IRB Administration Office
Telephone# (313) 577-1628
http://irb.wayne.edu/index.php

Exempt Reviewer Form

Principal Investigator:			
IRB #:		**Submission Date:**	

REVIEW RECOMMENDATIONS: It is recommended to first review the Summary & Purpose section and Background Procedures section of the eProtocol submission, then review all remaining information.

Protocol Information- Summary & Purpose section	**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 purpose and proposed research activities fall within the definition of human subject's research? **If No,** complete the Not Human Participants Research (**HPR**) steps below.	☐	☐	

☐ **Not Human Participants Research**

(a) Request review by the IRB Education Coordinator to determine not HPR.
or
(b) Send submission back to IRB with not HPR justification recommending not HPR and submission withdrawal. Email your reviewer sheet to IRBReview@wayne.edu informing the IRB of withdrawal.

☐ **Change Review Type:** Requires resubmission of a research project that would be reviewed and approved under an expedited or full board review process. Provide justification and submit justification in eProtocol. If assigned as the expedited reviewer STOP and use the Expedited Initial Reviewer form.

☐ **Full Board Review** or ☐ **Expedited Review**

Reviewer's Signature: _____

Sign here when Not HPR or changing the Review

CHANGING THE REVIEW TYPE OR NOT HPR STOP THE FORM IS COMPLETE

Notes: **Submit notes via eProtocol**

Background, Rationale, Data Analysis, and Procedures

NOTE SECTION A IS NOT REQUIRED FOR EXEMPT SUBMISSIONS

Section B: PROCEDURES

	Yes	**No**	**N/A**
ITEM b: Are the research activities and interventions described?	☐	☐	☐
ITEM c: Is a description provided regarding who will conduct research activities, where, and when?	☐	☐	☐
ITEM d: 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 SECTION C item F

Section C: DATA COLLECTION

	Yes	**No**	**N/A**

ITEM b: If data collection instruments are not in the public domain has appropriate permissions been addressed?	☐	☐	☐

Notes: Submit notes via eProtocol

Background, Rationale, Data Analysis, and Procedures
SECTION C: ITEM (d): USE OF DECEPTION

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

Exempt Category 3 is not allowed

	Yes	No	N/A
Is a rationale for use of deception provided?	☐	☐	☐

Note the consent information section will need an alteration of consent completed.

Notes: Submit notes via eProtocol

SECTION C: ITEM (e) AUDIO/VIDEO RECORDING & PHOTOGRAPHY

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

	Yes	No	N/A
ITEM (iv): Is the context of use for the audio/video/photography described as it relates to the research?	☐	☐	☐
ITEM (iv): Does the description of the collection process include a mechanism for the participant to prospectively agree to the intervention and information collection?	☐	☐	☐

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.

SECTION C: Item f: Use of Existing Data If not applicable, Select N/A and go to next section ☐ N/A

	Yes	No
ITEM (f): Are the responses to item (f) consistent with the described data collection procedures, and exempt category selected?	☐	☐

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)***	☐	☐	☐
COI SECTION: Have any key personnel indicated a conflict of interest?	☐	☐	
COI SECTION: If yes, is the management plan attached? **See Attachments section.** **If N/A go next 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 summary/purpose and study procedures have all applicable populations been selected?	☐	☐	

Note: Vulnerable Population Addenda are not required for Exempt studies
CITI Training is still required. PRISONERS CANNOT BE INCLUDED FOR EXEMPT RESEARCH

Notes: **Submit notes via eProtocol**

Study Location & Data Collection	Yes	No	N/A
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 or sites included outside of the PI's assigned 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**)?	☐	☐	☐
DMC, Karmanos, McLaren, JDVAMC (CIC), or Psychiatry are locations	☐	☐	☐

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)	☐	☐	☐

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 Section

Does the research include the following?

- ☐ **In-Person Activities:** *If conducted at non-WSU site/WSU affiliate sites check for letters of support*
- ☐ **Questionnaires/Survey:** *Check attachments section for the questionnaire/survey*
- ☐ **Interview:** *Check attachments section for script//outline*
- ☐ **Focus Group**: *Check attachments section for script/outline*
- ☐ **Internet:** *Check for completion of Internet Use in Research Addendum for eProtocol.*
- ☐ **International:** *Check for completion of International Research Addendum for eProtocol.*
- ☐ **Record Review:** *Check for waivers of consent/waiver of HIPAA, if applicable.*
- ☐ **Thesis or dissertation project**: *Check Personnel Information section for faculty sponsor/mentor*

Waivers & Data Agreements:

- ☐ **Waivers of Consent or Waiver of written documentation of consent**
- ☐ **Waivers of Consent to screen for eligibility**
- ☐ **HIPAA**- Use or collection of PHI: *must select HIPAA Authorization and complete HIPAA section*
- ☐ **Data Use Agreement or Limited Data Set:** *In comments inform the PI that they will need to contact mtainfo@wayne.edu for assistance. The agreement does not need to be attached to the IRB submission.*

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**

Exempt Application

Note items A, B, & C: **USER MUST SELECTS "NO" IN ORDER TO QUALIFY FOR EXEMPT**

	Yes	No	
Item D: Is item D completed with all risks identified? **The risks selected must be included for the consent/assent forms.**	☐	☐	☐ None

*Concurrence of Exempt Categories

☐ **Category 1**

Consent Types:

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

☐ **Category 2** **(THIS CATEGORY CAN ONLY INCLUDE CHILDREN IF THE FOLLOWING CRITERIA ARE MET)**

(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 if criteria met above
  - ☐ This requires a request for waiver of documentation of Parental Permission
  - ☐ Research Information Sheet for age-appropriate assent

☐ **If collecting identifiable data Limited IRB review is required, item 2(a) should be "Yes" and Limited IRB Review is completed for the Procedures to Maintain Confidentiality section.**

☐ **Category 3** **(THIS CATEGORY EXCLUDES CHILDREN & CANNOT INCLUDE DECEPTION)**

Consent Types:

- Adult Participants: Research Information Sheet
  - ☐ Waiver of written documentation of consent

☐ **If collecting identifiable data Limited IRB review is required, item 3(b) should be "Yes" and Limited IRB Review is completed for the Procedures to Maintain Confidentiality section.**

☐ **Category 4**

- Only applicable if there will be no contact with participants.

	• If not retaining any identifiable data category 4 applies. Researchers who must retain individually identifiable data in their records can only use exempt category 4 when that data is under the added protection of HIPAA regulations. • 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** • Adult Participants: Research Information Sheet ☐ Waiver of written documentation of consent
☐	**Category 6** • Adult Participants: Research Information Sheet ☐ Waiver of written documentation of consent

Notes: **Submit notes via eProtocol**

Participant Population

Section A	**Yes**	**No**	**N/A**
Has the expected age range and description of participants been provided?	☐	☐	☐
Has the number of records/charts/specimens been provided?	☐	☐	☐
Section C: STUDENTS INCLUDED AS RESARCH PARTICIPANTS **If not applicable, select N/A and go to next section ☐ N/A**	**Yes**	**No**	**N/A**
If there is a relationship between the PI or recruitment personnel and the students?	☐	☐	☐
Is the rationale appropriate for enrolling students (grade school and WSU higher education)?	☐	☐	☐
Are there measures to minimize risk of undue influence (noted as coercion)?	☐	☐	☐
Section D: EMPLOYEES **If not applicable, select N/A and go to next section ☐ N/A**	**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	☐	☐	☐
Is the rationale appropriate for enrolling WSU/WSU affiliate employees/staff?	☐	☐	☐
Are there measures to minimize risk of undue influence (noted as coercion)?	☐	☐	☐
Section E: NON-ENGLISH-SPEAKING PARTICIPANTS & STUDY SCREENING	**Yes**	**No**	**N/A**
If Non-English speaking participants will be included as participants: Check the Consent/Assent sections for translated consent/assent 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 if waiver is required. For example, conducting test, intervention, assessments, collection of identifiable information to determin eligibility.**	☐	☐	☐

Section F: PRINCIPAL INVESTIGATOR'S EXPERTISE	Yes	No	N/A
Does the PI have the appropriate expertise to conduct the study? See CV/resume for attachments section if additional information needed.	☐	☐	☐
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 ONLY (e.g., retrospective chart review), Select N/A and go to next section ☐ N/A

Section A: RECRUITMENT PROCESS	Yes	No	N/A
ITEM (i): Are recruitment procedures clearly described? Note: it is clear when, where, and how recruitment procedures are taking place.	☐	☐	☐

ITEM (ii):

- If DMC, VAMC, KCI, McLaren are selected check the attachments section for approvals.
- If a non-WSU or non-WSU affiliate site will provide direct access to prospective participants has this entity been listed for "Other"? ☐ Yes ☐ No ☐ N/A

Check the Attachments sections for letter(s) support from these entities.

Direct access includes the PI/study team directly recruiting participants from the site or directly sending recruitment materials.

For the item "*Please identify planned recruitment materials and or methods"* are any materials or methods selected? **If yes, check the attachment section for any of the items listed (flyers, email, social media posts/statements, advertisements, presentations etc.)**	☐	☐	☐

Note: ResearchMatch recruitment method ***cannot*** *be used for studies that do not have health related outcomes. For more information see the ResearchMatch website: https://research.wayne.edu/irb/researchmatch*

Notes: Submit notes via eProtocol

Section B: PARTICIPANT COMPENSATION

If No compensation, then select N/A and go to next section ☐ N/A

	Yes	No	N/A
Will participants be compensated for their time?	☐	☐	☐
If yes, does the 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 Are there any costs to participants? *If yes, this must be stated for the consent/assent forms.*	☐	☐	☐

Notes: Submit notes via eProtocol

Procedures to Maintain Confidentiality section	Yes	No	N/A
Has the appropriate data type been selected (identifiable, anonymous, de-identified, or coded)?	☐	☐	☐
ITEM a: If information will be disclosed outside of the research team, is there a description of whom the information will be shared? ☐ Yes ☐ No ☐ N/A			
ITEM b: If PHI will be used, has the HIPAA section been completed? If **yes,** HIPAA must be selected for the Protocol Checklist and then complete the HIPAA section	☐	☐	☐
ITEM c: Are there measures to protect privacy of participants?	☐	☐	☐
ITEM d: Are there measures to maintain confidentiality of data?	☐	☐	☐
ITEM g: If identifiable data will be collected and released (video, audio, photo) does the response state how permission will be obtained to release identifiable data?	☐	☐	☐
ITEM j: Is there an adequate plan for storage (including audio or video recordings)? IRB guidance recommends storage of all research data on an encrypted server. Password protection ONLY is not adequate for storing identifiable data. For use of PHI: user must follow the hospitals/clinical care facilities HIPAA compliant storage procedures.	☐	☐	☐
ITEM i: Is there an appropriate plan to dispose of data (a secure way to shred/delete data?	☐	☐	☐
Notes: Submit notes via eProtocol			

Procedures to Maintain Confidentiality Section

LIMITED IRB REVIEW (ONLY FOR EXEMPT CATEGORIES 2 & 3)

CONDUCTED BY IRB CHAIR OR DESIGNATED IRB MEMBER

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

	Yes	No	N/A
ITEM 1: Does the described risks include possibility of criminal or civil liability or include damaging participants' financial standing, employability, educational advancement, or reputation? **Note if yes, the study cannot be Exempt.**	☐	☐	☐
ITEM 1(a): Are there appropriate security controls in place to protect confidentiality of data and deter risk of information being lost, stolen, or compromised?	☐	☐	☐
ITEM 2(a): Is the de-identification of data being conducted by individuals that are listed as key Personnel for the Personnel Information section or personnel/entity included as part of a data agreement? The IRB does not process/review the agreement, response should address the agreement.	☐	☐	☐
ITEM 2(b): Is there a description to de-identify data prior to sharing with any outside party?	☐	☐	☐
Reviewer Limited IRB Review Acknowledgement by IRB Chair or designated IRB Member The IRB reviewer acknowledges that limited IRB review has been conducted and has determined that there are adequate provisions in place to protect participants' privacy and confidentiality of data. **IRB Chair/Designated IRB Member's Initials**:			
Notes: Submit notes via eProtocol			

Consent/Assent Information & Procedures If secondary data collection, select N/A and go to next section ☐ N/A If Children are included review the Assent section.	Yes	No	N/A
ITEM 10(a): Is the consent or assent process clearly defined?	☐	☐	☐
ITEM 10(c): If obtaining signed consent/assent are all individuals referenced obtaining consent/assent listed for the Personnel Information section?	☐	☐	☐
Is the appropriate type of consent/assent/information sheet provided? **Use of the WSU IRB's consent templates is highly recommended**	☐	☐	☐

Check that the following information has been addressed for the consent/assent documents:

☐	Statement that the research is voluntary.
☐	States the activities involves research.
☐	Description of ALL the study procedures, duration of procedures, & total duration of participation Description of audio & video recording.
☐	Risks are stated, if applicable (**Compare the eProtocol Exempt Paragraph selection**).
☐	Benefits are stated, if applicable or no direct benefit indicated
☐	The Research Related Injuries section has been removed, if appropriate
☐	Confidentiality/storage of data is described (including audio, video, photographs).
☐	If data will be shared for future use.
☐	Compensation is described, if applicable or a statement that there is no compensation
☐	Contact information of the Principal Investigator and IRB has been provided.
☐	There is a submission/revision date for the footer of the document.

IF INFORMATION NOT INCLUDED, THEN PLEASE REQUEST REVISIONS via eProtocol.

Notes: **Submit notes via eProtocol**

Consent Information/Assent Information (waivers and/or alterations of consent)

See exempt category notes regarding consent types

	Yes	No	N/A
Waiver of Consent **and/or** Parental Permission	☐	☐	☐
Waiver for written documentation of consent Use of Research Information Sheet (**RIS**) or Verbal Consent Script	☐	☐	☐
Waiver of consent and waiver of written document of consent to screen	☐	☐	☐
Alteration of informed consent *(Removing elements of consent from the RIS or use of deception)*	☐	☐	☐

The PI has provided specific justifications for the waiver statements	☐	☐	☐
USE OF DECEPTION ☐ **N/A**			
An alteration of consent has been completed and is appropriate.	☐	☐	☐
The study **ONLY** includes adult participants.	☐	☐	☐
There is a ***prospective*** agreement that informs the participant that they will be unaware or misled regarding the nature or purpose of the research.	☐	☐	☐
A debriefing script has been provided (check attachments).	☐	☐	☐

Notes: **Submit notes via eProtocol**

HIPAA If not applicable Select N/A and go to next section ☐ **N/A** REVIEW CONDUCTED BY IRB CHAIR OR DESIGNATED IRB MEMBER	**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	☐	☐	
All Data Collection Tools (questionnaires, surveys, etc.) are provided.	☐	☐	☐
Are data collection tools in easy-to-understand appropriate language?	☐	☐	☐
Recruitment Materials (flyers, advertisements, scripts etc.) are provided	☐	☐	☐
Does the recruitment materials meet the IRB's Criteria for Advertising?	☐	☐	☐

Advertising Criteria: (Flyers/Advertisements, recruitment emails, and scripts)

- Indicates that this is a Research Study
- 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
- If using ResearchMatch there are examples of the Contact Messages available at: https://research.wayne.edu/irb/researchmatch

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.

The following items may be included in advertisements, but 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.

Attachments (section) continued	Yes	No	N/A
Letters of Support provided (Non-Affiliate Sites & Outside of PI's Department)	☐	☐	☐
Ancillary Reviews/Approvals are required	☐	☐	☐

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 focused 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 for selected procedures (email, list servs, social media, etc)	☐	☐	☐
Data Collection conducted via internet. If yes, procedures are described.	☐	☐	☐
Are social media platforms being used?	☐	☐	☐
Site administrator(s) approval(s) for use of social media platforms are provided (check attachments section)	☐	☐	☐

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	☐	☐	☐
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 & assent process appropriate?	☐	☐	☐

Reviewer Determination

Concurrence of Exemption Granted

☐

☐ **Exemption category revised from PI's selection.**
State Revised Category

☐ **Specific Minor Revisions**
Submit comments in eProtocol
Date Revisions Requested:

Date Revisions Completed:

Approved Waivers and Documents

☐ **Waiver of consent to screen**	☐ **Waiver of written documenation of consent** Use of Research Information Sheets or Verbal Consent Scripts
☐ **Full waiver of consent for retrospective chart/record review**	☐ **Waiver of documentation of assent** Use of Adolecent Research Information sheets

Final Approved Consent/Assents Attachments	Date attached

Attachments section documents

Final Approved Recruitment Materials	Date attached

Final Approved Data Collection Tools/Questionnaires/Participant Informaton	Date attached

Concurrence of Exemption Period (select all that apply)	
Status Check-In Every 3 years ☐	**Status Check-In with Limited IRB Review Every 3 years** ☐

IF THIS SUBMISSION INCLUDES LIMITED IRB REVIEW OR HIPAA, THIS REVIEW MUST BE CONDUCTED BY THE IRB CHAIR OR DESIGNATED IRB MEMBER OF THE COMMITTEE FOR WHICH THIS STUDY IS ASSIGNED.

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.**

Additional Notes:

Submit notes via eProtocol