**IRB Administration Office**

87 E. Canfield, Second Floor

Detroit, MI  48201

[(313) 577-1628](callto:(313)%20577-1628)

irb.wayne.edu

**Investigator Self Pre-Review Tool:**

Use this tool to determine what type of IRB review your study will require and the required forms needed for the review of your Human Participant Research. **This tool does not need to be turned in. It is for your guidance only**.

**Note:** All investigators **must** complete CITI training prior to submitting any study to the IRB. [www.citiprogram.org](http://www.citiprogram.org).

**Note:** Revisions to the Federal DHHS Common Rule went into effect on January 21, 2019. This tool reflects those changes.

**VA Researchers:** We have not yet started accepting VA submissions through eProtocol. Links to the IRB applications that need to be completed for your paper submission, and instructions for the paper submission process are available in the VA Submission section near the end of this tool.

**If you are unsure if IRB review is required:** We have a Human Participant Research Determination tool that will help to determine if the project will require IRB review. If you would like an IRB official determination, you can send the completed tool to [irbquestions@wayne.edu](mailto:irbquestions@wayne.edu).

* [HPR Determination Tool](https://research.wayne.edu/irb/04_2015_forms/revised_common_rule_hpr_determination_tool.doc)
* [HPR Guidance](https://research.wayne.edu/irb/docs/hpr_guidance-_activities_that_are_not_hpr_4_10_19.pdf)

**Determining Risk Level**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | Does your study add to the risks your participants would encounter in their everyday life? | | No **– Continue to #2**  Yes- Your study requires a full board review. Skip to #5  Submission Deadlines and Meeting Dates apply only if you checked yes. See our [website for all submission deadlines and meeting dates.](https://research.wayne.edu/irb/meetings-deadlines) |
| 2. | Does the study involve protected health information? | | No  Yes: Please complete the HIPAA section in eProtocol. |
| **Exempt Review Categories** | | | |
| 3. | **If your study meets one or more of the categories below, please** select *Exempt* for the review type in eProtocol.  **Check the category(s) that BEST describes your study.**  Check out our [Exempt Research Guidance](http://research.wayne.edu/irb/04_2015_forms/revised_exempt_research_guidance_12_22_17.pdf) document for more information about the Exempt review categories | | |
|  |  | **Exempt Category 1:** Research is conducted ONLY in established or commonly accepted educational settings: Involving normal education practices.   * To be exempt under this category it must be unlikely to adversely impact the students’ opportunity to learn required educational content or the assessment of educators who provide instruction. | |
|  |  | **Exempt Category 2:** Research that involves the use of educational tests, survey procedures, interview procedures or observation of public behavior. If data is collected in a way that makes it possible to identify participants, [Appendix M: Limited IRB Review](http://research.wayne.edu/irb/04_2015_forms/appendix_m-_limited_irb_review-corrected_2_1_19.docx) must be included with your submission.  You will need to introduce the research to participants using an Information Sheet as an unsigned form of consent. More information available in number 5 & 6. | |
| **Disqualifying Conditions** If the following conditions apply to your study, your study will require an expedited review. | |
| **Do not** check this box if:   1. Children are involved in survey procedures or interview procedures 2. Children are involved and the investigator is participating in the activities being observed and 3. data is being collected in a way that makes it possible to directly or indirectly identify participants      1. Any disclosure of the participant’s data outside of the research could place participants at risk of criminal or civil liability, or be damaging to the participant’s financial standing, employability or reputation   **Note:** If any of these conditions apply to your research, your study falls under expedited category 7- described in detail on page 3 | |
|  |  | **Exempt Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses or audiovisual recording if the participant prospectively agrees to the intervention and information collection. For more information about this category review our [Benign Behavioral Interventions Guidance Tool](http://research.wayne.edu/irb/04_2015_forms/benign_behavioral_interventions.pdf)  If data is collected in a way that makes it possible to identify participants, [Appendix M: Limited IRB Review](http://research.wayne.edu/irb/04_2015_forms/appendix_m-_limited_irb_review-corrected_2_1_19.docx) must be included with your submission. | |
| **Disqualifying Conditions** If the following conditions apply to your study, your study will require an expedited review. | |
| **Do not** check this box if:   1. The research involves children 2. Any disclosure of the participant’s data outside of the research could place participants at risk of criminal or civil liability, or be damaging to the participant’s financial standing, employability or reputation | |
|  |  | **Exempt Category 4:** Research involving the study or collection of **existing data,** documents, records, pathological specimens or diagnostic specimens if:   1. Sources are publicly available or, 2. the investigator does not contact participants, or re-identify participants 3. The only collection of identifiable data is that which is protected by HIPAA regulations   **Disqualifying Condition:** | |
| Do not check this box if there will be any interactions or interventions with the individuals associated with the data being collected under this category. This category cannot be combined with any other category.  If this is the case, your study would fall under expedited category 5 plus the appropriate expedited category that describes the interactions or interventions with research participants as described below in #4 | |
|  |  | **Exempt Category 5:** Research and demonstration projects that are subject to the approval of Department or Agency heads and are designed to study, evaluate, or otherwise examine:   1. Public benefit or service programs 2. Procedures for obtaining benefits or services under those programs 3. Possible changes in, or alternatives to those programs or procedures 4. Possible changes in methods or levels of payment for benefits or services under those programs | |
|  |  | **Exempt Category 6:** Taste and food quality evaluation studies and consumer acceptance studies if:   1. Wholesome foods without additives are consumed or 2. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture. | |

**Expedited Review Categories**

|  |  |  |  |
| --- | --- | --- | --- |
| 4. |  | If your study didn’t meet any of the exempt categories above, it will undergo either an expedited review, or full board review.  If your study meets one or more of the categories below, please select *Expedited* for the review type in eProtocol.  **Note:** You cannot combine exempt and expedited categories.  **Check the category(s) that BEST describes your study to determine if your study can receive an expedited review** | |
|  |  | **Expedited Category 1:** Clinical study of drugs and medical devices if either   1. Research on drugs for which an investigational new drug application is not required 2. Research on medical devices in which an investigational device exemption application is not required; or the medical device is cleared, approved for marketing and the medical device is being used in accordance with it’s cleared/approved labeling | |
|  |  | **Expedited Category 2:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:   1. From healthy, non-pregnant adults who weigh at least 110 pounds. Amounts drawn for these participants must not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week or; 2. From other adults and children, considering the age, weight, and the health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml, or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. | |
|  |  | **Expedited Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means. Examples:   1. hair and nail clippings in a non-disfiguring manner; 2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; 3. permanent teeth if routine patient care indicates a need for extraction; 4. excreta and external secretions (including sweat); 5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; 6. placenta removed at delivery; 7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; 8. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; 9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 10. sputum collected after saline mist nebulization. | |
|  |  | **Expedited Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:   1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; 2. weighing or testing sensory acuity; 3. magnetic resonance imaging; 4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; 5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. | |
|  |  | **Expedited Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.) | |
|  |  | **Expedited Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes. | |
|  |  | **Expedited Category 7**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human participants 45 CFR 46.l0l (b)(2) and (b)(3). This listing refers only to research that is not exempt.) | |
| **Appendices to the Initial IRB Application in eProtocol** | | | |
| 5. | **Check all that apply:**  Click on the link to complete the appendix for each box you check.  ALL applicable appendices must be completed and included in your submission to be assigned to a reviewer. | | [Participants with Impaired Decision-Making Ability](http://research.wayne.edu/irb/04_2015_forms/revised_common_rule_psf_appendix_d-_participants_with_impaired_decision_making_ability.doc)  [Use of Drugs, Biologic Agents or Devices](https://research.wayne.edu/irb/04_2015_forms/appendix_f_04_2015a.doc)  [Imaging/Diagnostic Radiation](https://research.wayne.edu/irb/04_2015_forms/appendix_g_04_2015.doc) [Dose Calculation Tool](https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp)  [Use of Biological Specimens](http://research.wayne.edu/irb/04_2015_forms/revised_common_rule_appendix_h-_use_of_biological_specimens_rev1.doc)  [Studies Conducted at or by the VA](https://research.wayne.edu/irb/04_2015_forms/appendix_j_04_2015.doc)- VA studies must submit via paper process described below. |

**Informed Consent**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 5. | | **Waiver or Alteration Criteria**  All of the following criteria must apply in order for a waiver or alteration of consent to be granted: | | |
|  |  | | The Research involves no more than minimal risk to the participants | |
|  |  | | The research could not practicably be carried out without the waiver or alteration of consent | |
|  |  | | The waiver or alteration will not adversely affect the rights and welfare of the participants | |
|  |  | | Whenever appropriate, the participants will be provided with additional pertinent information after participation. | |
| If you did not check all of the boxes above, then you must prepare an informed consent document to be signed by to your participants prior to their involvement in the research.  **If you did check all boxes above, skip to #7.** | | | | |
| 6. | **Check all that apply:**  Click on the link that describes your research to access the Informed Consent template for each box you check.  ALL applicable informed consent versions must be completed and included in your submission to be assigned to a reviewer. | | | **Medical Research**  [Research with Adults](https://research.wayne.edu/irb/docs/medical_adult_research_informed_consent_template_revised_v_03-2019.doc)  [Research Assent ages 13-17 (Enrolling Minor Participants)](https://research.wayne.edu/irb/docs/medical_adolescent_assent_form_v_03-2019.doc)  [Research Using DMC Services](https://research.wayne.edu/irb/docs/dmc-_tenet_medical_research_informed_consent_template_v_03-2019.doc)  [Research Conducted at a McLaren Facility](https://research.wayne.edu/irb/docs/medical_research_informed_consent_mclaren_v_08-06-2019.doc) |
| **Medical/Behavioral Research**  [Anonymous Survey Adult Research: Information Sheet](https://research.wayne.edu/irb/docs/adult_research_information_sheet_template_v_03-2019.doc)  [Parental Permission for research with children](https://research.wayne.edu/irb/docs/parental_permission_research_informed_consent_template_v_03-2019.doc)  [Oral Assent Script:](https://research.wayne.edu/irb/docs/oral_assent_script_template_3_2019.docx) Children ages 7-12 |
| **Behavioral Research**  [Behavioral Research with Adults](https://research.wayne.edu/irb/docs/behavioral_adult_research_informed_consent_template_v_03-2019.doc)  [Behavioral Research with Minors ages 13-17: Assent](https://research.wayne.edu/irb/docs/behavioral_adolescent_assent_form_v_03-2019.doc)  [School Research When Parental Permission is Waived.](https://research.wayne.edu/irb/docs/school_parent_supplemental_information_letter-_decline_participation_template_v_03-2019.doc)  [School Research When Parental Permission is Required](https://research.wayne.edu/irb/docs/school_parental_permission_research_informed_consent_template_v_03-2019.doc) |
| **Note:** Assent is a shortened consent form written in a way that the minor between the ages of 13 and 17 can understand. When this applies, the minor’s legal guardian must also sign a full informed consent. | | | | |

**HIPAA**

|  |  |
| --- | --- |
| 7. | If your study involves the collection of protected health information, the HIPAA section of the eProtocol application is required. |
| For studies involving the collection of protected health information and a signed consent form, the HIPAA Authorization language contained within the informed consent template must be included in the final consent form submitted for IRB review. |

**Additional Required Materials:**

**Protocol:** A protocol or research proposal that describes the background, objectives/aims, participant population/ data characteristics, methodology and references must be included in every submission. Make sure information in all applications and consent forms are consistent with the protocol.

A protocol is required for all types of research. The protocol should serve as your source document for completing all other IRB documents.

**Data Collection Tool:** A copy of the data collection tool must be submitted for every study.

**Survey/interview questions/scripts/ recruitment flyers:** A copy of any surveys, interview questions, telephone scripts etc. must be included in your submission package. Generally anything related to the research that the participants or potential participants will see must be reviewed by the IRB.

**Additional Considerations:**

**Questions**: Any questions that come up as you prepare your IRB submission can be directed to [irbquestions@wayne.edu](mailto:irbquestions@wayne.edu)

Technical questions about eProtocol can be directed to [wsuirbinfo@wayne.edu](mailto:wsuirbinfo@wayne.edu)

**Single IRB Review**: Any single IRB related questions should be directed to [relyirb@wayne.edu](mailto:relyirb@wayne.edu). Additional information and submission forms are available on our [Reliance Agreements Webpage](https://research.wayne.edu/irb/reliance-agreements).

**DMC Research by WSU Faculty:** Research that takes place at DMC will undergo a concurrent DMC review: A detailed description of the [DMC Review Process](http://www.dmc.org/researchreviewprocess/) is available on the website.

**Material Transfer Agreements (MTA):** MTA’sare used when data or specimens are being transferred from one institution to another. It is a contract between two parties that describes the terms and conditions underlying the transfer of biological materials, chemical compounds, and other tangible research data or materials. To request an MTA visit [WSU’s Technology Commercialization website](http://www.techtransfer.wayne.edu/industry/mta.php)

**Conflicts of Interest:** If you have any conflicts of interest (COI), you must bring it to the attention of the COI Committee before submitting your study to the IRB. Visit the [WSU Conflict of Interest Committee website](http://research.wayne.edu/coi/index.php) for more information.

**Investigator Initiated Research:** When a Principal Investigator (PI) initiates research using an investigational or unlicensed test article (drug or device) the PI assumes the obligations and responsibilities of a sponsor in sponsored research. Because of the added risk to participants in investigator initiated research, there are additional regulations and policies to follow. Review the [WSU policy on investigator initiated research](file:///C:\Users\hpark-may\AppData\Roaming\Microsoft\Word\Stock%20Images) before preparing an IRB submission for investigator initiated research.

**Tips for a Smooth Review:**

1. **Check out our guidance tools!**

**Getting Started Guidance**

* + 1. [**What Students Should Know Before Conducting Research**](http://research.wayne.edu/irb/pdf/the-irb-what-students-should-know.pdf)
    2. [**What to Include in a Research Proposal/Protocol**](http://research.wayne.edu/irb/pdf/what-to-include-in-a-research-proposal.pdf)
    3. [**Exempt Review Categories**](http://research.wayne.edu/irb/04_2015_forms/revised_exempt_research_guidance_12_22_17.pdf)
    4. [**Expedited Review Categories**](http://research.wayne.edu/irb/04_2015_forms/expedited_research_guidance.pdf)
    5. [**Benign Behavioral Interventions**](http://research.wayne.edu/irb/04_2015_forms/benign_behavioral_interventions.pdf)**- Exempt Category 3**
    6. [**Key Personnel**](https://research.wayne.edu/irb/04_2015_forms/key_personnelguidance_02_2019.pdf)

**Recruitment and Consent**

* + 1. [**Advertising to Recruit Participants**](http://research.wayne.edu/irb/pdf/advertising-to-recruit-research-participants.pdf)
    2. [**Waiver and Alteration of Consent**](http://research.wayne.edu/irb/04_2015_forms/waiver_and_alteration_of_informed_consent_guidance.pdf)
    3. [**Informed Consent Options**](http://research.wayne.edu/irb/pdf/informed-consent-options.pdf)
    4. [**Required Elements of Informed Consent**](http://research.wayne.edu/irb/pdf/required-elements-of-informed-consent.pdf)
       1. [Key Information](https://research.wayne.edu/irb/docs/key_information_guidance_2_7_19_1.pdf)
    5. [**How to Check the Reading Level of a Consent Document**](http://research.wayne.edu/irb/docs/test-your-document-s-readability-5-15-2013.docx)
    6. [**Sample of Lay Language for Risks**](http://research.wayne.edu/irb/docs/sample_lay_language_for_risks.doc)
    7. [**Research Translation Requirements for Non-English Speakers**](http://research.wayne.edu/irb/pdf/research-translation-requirements-non-english-speakers.pdf)

**Data Collection and Protection**

* + 1. [**Privacy and Confidentiality**](http://research.wayne.edu/irb/pdf/privacy-and-confidentiality.pdf)
    2. [**Retrospective Chart Review**](http://research.wayne.edu/irb/pdf/guidance-for-research-conducted-via-retrospective-chart-review-1-21-2011.pdf)
    3. [**Data Use Agreements and Limited Data Sets**](https://research.wayne.edu/irb/docs/dua_and_limited_data_sets-_applying_the_hipaa_privacy_rule_to_research_5_9_19.pdf)

**Research involving outside organizations (Organizations that are not WSU or a WSU affiliate)**

* 1. [**Letters of Support**](http://research.wayne.edu/irb/pdf/letters-of-support-guidance.pdf)
  2. [**International Research**](http://research.wayne.edu/irb/pdf/international-research-guidance.pdf)

**Biospecimen Research**

* 1. [**Private Information/Bio Specimens Decision Chart: Determining if IRB review is required**](http://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf)
  2. [**PRIM&R Collection and Banking Specimens for Research Charts: Determining if IRB review is required**](http://research.wayne.edu/irb/pdf/prim-r-collection-banking-specimens-for-research-charts-2007.pdf)
  3. [**Resource List for Specimen Banking**](http://research.wayne.edu/irb/docs/resource-list-for-specimen-banking-11-11-11.doc)

1. **Use most current forms available on the website.** Do not use a form you previously completed and saved on your computer as forms are routinely updated to comply with changing processes and regulations.
2. **Do a final check for completeness:** Turning in a complete submission package to the IRB will help reduce the turnaround time for your review. **The checklist below will help with your final check. Note: Not everything in this list will apply to your study.**
3. **Make sure the you have the correct Department Dean or Chair sign off on your protocol.** Link to guidance provided in eProtocol Guidance Tools
4. **Make sure you include other ancillary review approval documents** such as PRMC approval for Karmanos studies, or Radiation Safety Committee approval for studies that expose participants to radiation.



**eProtocol Check for Completeness Checklist:**

|  |  |
| --- | --- |
| **Note:** eProtocol takes you through a “Check for Completeness” before you can submit your study to make sure you have everything needed. There are additional items that may be required for your submission that may not be included in your eProtocol check for completeness. These are listed below: | |
| **Required Items as Applicable** | |
|  | All appendices that apply have been completed |
|  | A bio-sketch for the PI is included (Not required for exempt review) |
|  | Any communication from the Financial Conflict of Interest (FCOI) committee regarding FCOI disclosures is included (May not apply if there are no FCOI’s to report) |
|  | Letters of approval from all required review committees are included |
|  | Letters of support for research activity at outside institutions are included |
|  | Advertisements (flyers, emails, study brochures) |
|  | Data collection tools (survey questions, questionnaires) |
|  | Consent/Assent/parental permission documents using templates available on website. |
|  | Information Sheet (required as a form of consent for all survey studies) |
|  | Investigational Drug Brochures (IBs) or drug package inserts are included |

**Electronic Submission using e-Protocol**

New submissions for all research that is not conducted at the Veterans Administration Medical Center must be submitted using eProtocol. Follow links below for resources available to help navigate the eProtocol online submission system.

You must have your WSU Access ID number (This is the two letter +four number combination ID that WSU assigns all faculty, students and staff) added to your CITI training profile before you can submit a new initial submission in eProtocol.

If you do not have a WSU Access ID number you can request one by emailing a request for a guest Access ID to [wsuirbinfo@wayne.edu](mailto:wsuirbinfo@wayne.edu)

**eProtocol** Guidance Tools:

1. [Initial Submission Checklist](https://research.wayne.edu/irb/docs/irb_eprotocol_submitters_checklist_revised_2_5_2019_docx.pdf)
2. [CITI Training Tool](https://research.wayne.edu/irb/04_2015_forms/revised_citi_profile_instructions.pdf) (Includes instructions for updating your CITI profile with your Access ID)
3. [Key Personnel Sign off and Conflict of Interest Tool](https://research.wayne.edu/irb/eprotocol/key_personnel_completing_coi_obligations.pdf)
4. [Authorized Signatory Chair/Dean Sign Off and Conflict of Interest Tool](https://research.wayne.edu/irb/eprotocol/dean_chair_completing_department_cerftifications_docx.pdf)
5. [Labeling eProtocol Attachments](https://research.wayne.edu/irb/docs/revised_eprotocol_attachment_labeling_9_2019_docx.pdf)
6. [Consent Waiver and Alteration of Consent](https://research.wayne.edu/irb/docs/eprotocol_waiver_requests.pdf)

**How can I get help using eProtocol?**

* Technical questions about using eProtocol should be directed to [wsuirbinfo@wayne.edu](mailto:wsuirbinfo@wayne.edu)
* eProtocol drop in training events are scheduled regularly. Visit our [Education Webpage](https://research.wayne.edu/irb/education) for our schedule of drop in training events

**Paper Submissions: Veterans Affairs (VA) Only.**

Research being conducted at or by the VA, please submit following the instructions below. All other research must submit using eProtocol following instructions and guidance provided above.

Note: This list of IRB applications covers the more commonly used applications. There are others that may apply to your research in less common situations. Please see our [Forms and Submission Requirements webpage](https://research.wayne.edu/irb/forms-requirements-categories) for a complete list.

In addition to the IRB applications that apply to your research, and other required documents as applicable, you must also include the **VA Approval (CIC) memo** with your submission documents.

**Links to IRB Applications:**

* [Exempt Medical Protocol Summary Form:](https://research.wayne.edu/irb/docs/medical_exempt_protocol_summary_form.doc) Use this form if your study is considered medical research met one or more of the exempt categories described in #3.
* [Exempt Behavioral Protocol Summary Form:](https://research.wayne.edu/irb/docs/common_rule_sbr_exempt_protocol_summary_form_rev1.doc) Use this form if your study is considered behavioral, social, or education research and it met one or more of the exempt categories described in #3

**Exempt Category Appendices:** Note- If your study falls under any of the exempt review categories below, you will need to include the corresponding appendix with your submission.

* + [Exempt Category 1 Appendix](https://research.wayne.edu/irb/04_2015_forms/exempt_category_1_appendix.doc)
  + [Exempt Category 2 Appendix](https://research.wayne.edu/irb/docs/exempt_category_2_appendix_correction_5_9_19.doc)
  + [Exempt Category 3 Appendix](https://research.wayne.edu/irb/04_2015_forms/exempt_category_3_appendix_rev1.doc)
  + [Exempt Category 4 Appendix](https://research.wayne.edu/irb/04_2015_forms/exempt_category_4_appendix.doc)
  + [Appendix M: Limited IRB Review:](https://research.wayne.edu/irb/04_2015_forms/appendix_m-_limited_irb_review-corrected_2_1_19.docx) Use this form if your study falls under exempt category 2 or 3 and you will be collecting identifiable data from your research participants.
* [Medical/Behavioral Protocol Summary Form:](https://research.wayne.edu/irb/docs/updated_protocol_summary_form_revision_updated_4_2019.doc) Use this form if your study falls under one or more expedited category described in #4 or is considered greater than minimal risk (research that adds to the risk a reasonable individual encounters in their everyday life) and requires review by a fully convened board.

**Appendices**: Note- if your study involves any of the elements associated with the appendices listed below, you will need to include the corresponding appendix with your submission.

* [Appendix A- International Research](https://research.wayne.edu/irb/04_2015_forms/appendix_a_04_2015.doc)
* [Appendix B- Internet Use in Research](https://research.wayne.edu/irb/04_2015_forms/appendix_b_04_2015.doc)
* [Appendix C- Children as Research Participants](https://research.wayne.edu/irb/04_2015_forms/appendix_c_04_2015.doc)
* [Appendix D- Adult Research Participants with Impaired Decision-Making Ability](https://research.wayne.edu/irb/04_2015_forms/revised_common_rule_psf_appendix_d-_participants_with_impaired_decision_making_ability.doc)
* [Appendix E- Prisoners as Research Participants](https://research.wayne.edu/irb/04_2015_forms/appendix_e_04_2015.doc)
* [Appendix F- Use of Drugs, Biologic Agents, or Devices](https://research.wayne.edu/irb/04_2015_forms/appendix_f_04_2015a.doc)
* [Appendix G- Imaging/Diagnostic Radiation](https://research.wayne.edu/irb/04_2015_forms/appendix_g_04_2015.doc)
  + [Radiation Exposure Calculation](https://vmw-oesoapps.duhs.duke.edu/radsafety/consents/irbcf_asp/default.asp)
* [Appendix H- The use of Biological Specimens](https://research.wayne.edu/irb/04_2015_forms/revised_common_rule_appendix_h-_use_of_biological_specimens_rev1.doc)
* [Appendix I- Research Funded by a Component of the Department of Defense (DOD)](https://research.wayne.edu/irb/04_2015_forms/appendix_i_04_2015.doc)
* [Appendix J- Studies Conducted at or by the VA](https://research.wayne.edu/irb/04_2015_forms/appendix_j_04_2015.doc)- This is required for all studies conducted at or by the VA.
* [Appendix K- Pregnancy, Fetuses, Neonates](https://research.wayne.edu/irb/04_2015_forms/appendix_k_04_2015.doc)
* [Appendix L- NIH Genomic Data Sharing](https://research.wayne.edu/irb/04_2015_forms/appendix_l_04_2015.doc)
  + [Institutional Certification: Genetic/Genomic Data Sharing](https://research.wayne.edu/irb/04_2015_forms/institutional_certification_04_2015.doc)

Additional Forms That May Be Required:

* [HIPAA Summary Form: Use this form if your study involves Protected Health Information (PHI)](https://research.wayne.edu/irb/04_2015_forms/hipaa_summary_04_2015.doc)
* [VA Studies Documentation of Waiver of HIPAA Authorization for Research- Use this form if you are requesting a waiver of HIPAA Authorization.](https://research.wayne.edu/irb/docs/va_form_10-0521_hippawaiverrequest.pdf)
* VA Informed Consent Form –Template available on our [Informed Consent/Assent Templates webpage](https://research.wayne.edu/irb/informed-consent).

|  |  |
| --- | --- |
| **Assembly and submission requirements for all VA studies** | |
|  | Staple each document individually |
|  | Assemble all stapled documents into one packet using a binder clip |
|  | Deliver paper copy of assembled submission package with original signatures in ink to the IRB administration office: 87 E. Canfield 2nd Floor Detroit MI 48201 |
| **Full Board Studies- B3 & M1:** Additional assembly and submission requirements  **Note:** Medical exempt and expedited studies only need to complete assembly and submission requirements listed above for all studies. | |
|  | Assemble 3 packets containing the following:   |  |  | | --- | --- | |  | Protocol Summary Form + all applicable appendices | |  | All consent documents | |  | Non-standardized instruments (data collection tools developed by the PI) | |  | Data collection tools that deal with sensitive subjects (drug use or sexual practices) | |  | Any advertisements or flyers | |  | VA CIC Approval Memo | |
|  | Send all submission documents to the respective IRB email addresses:  Medical Research: [m1board@wayne.edu](mailto:m1board@wayne.edu)  Social/Behavioral/Educational Research: [b3board@wayne.edu](mailto:b3board@wayne.edu) |

**If you are unsure what committee will review your study, call the IRB Administration Office at:**

**313-577-1628**