: Materials are evaluated on the criteria as set forth on the Dept. of Human Health Services, Office of Human Research Protections and PCC policy related to use of PCC resources

4. Upon completion of the application review, the Assistant Vice Chancellor of STAR is provided with a decision letter containing the rationale of the decision, including the comments describing risk-level and need resources, in addition to all application materials.
5. Assistant Vice Chancellor of STAR decides on whether to accept or reject the project or whether it should be forwarded to the PCC Legal Counselor or Human Subject Review Committee for further review or consideration.
6. Depending on the decision made in Step 5, the Assistant Vice Chancellor of STAR will either notify the applicant on PCC's decision to accept or reject the proposal, or will forward the project to the PCC Legal Counselor or Human Subject Review Committee. If an application is forwarded to the Human Subject Review Committee, the Executive Director of PIR will notify the applicant of the final decision.

TIMELINE (Time per step):

1. Due to the fact that much communication can occur with an applicant prior to the completion of an HSR application (and this may be intermittent and time consuming in itself), this is the most variable stage of this process and can take up to several months before a completed application is available for review. Recommendation: The review "clock starts" when a complete application** is submitted.
2. Once a complete application has been received, the primary review should be completed within one month (*ceteris paribus*). A subsequent review can be performed forthwith after the first (in another week or two).
3. Once the review is completed and submitted to the Assistant Vice Chancellor of STAR, a decision of acceptance/denial/forwarding to the Legal Counselor or Human Subject Review Committee should be completed within one month.

4. If the application is forwarded to the Legal Counselor or Human Subject Review Committee, it may take up to an additional two months to receive a decision on the recommendation.

NOTE: The Human Subject Review Committee does not meet during the summer; therefore no applications will be reviewed in between May to September.

5. Once a decision is made, whether by the Assistant Vice Chancellor of STAR alone or in conjunction with the Legal Counselor or Human Subject Review Committee, the applicant will be notified by email within three business days of the decision.