



HUMAN RESEARCH SCIENTIFIC MERIT & FEASIBILITY ATTESTATION FORM

For non-exempt research taking place on Wright State campus, this attestation is to be made by the appropriate department head or designee. Provide the department head or designee a copy of your IRB application along with all supporting materials. Upload this completed and signed form in the appropriate section of the IRB Initial submission.

PRINCIPAL INVESTIGATOR	
Name	Email
Department	IRB Number
POINT OF CONTACT (IF OTHER THAN PI)	
Name	Email
STUDY TITLE	
OTHER STUDY IDENTIFIER (e.g., grant ID, sponsor, etc.)	

Scientific Merit	Yes	No
The rationale, specific aims, and objectives for the study are clearly stated and scientifically sound.	<input type="checkbox"/>	<input type="checkbox"/>
The research will utilize procedures that are scientifically and statistically sound, appropriate to the study design, and do not unnecessarily expose human subjects to risk.	<input type="checkbox"/>	<input type="checkbox"/>

Feasibility Domain	Feasible (Agree)	N/A
1. Department & Scholarly Merit		
The study aligns with department priorities or has the potential for scholarly output (e.g., publications).	<input type="checkbox"/>	<input type="checkbox"/>
2. Fiscal		
External/internal funding sources have been/will be secured and are/will be sufficient to cover total study budget expenses inclusive of regulatory (e.g., IRB) and non-departmental ancillary service fees (e.g., CoCONNECT MRI Center, CTRA).	<input type="checkbox"/>	<input type="checkbox"/>
3. Personnel		
All personnel who will engage in the study: <ul style="list-style-type: none"> have appropriate experience, credentials, and training; have sufficient time available to conduct the research; will perform study activities commensurate with their job description and scope of practice; and will be appropriately supervised and monitored. 	<input type="checkbox"/>	<input type="checkbox"/>
4. Space and Facilities		
Appropriate approvals and safeguards are/will be in place for both clinical and non-clinical space and facilities where study activities may occur. Type and risk-level of procedures have been accounted for when selecting space and facilities.	<input type="checkbox"/>	<input type="checkbox"/>
5. Equipment and Test Articles		
<ul style="list-style-type: none"> Equipment used in the study will be appropriately housed, inventoried, certified, and returned. Investigational and commercially available test articles (e.g., drugs, devices) will be procured, inventoried, stored, secured, dispensed, labeled and disposed of in accordance with FDA regulations and institutional policies. 	<input type="checkbox"/>	<input type="checkbox"/>

Feasibility Domain	Feasible (Agree)	N/A
6. Constituent Endorsement		
Departments, clinics, and other operational units that may be impacted by, or provide services for, the research (e.g., informatics, pharmacy, nursing, laboratory, imaging, EHS, CaTS, Institutional Research, etc.) have been informed of and agree to support conduct of the study.	<input type="checkbox"/>	<input type="checkbox"/>
7. Acceptable Practice		
The proposed research utilizes acceptable practice for the discipline.	<input type="checkbox"/>	<input type="checkbox"/>
8. Recruitment		
There is a sufficient study population from which to recruit participants and the accrual goal is likely to be achieved.	<input type="checkbox"/>	<input type="checkbox"/>
9. Data Security Considerations		
Safeguards and resources are present for the secure collection, transfer, storage and retention of research data. All institutional policies are being followed.	<input type="checkbox"/>	<input type="checkbox"/>
Any necessary data agreements (e.g., Data Use Agreement, Materials Transfer Agreements) have/will be obtained.	<input type="checkbox"/>	<input type="checkbox"/>
10. Multi-Site Investigator-Initiated Research		
If WSU will serve as the lead institution of a multi-site investigator-initiated study, the other performance sites have/will be vetted. If performance sites have not yet been selected, the study is likely to solicit the interest of a sufficient number of investigators.	<input type="checkbox"/>	<input type="checkbox"/>

COMMENTS

The signature(s) below indicate the proposed research study has underwent scientific merit and feasibility assessment by the PI and appropriate individuals in accordance with departmental procedures, and the necessary resources are available to successfully implement and complete the study.

Principal Investigator

Department Chair or Designee

Signature

Date

Signature

Date

Name

Name

Title

Title