



IRB Administration Office

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<http://irb.wayne.edu/index.php>

Exempt Reviewer Form

Principal Investigator:			
IRB #:		Submission Date:	
Study Title:			

Review Recommendations: It is recommended to first review the Summary & Purpose section and Background & Rationale section of the eProtocol submission. Please also refer to the Protocol/Proposal document. Then review all remaining eProtocol tabs.

Summary & Purpose	Yes	No	N/A
Is the proposed start date appropriate? (i.e. not before IRB review and approval)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the summary and Purpose clear and concise?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the proposed research activities fall within the definition of human subjects research? (if No go the reviewer's recommendations section of this form)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes: Submit notes via eProtocol

Background, Rationale	Yes	No	N/A
PROCEDURES			
Is relevant background information provided to understand the study details?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the sample size justification provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes: Submit notes via eProtocol

Personnel Information & COI	Yes	No	N/A
If the Principal Investigator has the role of “Student/Resident/Fellow” is a Faculty Sponsor/Mentor listed? <i>(The Faculty Sponsor cannot also be the authorized signatory, must be listed as one or the other)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COI SECTION: Have any key personnel indicated a conflict of interest?	<input type="checkbox"/>	<input type="checkbox"/>	
COI SECTION: If yes, is the management plan attached? See Attachments section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>COI Management Plan: (i) If there is a management plan, are there any additional conditions that should be added to the management plan? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, include with your eProtocol comments.</p> <p>(ii) Does the management plan include information that should be added to the consent/assent? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes has that information been added? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>			
<p>Notes: Submit notes via eProtocol</p>			

Participant Checklist	Yes	No	N/A
Based on review of the protocol/research proposal, consent/assents etc. all applicable populations have been selected.	<input type="checkbox"/>	<input type="checkbox"/>	
<p>Note Vulnerable Population Addenda are not required for Exempt Submissions Prisoners cannot be included for Exempt research</p>			
<p>Notes: Submit notes via eProtocol</p>			

Study Location	Yes	No	N/A
Is the correct study location indicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If research activities include online activities, does the Location section state “Online/Virtual/Remote” and the Online/Virtual/Remote platform?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any non-WSU sites?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are sites included that are outside of the PI's Department?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If : (a) Non-WSU Site or (b) site outside of PI's department Are Letters of support included? (see the Protocol Information-Attachments section)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If taking place at DMC, Karmanos, McLaren, JDVAMC (CIC), or Psychiatry are the appropriate approval letters included? (see the Protocol Information-Attachments section)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Notes: Submit notes via eProtocol</p>			

COORDINATING CENTER APPLICATION			
	Yes	No	N/A
If not applicable Select N/A and go to next section <input type="checkbox"/> N/A			
If WSU is the Coordinating Center for this study is the Coordinating Center Form attached? (If yes, complete the coordinating center reviewer form)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If International site, see International Addendum & see International Research checklist.			

VAMC Checklist			
	Yes	No	N/A
If not applicable Select N/A and go to next section <input type="checkbox"/> N/A			
Is the John D. Dingell Veterans Administration indicated as a study location?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes, has the reviewer completed the VAMC reviewer Checklist?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please complete the IRB Reviewer Form for VAMC and submit with this reviewer checklist			

Notes: Submit notes via eProtocol

Protocol Checklist			
	Yes	No	N/A
Will in-person activities take place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Does the research include the following?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Questionnaires/Survey <input type="checkbox"/> Interview <input type="checkbox"/> Focus Group <p>If yes, go to the Background Rationale section for a description of procedures. Check Protocol Information-Attachment sections for surveys/questionnaires/scripts.</p> <ul style="list-style-type: none"> <input type="checkbox"/> Internet-Check for completion of Internet Use in Research Addendum for eProtocol. <input type="checkbox"/> International-Check for completion of International Research Addendum for eProtocol. <input type="checkbox"/> Record Review (etc, retrospective chart medical record review, education record review) check for waivers of consent/HIPAA, if applicable <p>Waivers:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Waivers of Consent or Waiver of Written documentation of consent <input type="checkbox"/> Waivers of Consent to screen for eligibility <p>Check that the waiver is completed for the Consent Information section. If HIPAA applies (use of medical records of databases) review HIPAA section</p>			

Notes: Submit notes via eProtocol

Funding	Yes	No	N/A
Is the study funded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the study supported by the U.S. Department of Defense (DOD) or U.S. Department of Energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes for DOD funding, DOD Addendum must be completed (also see DOD reviewer checklist to complete review).			
If sponsored by the Department of Energy (DOE) did the PI provide the DOE Checklist for IRBs to Use in Verifying that Human Subjects Research Protocols are in Compliance with Department of Energy (DOE) Requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Check the Protocol Information-Attachments Tab			

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*Concurrence of Exempt Categories

<input type="checkbox"/>	Category 1	<p>Research conducted in commonly accepted educational settings that specifically involve normal educational practices not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p> <p>Consent Types:</p> <ul style="list-style-type: none"> • Adult Participants: Research Information Sheet <ul style="list-style-type: none"> ○ <input type="checkbox"/> Waiver of written documentation of consent • Child Participants: Parental Permission obtained with a School Parent Supplemental Letter <ul style="list-style-type: none"> ○ <input type="checkbox"/> This requires a request for waiver of documentation of Parental Permission ○ <input type="checkbox"/> Research Information Sheet for age appropriate assent
<input type="checkbox"/>	Category 2	<p>Research that only includes interactions that use educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.</p> <p style="text-align: center;">If data is identifiable, Limited IRB review is required (see below)</p> <p>Children can only be included when the research involves: (i) educational tests and/or (ii) the observation of public behavior (as long as the investigator(s) do not participate in the activities being observed)</p>

		<p>Consent Types:</p> <ul style="list-style-type: none"> • Adult Participants: Research Information Sheet <ul style="list-style-type: none"> ○ <input type="checkbox"/> Waiver of written documentation of consent • Child Participants: Parental Permission obtained with a School Parent Supplemental Letter <ul style="list-style-type: none"> ○ <input type="checkbox"/> This requires a request for waiver of documentation of Parental Permission ○ <input type="checkbox"/> Research Information Sheet for age appropriate assent
<input type="checkbox"/>	Category 3	<p>Benign Behavioral Intervention: Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection. Interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, and the investigator has no reason to think the participants will find the interventions offensive or embarrassing.</p> <p>This category excludes children & cannot include deception. If data is identifiable, Limited IRB review is required (see below)</p> <p>Consent Types:</p> <ul style="list-style-type: none"> • Adult Participants: Research Information Sheet <ul style="list-style-type: none"> ○ <input type="checkbox"/> Waiver of written documentation of consent
<input type="checkbox"/>	Category 4	<p>Secondary research for which consent is not required. The collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.</p> <ul style="list-style-type: none"> • Only applicable if there will be no contact with participants • Collection of identifiable data that does not fall under the protection of HIPAA regulations is not permitted under this category (Expedited category 5 applies in this case). <p>Consent Types:</p> <ul style="list-style-type: none"> • <input type="checkbox"/> Waiver of Consent and Waiver of Written Documentation of Consent • <input type="checkbox"/> Waiver of HIPAA Authorization is required when medical records are being accessed
<input type="checkbox"/>	Category 5	<p>Research and demonstration projects conducted or supported by a Federal department or agency that is designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, or possible changes to those programs or procedures.</p>
<input type="checkbox"/>	Category 6	<p>Taste and food quality evaluation and consumer acceptance studies.</p>

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Limited IRB Review	If not applicable, select N/A and go to next section	<input type="checkbox"/> N/A	Yes	No	N/A
Is the Limited IRB Review Appendix provided? (see attachments section for the Limited IRB Review Appendix M)			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the following apply? The information obtained is recorded by the investigator in such a manner that the identity of the participants can readily be ascertained, directly or through identifiers linked to the participants.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the following apply? Any disclosure of participants' responses outside the research would reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Note if yes, the study should not be Exempt.
 These provisions also apply to VA regulated research

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Background, Rationale, Data Analysis, and Procedures

Section B: PROCEDURES

	Yes	No	N/A
Are the research activities and interventions described?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the research site and/or the study include public health pandemic mitigation procedures? If No, is appropriate justification provided? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is a description provided regarding who will conduct research activities, where, and when?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the frequency of study visits and total duration of study participation (total time commitment) provided? If secondary data collection (e.g. retrospective chart review) Select N/A and go to next section.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Section C: DATA COLLECTION

	Yes	No	N/A
If there are data collection instruments, are all instruments, surveys and/or educational materials included for the Protocol Information-Attachments section?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If participants will complete the survey/questionnaire or review the materials, are they in easy to understand language?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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AUDIO/VIDEO RECORDING

If secondary data collection (e.g., retrospective chart review) Select N/A and go to next section N/A

If yes, is audio/video recording information listed in consent/research information sheet with a statement regarding when recordings will be destroyed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If audio/visual recording, is there a mechanism for the participant to prospectively agree to the intervention and information collection and at least one of the following criteria is met:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If Yes, then Exempt Category 3 must apply with at least one of the following:

- (a) The information obtained is recorded by the investigator in such a manner that the identity of the participant cannot readily be ascertained, directly or through identifiers linked to the participants
- (b) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation
- (c) The information obtained is recorded by the investigator in such a manner that the identity of the participants' can be readily ascertained, directly or through identifiers linked to the participants, Limited IRB must be conducted to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Notes: Submit notes via eProtocol

USE OF DECEPTION

If secondary data collection, Select N/A and go to next section N/A

Category 3 is not allowed

	Yes	No	N/A
When there is a potential for deception or experimental manipulation, is protocol-specific scientific justification provided and does the reviewer agree? If yes, the study must meet the criteria for an alteration to informed consent.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Deception in exempt research can be done only with adult participants with a prospective agreement that informs the participant that he/she will be unaware of or misled regarding the nature or purposes of the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There is an acceptable plan to debrief participants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Participant Population			
Section C	Yes	No	N/A
Are WSU students being recruited campus wide (not only in the PI's department and/or college)? If yes, has WSU Dean of Students approval been provided (see Attachments section)? Yes No	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Section D	Yes	No	N/A
If enrolling WSU/WSU affiliate employees/staff: Is the PI the direct supervisor of the WSU/WSU affiliate employees/staff? If yes, the recruiting procedures must be revised. See the WSU IRB Policy on Vulnerable Populations: Students, Trainees, and Employees	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Section E	Yes	No	N/A
If Non-English speaking participants will be included as participants check the Consent/Assent sections for translated consent documents. Check the Attachments section for translated data collection tools and recruitment materials, if applicable. See WSU IRB's Informed Consent for Non-English Speaking Participants policy for information regarding non-English speaking participants.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If there are screening procedures, determine whether a waiver of consent/assent is required (see consent information or assent information sections)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Section F:	Yes	No	N/A
Does the PI have the appropriate expertise to conduct the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the PI is a student/resident/fellow does the faculty sponsor/mentor have the appropriate expertise to provide oversight of the conduct of research activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Notes: Submit notes via eProtocol Please include any notes if there are concerns regarding Students or Employee participants.</p>			

Recruitment Process, Participant Compensation & Costs			
If secondary data collection (e.g., retrospective chart review), Select N/A and go to next section <input type="checkbox"/> N/A			
Section A: RECRUITMENT PROCESS	Yes	No	N/A
Recruitment procedures are clearly defined.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If use of recruitment materials is indicated, those materials (i.e., flyers, notices, advertisements, verbatim scripts, etc. are included for the eProtocol Information-Attachments tab.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If recruitment materials are used, materials meet the IRB's Advertising policy standards (see standards at the end of this form)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Section B: PARTICIPANT COMPENSATION	Yes	No	N/A
Will participants be compensated for their time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, does Participant Compensation meet IRB policy guidelines ? <ul style="list-style-type: none">• Minimally invasive studies: \$5-\$50 per study visit• Moderately, Extremely Invasive or Time-Consuming Study Procedures: \$50-\$250 per study visit• Total Compensation for Multiple Visits: \$100-\$1000 total• Transportation Costs Regardless of Type of Study:• \$10-\$50 for transportation to performance sites that are distant from the participant's home. Compensation for actual travel expenses (or similar costs such as childcare) could be offered in addition to compensation to participate in the study procedures.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Section C: STUDY COSTS	Yes	No	N/A
If participants will incur additional costs, is the information clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Risks	Yes	No	N/A
Are the risks to participants more than minimal? If yes, the study does not qualify for exempt review	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the risks described accurately and included in the consent/assent/information sheet forms? If secondary data collection, Select N/A and go to next section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are all activities that could potentially result in identification of child abuse, reportable diseases, and criminal activities addressed? If secondary data collection, Select N/A and go to next section	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Benefits	If not applicable, Select N/A and go to next section	N/A	Yes	No	N/A
Are the benefits accurately stated, if any?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the benefits, if any, also described in the consent/assent/information sheet?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are the benefits to society, if any, clearly described?		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Procedures to Maintain Confidentiality	Yes	No	N/A
Are the measures to maintain confidentiality clearly stated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There is an adequate plan for storage and disposal of data (including audio or video recordings). For audio/video recordings, see exempt categories above IRB guidance recommends storage of all research data on an encrypted server. Note: One Drive is a cloud-based encrypted server that is available to all Wayne State University faculty, students and staff. Please revise your response and procedures to indicate that the data will be stored on an encrypted server.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There are adequate provisions to protect the personal privacy interests of the participant(s).	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Consent Information (Procedures)	Yes	No	N/A
If secondary data collection, select N/A and go to next section <input type="checkbox"/> N/A			
Item#10(a) Is the consent process clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Item #10(c) Are the individuals listed as obtaining consent also included under the Personnel information section as key personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the appropriate type of consent/assent/information sheet selected and included with the submission? Use of the WSU IRB's consent templates is highly recommended	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Consent Information (waivers and/or alterations of consent)**See exempt category notes regarding consent types**

When using a Research Information Sheet, a waiver of written documentation of consent is requested.	Yes	No	N/A
Waiver of Consent and/or Parental Permission	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waiver for written documentation of consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Waiver of consent and waiver of written document of consent to screen	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Alteration of informed consent <i>(Removing elements of consenting/or elements from the research information sheet)</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a waiver or alteration of consent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If there is an alternative to written consent requested, is the justification stated and appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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HIPAA	Yes	No	N/A
If not applicable Select N/A and go to next section <input type="checkbox"/> N/A			
If identifiable information from medical records, clinical databases, specimen or tissue banks, repositories, will be accessed for research are there any HIPAA concerns?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is a waiver of HIPAA Authorization requested? Waiver of HIPAA Authorization is required when medical records are being accessed for exempt category 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If a waiver of HIPAA Authorization is requested, is a waiver of consent also requested (see Consent Information section)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes: Submit notes via eProtocol

Protocol Information-Attachments Checklist

	Yes	No	N/A
PI's CV/Resume is attached	<input type="checkbox"/>	<input type="checkbox"/>	
Research Proposal/Protocol/Dissertation is attached (not required for Exempt Submissions)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Collection Tools (questionnaires, surveys, etc.) are provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recruitment Materials (flyers, advertisements, etc.) are provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the recruitment materials meet the IRB's Criteria for Advertising?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Advertising Criteria:

- Purpose indicates that the activity is research
- Potential benefits of participation are not coercive or misleading
- Compensation is not overly emphasized, coercive, or misleading
- Free of deception and exculpatory language
- Font size or other visual effect is not coercive or misleading
- Language and terminology is appropriate for the intended audience

Recruitment materials/advertisements DO NOT:

- Imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- Include exculpatory language (e.g., releasing the investigator or sponsor from liability)
- Perceive to be coercive or imply undue pressure.

FDA Regulated Research: Recruitment materials/advertisements DO NOT:

- Make any claim (directly stated or implied) that the drug, biologic or device being studied is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device, or otherwise promote the test article.
- Use the terms "new treatment", "new medication" or "new drug" without explaining that the test article is investigational.
- Make any claim (explicit or implicit) about a drug, biologic, or device being studied that is inconsistent with FDA labeling
- Include any statement (direct or implied) that the research is approved by the FDA

	Yes	No	N/A
Scripts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letters of Support (Non-Affiliate Sites & Outside of PI's Department)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COVID -19 Participant Information documents attached (not required)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ancillary Reviews/Approvals are provided	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Ancillary Reviews include:

<input type="checkbox"/> DMC	<input type="checkbox"/> PRMC-Protocol Review and Monitoring Committee (KCI/Cancer Studies)	<input type="checkbox"/> VA Clinical Investigation Committee (CIC)
<input type="checkbox"/> Department of Psychiatry	<input type="checkbox"/> Radiation Safety Committee (RSC)	<input type="checkbox"/> Institutional Biosafety Committee (IBC)
<input type="checkbox"/> Export Control (International Research)	<input type="checkbox"/> Dean of Students (WSU Campus wide student recruitment)	<input type="checkbox"/> McLaren Approval & Authorization

Notes: If revisions are required for these documents, submit notes via eProtocol



eProtocol Internet Addendum Checklist

If not applicable, select N/A and go to next section N/A

	Yes	No	N/A
Internet Addendum is completed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recruitment conducted via internet. If yes, procedures are described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Data Collection conducted via internet. If yes, procedures are described.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are social media platforms being used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, site administrator(s) approval(s) has been provided from social media platforms that are being used. (Check the Protocol Information Attachments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes: Submit notes via eProtocol



eProtocol International Addendum Checklist

If not applicable, Select N/A and go to next section N/A

	Yes	No	N/A
International Addendum is completed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Approval from Export control is provided (Check the Protocol Information Attachments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Local IRB review/approval provided. (Check the Protocol Information Attachments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If local IRB review is not available, has the researcher provided documentation of the following: (1) lack of local IRB review and (2) plans for observing local ethical standards? DOD research requires local ethics review.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Letters of Support provided (Check the Protocol Information Attachments)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigator and research staff are qualified for conducting research in respective country.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Informed consent/assent/questionnaires/surveys are written both in English and the in the native language of the proposed research site.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Risks are minimized

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Additional Reviewer Checklists

Please complete the following additional checklists if applicable.
Please submit with this initial reviewer checklist to the IRB Administrator.

All IRB reviewer forms are available on the [IRB Reviewer Forms and Tools website](#)

	Yes	No	N/A
Coordinating Center Reviewer Checklist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NIH Genomic Data Sharing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
VAMC Checklist for John D. Dingell VAMC Site	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Criteria for Approval

Criteria for approval must be met to provide Concurrence of Exemption

	Yes	No	N/A
Is the research more than minimal risk to participants? If yes, study is not eligible for exempt review.	<input type="checkbox"/>	<input type="checkbox"/>	
Is the selection of participants equitable?	<input type="checkbox"/>	<input type="checkbox"/>	
Are there adequate provisions to maintain participant privacy and confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the consent process appropriate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Notes: Submit notes via eProtocol

Reviewer Determination

<p>Concurrence of Exemption Granted</p> <p align="center"><input type="checkbox"/></p>	<p>Different exemption category applies than PI selected. State Categories</p> <p align="center"><input type="checkbox"/></p> <p>And request change or complete administrative change to categories</p> <p align="center">New Category</p> <p align="center">_____</p>	<p>Specific Minor Revisions</p> <p>Submit comments in eProtocol</p> <p align="center"><input type="checkbox"/></p> <p>Date Revisions Requested:</p> <p align="center">_____</p> <p>Date Revisions Completed:</p> <p align="center">_____</p>	<p>Change Review type</p> <p align="center"><input type="checkbox"/></p> <p>Require resubmission of a research project that would be reviewed and approved under an expedited or full board review process,</p> <p>Recommend</p> <p><input type="checkbox"/> Full Board Review</p> <p><input type="checkbox"/> Expedited Review</p> <p>Provide justification in notes below.</p>
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Notes:

Submit notes via eProtocol

Concurrence of Exemption Period (select all that apply)	
<p>Status Check-In every 3 years</p> <p align="center"><input type="checkbox"/></p>	<p>Limited IRB Review every 3 years</p> <p align="center"><input type="checkbox"/></p>

Reviewer's Signature:	Date:
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Email completed reviewer sheets to: IRBReview@wayne.edu

***Exempt Categories NOTE:** The WSU IRB has elected to opt out of the optional categories #7 and #8 as described in 45CFR 46.104. These categories involve research with biospecimens in which broad consent is obtained. Any study with broad consent will not be eligible for exempt review under this policy.

Advertising Policy: Criteria for advertisement review includes the following:

- Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- No claims should be made that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- The terms "new treatment", "new medication" or "new drug" should not be used without explaining that the test article is investigational.
- Advertisements should not promise "free treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
- Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type. See the IRB policy on "Compensation for Research Participants" for guidelines on compensation.
- Advertisements should state that it is for a research study.
- Advertisements may not be coercive or imply undue pressure.
- Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
- Advertisements may not include exculpatory language.

The following items may be included in advertisements (the inclusion of all of the listed items is not required):

1. The name and address of the clinical investigator and the identity of the research facility.
2. The condition under study and/or the purpose of the research.
3. The criteria, in summary form, that will be used to determine eligibility for the study.
4. A brief list of the benefits or incentives of participation, if any.
5. The time or other commitment required of the participants.
6. The name of the person or office to contact for further information.