IRB Administration Office
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Telephone# (313) 577-1628
Detroit, MI 48201
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)	☐	☐	☐
Is the summary and Purpose clear and concise?	☐	☐	☐
Does the proposed research activities fall within the definition of human subjects research? (if No go the reviewer's recommendations section of this form)	☐	☐	☐

Notes: **Submit notes via eProtocol**

Background, Rationale	**Yes**	**No**	**N/A**
PROCEDURES			
Is relevant background information provided to understand the study details?	☐	☐	☐
Is the sample size justification provided?	☐	☐	☐

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? *(The Faculty Sponsor cannot also be the authorized signatory, must be listed as one or the other)*	☐	☐	☐
COI SECTION: Have any key personnel indicated a conflict of interest?	☐	☐	
COI SECTION: If yes, is the management plan attached? **See Attachments section**	☐	☐	☐

COI Management Plan: (i) If there is a management plan, are there any additional conditions that should be added to the management plan? ☐ Yes ☐ No

If yes, include with your eProtocol comments.

(ii) Does the management plan include information that should be added to the consent/assent? ☐ Yes ☐ No

If yes has that information been added? ☐ Yes ☐ No

Notes: **Submit notes via eProtocol**

Participant Checklist	Yes	No	N/A
Based on review of the protocol/research proposal, consent/assents etc. all applicable populations have been selected.	☐	☐	

Note Vulnerable Population Addenda are not required for Exempt Submissions

Prisoners cannot be included for Exempt research

Notes: **Submit notes via eProtocol**

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

Notes: **Submit notes via eProtocol**

COORDINATING CENTER APPLICATION If not applicable Select N/A and go to next section ☐ N/A	Yes	No	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)	☐	☐	☐

If International site, see International Addendum & see International Research checklist.

VAMC Checklist If not applicable Select N/A and go to next section ☐ N/A	Yes	No	N/A
Is the John D. Dingell Veterans Administration indicated as a study location?	☐	☐	☐
If Yes, has the reviewer completed the VAMC reviewer Checklist?	☐	☐	☐

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?	☐	☐	☐

Does the research include the following?

☐ Questionnaires/Survey
☐ Interview
☐ Focus Group

If yes, go to the Background Rationale section for a description of procedures.
Check Protocol Information-Attachment sections for surveys/questionnaires/scripts.

☐ Internet-Check for completion of Internet Use in Research Addendum for eProtocol.
☐ International-Check for completion of International Research Addendum for eProtocol.
☐ Record Review (etc, retrospective chart medical record review, education record review) check for waivers of consent/HIPAA, if applicable

Waivers:

☐ Waivers of Consent or Waiver of Written documentation of consent
☐ Waivers of Consent to screen for eligibility

Check that the waiver is completed for the Consent Information section.
If HIPAA applies (use of medical records of databases) review HIPAA section

Notes: **Submit notes via eProtocol**

Funding	Yes	No	N/A
Is the study funded?	☐	☐	☐
Is the study supported by the U.S. Department of Defense (DOD) or U.S. Department of Energy?	☐	☐	☐
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? **Check the Protocol Information-Attachments Tab**	☐	☐	☐

Notes: **Submit notes via eProtocol**

*Concurrence of Exempt Categories

☐	**Category 1**	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.
		Consent Types:
		• Adult Participants: Research Information Sheet
		  ○ ☐ Waiver of written documentation of consent
		• Child Participants: Parental Permission obtained with a School Parent Supplemental Letter
		  ○ ☐ This requires a request for waiver of documentation of Parental Permission
		  ○ ☐ Research Information Sheet for age appropriate assent

☐	**Category 2**	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. **If data is identifiable, Limited IRB review is required (see below)** **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)

		Consent Types:
		• Adult Participants: Research Information Sheet
		  ○ ☐ Waiver of written documentation of consent
		• Child Participants: Parental Permission obtained with a School Parent Supplemental Letter
		  ○ ☐ This requires a request for waiver of documentation of Parental Permission
		  ○ ☐ Research Information Sheet for age appropriate assent

☐	**Category 3**	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. **This category excludes children & cannot include deception.** **If data is identifiable, Limited IRB review is required (see below)** **Consent Types:** • Adult Participants: Research Information Sheet ○ ☐ Waiver of written documentation of consent
☐	**Category 4**	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. • 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). **Consent Types:** • ☐ Waiver of Consent and Waiver of Written Documentation of Consent • ☐ Waiver of HIPAA Authorization is required when medical records are being accessed
☐	**Category 5**	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.
☐	**Category 6**	Taste and food quality evaluation and consumer acceptance studies.

Notes: **Submit notes via eProtocol**

Limited IRB Review **If not applicable, select N/A and go to next section** ☐ **N/A**	**Yes**	**No**	**N/A**
Is the Limited IRB Review Appendix provided? (**see attachments section for the Limited IRB Review Appendix M**)	☐	☐	☐
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.	☐	☐	☐
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.	☐	☐	☐

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

Notes: **Submit notes via eProtocol**

Background, Rationale, Data Analysis, and Procedures

Section B: PROCEDURES

	Yes	No	N/A
Are the research activities and interventions described?	☐	☐	☐
Does the research site and/or the study include public health pandemic mitigation procedures? If No, is appropriate justification provided? ☐ Yes ☐ No	☐	☐	☐
Is a description provided regarding who will conduct research activities, where, and when?	☐	☐	☐
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.**	☐	☐	☐

Notes: **Submit notes via eProtocol**

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?	☐	☐	☐
If participants will complete the survey/questionnaire or review the materials, are they in easy to understand language?	☐	☐	☐

Notes: **Submit notes via eProtocol**

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?	☐	☐	☐
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:	☐	☐	☐

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.	☐	☐	☐
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.	☐	☐	☐
There is an acceptable plan to debrief participants.	☐	☐	☐

Notes: Submit notes via eProtocol

Participant Population

Section C	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	☐	☐	☐
Section D	**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	☐	☐	☐
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.	☐	☐	☐
If there are screening procedures, determine whether a waiver of consent/assent is required (**see consent Information or assent information sections)**	☐	☐	☐
Section F:	**Yes**	**No**	**N/A**
Does the PI have the appropriate expertise to conduct the study?	☐	☐	☐
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?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Please include any notes if there are concerns regarding Students or Employee participants.

Recruitment Process, Participant Compensation & Costs

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

Section A: RECRUITMENT PROCESS	Yes	No	N/A
Recruitment procedures are clearly defined.	☐	☐	☐
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.	☐	☐	☐
If recruitment materials are used, materials meet the IRB's Adverting policy standards (see standards at the end of this form)	☐	☐	☐

Notes: Submit notes via eProtocol

Section B: PARTICIPANT COMPENSATION	Yes	No	N/A
Will participants be compensated for their time?	☐	☐	☐
If yes, does Participant Compensation meet IRB policy guidelines? • **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.	☐	☐	☐

Section C: STUDY COSTS	Yes	No	N/A
If participants will incur additional costs, is the information clearly stated?	☐	☐	☐

Notes: Submit notes via eProtocol

Risks	Yes	No	N/A
Are the risks to participants more than minimal? **If yes, the study does not qualify for exempt review**	☐	☐	☐
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**	☐	☐	☐
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**	☐	☐	☐

Notes: Submit notes via eProtocol

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?	☐	☐	☐
Are the benefits, if any, also described in the consent/assent/information sheet?	☐	☐	☐
Are the benefits to society, if any, clearly described?	☐	☐	☐

Notes: Submit notes via eProtocol

Procedures to Maintain Confidentiality	Yes	No	N/A
Are the measures to maintain confidentiality clearly stated?	☐	☐	☐
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.	☐	☐	☐
There are adequate provisions to protect the personal privacy interests of the participant(s).	☐	☐	☐

Notes: Submit notes via eProtocol

Consent Information (Procedures) If secondary data collection, select N/A and go to next section ☐ N/A	Yes	No	N/A
Item#10(a) Is the consent process clearly defined?	☐	☐	☐
Item #10(c) Are the individuals listed as obtaining consent also included under the Personnel information section as key personnel?	☐	☐	☐
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**	☐	☐	☐

Notes: Submit notes via eProtocol

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	☐	☐	☐
Waiver for written documentation of consent	☐	☐	☐
Waiver of consent and waiver of written document of consent to screen	☐	☐	☐
Alteration of informed consent (*Removing elements of consenting/or elements from the research information sheet*)	☐	☐	☐
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?	☐	☐	☐
If there is an alternative to written consent requested, is the justification stated and appropriate?	☐	☐	☐
Notes: Submit notes via eProtocol			

HIPAA If not applicable Select N/A and go to next section ☐ N/A	Yes	No	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?	☐	☐	☐
Is a waiver of HIPAA Authorization requested? Waiver of HIPAA Authorization is required when medical records are being accessed for exempt category 4	☐	☐	☐
If a waiver of HIPAA Authorization is requested, is a waiver of consent also requested (see Consent Information section)?	☐	☐	☐
Notes: Submit notes via eProtocol			

Protocol Information-Attachments Checklist

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

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

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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	☐	☐	☐
Letters of Support (Non-Affiliate Sites & Outside of PI's Department)	☐	☐	☐
COVID -19 Participant Information documents attached (not required)	☐	☐	☐
Ancillary Reviews/Approvals are provided	☐	☐	☐

Ancillary Reviews include:

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

Notes: **If revisions are requred 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.	☐	☐	☐
Recruitment conducted via internet. If yes, procedures are described.	☐	☐	☐
Data Collection conducted via internet. If yes, procedures are described.	☐	☐	☐
Are social media platforms being used?	☐	☐	☐
If yes, site administrator(s) approval(s) has been provided from social media platforms that are being used. (Check the Protocol Information Attachments)	☐	☐	☐

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.	☐	☐	☐
Approval from Export control is provided (**Check the Protocol Information Attachments**)	☐	☐	☐
Local IRB review/approval provided. (**Check the Protocol Information Attachments**)	☐	☐	☐
If local IRB review is not available, has the researcher provided documentation of the following: (I) lack of local IRB review and (2) plans for observing local ethical standards? DOD research requires local ethics review.	☐	☐	☐
Letters of Support provided (**Check the Protocol Information Attachments**)	☐	☐	☐
Investigator and research staff are qualified for conducting research in respective country.	☐	☐	☐
Informed consent/assent/questionnaires/surveys are written both in English and the in the native language of the proposed research site.	☐	☐	☐

Risks are minimized	☐	☐	☐

Notes: Submit notes via eProtocol

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	☐	☐	☐
NIH Genomic Data Sharing	☐	☐	☐
VAMC Checklist for John D. Dingell VAMC Site	☐	☐	☐
Other:	☐	☐	☐

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.**	☐	☐	
Is the selection of participants equitable?	☐	☐	
Are there adequate provisions to maintain participant privacy and confidentiality?	☐	☐	☐
Is the consent process appropriate?	☐	☐	☐

Notes: Submit notes via eProtocol

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

Concurrence of Exemption Period (select all that apply)	
Status Check-In every 2 years ☐	**Limited IRB Review Every 2 years** ☐

Reviewer's Signature:	Date:

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.**

<u>Advertising Policy:</u> 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.