STUDY STATUS REPORT

For Medical (Clinical), Scientific (Non-Clinical), Animal, Plant, or Humanities Research Studies

Study Title_____

Principal Investigator_____

Department/College_____

Mailing Address_____

Phone_____

Email_____

I hereby confirm that I have carefully examined the details included in this report form and affirm that the information provided is correct and complete.

Signature of Principal Investigator_____

Date_____

1. Type of Report

☐Interim

☐Continuing Review

2. Study Summary

Provide a concise overview of the study objectives along with progress achieved so far, noting whether outcomes align with the initial expectations.

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3. Review Category

This study qualifies for :

☐Full Review

☐Expedited Review

The study was approved as expedited review:
☐Yes ☐ No
Expedited Category
The study has stopped enrolling new participants, with activity limited to follow-up only :
☐Yes ☐ No
Remaining activities are restricted to data analysis only:
☐Yes ☐ No
*Expedited Review: An assessment performed by the LCBE for new or modified studies that involve no more than minimal risk to participants.

Initial approval date_____

Date of first subject consent _____

Expected enrollment completion date_____

4. Activities Since Last Report

a. New advertisements/recruitment materials ☐ Yes ☐ No

b. Significant protocol deviations ☐ Yes ☐ No

c. Protocol amendments ☐ Yes ☐ No

d. Change of Principal Investigator ☐ Yes ☐ No

e. Changes in study staff ☐ Yes ☐ No

5. Risk Considerations

a. Any unexpected issues posing risk to subjects or others (e.g., higher AE/SAE rates, confidentiality breaches, unexpected financial burden)? ☐ Yes ☐ No

If yes, explain: _____

b. Any new information given to participants that could influence their decision to continue in the study? ☐ Yes ☐ No

If yes, explain:_____

c. Any claims for compensation due to study-related harm or complaints regarding study

conduct? ☐ Yes ☐ No

If yes, explain_____

d. Any developments that might affect the original risk/benefit evaluation of the study?

☐ Yes ☐ No

If yes, explain_____

6. Vulnerable Populations

Have participants been recruited from vulnerable groups since the last report? ☐ Yes ☐ No

If yes, check all applicable:

☐AIDS/HIV patients
☐Children
☐Cognitively impaired
☐Elderly
☐Institutionalized (non-prisoners)
☐Fetuses
☐In-vitro fertilization
☐KSU employees/students
☐Minorities
☐ Physically disabled
☐Pregnant women
☐Prisoners
☐ Other:_____

7. Signatures

Prepared by: _____ Date:_____

Reviewed/Approved by: _____ Date:_____