West Michigan Cancer Center
& INSTITUTE FOR BLOOD DISORDERS
A Borgess Bronson Collaboration

IRB Application for Research Protocols

Please provide the information requested below:

PRINCIPAL INVESTIGATOR (WMU School of Medicine Medical students or residents must be Co-Investigator(s), with faculty as Principal Investigator)	
Name:	
Job Title:	
Complete Mailing Address:	
Company/Organization	Department:

PRIMARY CONTACT PERSON (If not PI)	
Name:	Study Role:
Telephone:	E-mail:
Address:	
Preferred Contact Method: ☐ Phone ☐ E-mail Comments:	

RESEARCH PROTOCOL DETAILS
Title:
Proposed Beginning Date:
Proposed Project Completion Date (including data analysis):
If dissertation or thesis, list advisor:

FUNDING
Is this research sponsored? ☐Yes ☐ No If yes, list sponsor(s):
Has this research been submitted for funding? ☐Yes ☐ No
List funding agencies supporting this research:
Type of agency: ☐Commercial/Industry ☐ Federal ☐University ☐ Other If Other, please define:

PARTICIPATION OF ORGANIZATIONAL PARTNERS
Will another organization (ex., hospitals, schools) help in the recruitment of research subjects? ☐Yes ☐ No **If yes, list all institutions**:
Will assistance with the data collection be obtained from another organization? ☐Yes ☐ No **If yes, list all institutions**:

OTHER REVIEWS (Intention to submit to additional IRBs and the status of each submission)

Other IRB:
STATUS ☐Plan to submit ☐ Pending ☐Approved Date submitted:

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Has this protocol been suspended or closed by another IRB? ☐Yes ☐ No
If yes, explain:

PROTOCOL CLASSIFICATIONS
Subject Classification (Check all that apply):

☐Adults (> 18 years)
☐Children (< 18 years)
☐ Pregnant women/fetuses
☐Non-English speaking
☐Employees
☐Students
☐ Persons permanently or temporarily unable to consent
☐ Cognitively impaired persons
☐ Adults with diminished decision-making capacity
☐ Prisoners
☐ Other institutionalized individuals
☐ Other

Please explain the rationale for the involvement of the above special classes of subjects:

This study will involve (Check all that apply):

☐ Use of protected health information (PHI) without consent (Attach Request for Waiver)
☐ Radiation
☐ New Drugs (IND) IND# _____ Attach Approval
☐ Non-approved Use of Drug(s)
☐ Investigational Device Exemption (IDE) #_____Attach Approval
☐ Non-approved Devices
☐ Humanitarian Use Device (HUD) # _____ Attach Approval

☐Stem cells
☐Discarded tissue
☐ Fetal tissue
☐Human blood or fluids
☐Genetic research
☐Other: _____
☐None of the above will apply

SUMMARY OF THE PROTOCOL **(**Include an attached brief statement for each of the following):

1. Purpose of study
2. Study design
3. Summary of methods
4. Planned statistical analysis
5. List subject inclusion & exclusion criteria
6. Method of selection and recruitment
7. Number of subjects to be enrolled in the study
8. Potential risks and benefits to the subject
9. Scientific benefits
10. Is there intent to present or publish research outside of the institution? [ ] Yes [ ] No Specify:

Research Team Members

A research team member is anyone who interacts with subjects, research data, or PHI related to the study.

(Copy this page if additional space is needed).

Name and Address Include department name and mail code number. *Please notify and provide IRB with any change in address or affiliation.	Degree	Contact Information	Role on Project (PI, Co-PI, research team member, coordinator, volunteer, etc.)	Company / Institution	If this person will be working at a hospital facility, list department and manager name	If research will be conducted on site at a hospital or affiliated entity, please check the following that apply:			Protection of Human Subjects in Research education completion date
						In office area	Out patient	In patient	
		Wk Phone #: Cell/Pager #: Fax #: E-mail: If resident, graduation date:							
		Wk Phone #: Cell/Pager #: Fax #: E-mail: If resident, graduation date:							
		Wk Phone #: Cell/Pager #: Fax #: E-mail: If resident, graduation date:							

Provide evidence that <u>all</u> individuals on the research team have participated in education regarding the protection of human subjects. Human Participant Protection education is required every two years. Attach all certificates.

I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports.

Printed Name of Principal Investigator:

Signature of Principal Investigator:

Date: _____

Printed Name of Resident/Medical Student Investigator:

Signature of Resident/Medical Student Investigator:

Date: _____