Steps for Getting WSU IRB Approval to Conduct Human Participant Research

1. **Start well in advance**— allow ample time to get through the review process.

2. Access the IRB website at http://irb.wayne.edu/index.php

3. Download the Handbook for Investigators: A Guide to the IRB and Human Research Protection Program. This is your reference guide for everything you need to know about the IRB review process in one place. Keep this resource handy. Our phone number is in the back.

4. Join our listserv to keep up to date on form changes, training opportunities, policy changes, and other occasional announcements. To join IRB-info@lists.wayne.edu, click here: http://irb.wayne.edu/education/wsu_irb_listserve_7_25_2011.pdf

5. Download an IRB Protocol Submission form (http://irb.wayne.edu/forms-requirements-categories.php)-- there are 3 different types: Exempt, Expedited, or Full Board and then medical vs. social/behavioral/education.

    - Medical **Exempt** Protocol Summary Form is for Exempt Medical Research
    - Social/Behavioral/Education **Exempt** Protocol Summary Form is for Exempt Social, Behavioral, or Educational research.
    - Medical/Behavioral Protocol Summary Form for all **Expedited** or **Full Board** Medical or Social, Behavioral, or Education research.

    To determine the types of review that is needed, refer to the helpful links below. If the research does not meet those requirements, it should be submitted for ***Full Board*** approval.

    - Expedited description and categories
    - Exempt description and categories and http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c3
    - Decision chart for Exempt and Expedited

6. Review all sections and instructions of the Protocol Summary Form—you may need Appendixes, HIPAA, and consent or assent or information sheet templates or other attachments. These forms can be found on the forms page of the IRB website, also: http://irb.wayne.edu/forms-requirements-categories.php. The Protocol Summary Form will tell you everything that you need to do, so if you follow all of the instructions, you will have a complete packet.

7. To make sure you have the most current version, download a **new copy** of the Protocol Summary Form every time you submit a protocol. If you submit on an old version, the form will be returned to you ☹

8. The investigator, ALL key personnel, the Faculty Sponsor or Supervisor (if applicable), and the Authorized Signatory Official signing the form will all need to have completed the CITI training ***PRIOR*** to submitting the forms. If they have not done so, your form will be returned to you ☹. For the CITI training, go to: https://www.citiprogram.org.

9. If you are submitting a Protocol Summary Form for full board review, check the deadline due dates at: http://irb.wayne.edu/meetings-deadlines.php

10. If the protocol is considered **VA research**, you must obtain approval from the VA CIC Committee ***prior*** to submitting to the IRB. Attach the review memo that you get back from the CIC with your IRB submission.

11. Federal **Export Control** Regulations prohibit disclosure of certain information, technology and products to designated persons or entities, whether on U.S. soil ("deemed exports") or abroad. If the protocol involves this or traveling outside of the USA, refer to the Export Control department at http://research.wayne.edu/export-control/ to see if you are required to do anything further.

12. If you have a **Conflict of Interest**, you must bring this to the attention of the Conflict of Interest Committee ***prior*** to submitting to the IRB. The Conflict of Interest Committee will provide you with either documentation that no further action is required or a management plan that you need to decide whether to accept or not. Once you have an accepted management plan or documentation that no action is required, you can submit to the IRB, including this documentation. For more info, contact the Conflict of Interest Committee: http://research.wayne.edu/coi/

13. **If your institution or department has an internal review process**, you must go through that ***prior*** to submitting to the IRB (for example, Karmanos employees or any research studies that involve cancer need to obtain a PRMC review first and submit their review letter with the IRB forms, the Dept. of Psychiatry has it's own committee, DMC has a review committee, etc.).

14. If you are using **radiation**, you will need to go through a Radiation Safety Committee ***prior*** to submitting to the IRB. The information about this is on the Radiation Appendix: http://irb.wayne.edu/policies/17-18g-appendix-g-procedures-involving-radiation.doc

15. If you are doing **research at another institution** that is not under the purview of the WSU IRB (see main page of our website for the list of affiliate sites), you will need to complete the appropriate forms (also on the forms page of the website) to have that entity's IRB review your protocol:

    - Administrative Application
    - Authorization to Use Another IRB for Protocol Approval Agreement

    These forms should be submitted to the WSU IRB. You do not need to complete a Protocol Summary Form at WSU, as you will be submitting to a different institution's IRB for review and approval if the agreement is granted.

16. If you are doing **research in collaboration with another institution** that is not under the purview of the WSU IRB (see main page of our website for the list of affiliate sites), you

may want to have the same protocol be reviewed by one of the IRBs instead of both IRBs. To apply to have your collaborators be reviewed by WSU IRB, you will need to complete a Protocol Summary Form *plus* the appropriate form below (also on the forms page of the website):

- Authorization to be the IRB of Record for Collaborating Entity

17. If you are not sure if your proposal is **even human subjects research** or think it maybe **Quality Improvement**, refer below or to the education page of our website for helpful documents to help you decide. If you are still unsure, give the Education Coordinator a call.

    - http://irb.wayne.edu/forms/is_it_human_subjects_research.docx
    - http://answers.hhs.gov/ohrp/categories/1569

18. If you are struggling with understanding what is being asked in the forms, talk to your Faculty Supervisor or Faculty Sponsor, if you have one, and attend a free IRB training session held weekly at different times and locations. Join the listserv to receive the training schedule or go to the website for the schedule and pre-recorded training Power Point presentations and other helpful resources: http://irb.wayne.edu/education.php

19. If you are struggling with the proposed design or analysis of your research study, talk to your Faculty Supervisor or Faculty Sponsor for guidance. The *WSU Research Design and Analysis Unit* on main campus also provide assistance with the design of research projects and the statistical analysis of data. The service is available free of charge to Wayne State University faculty, staff, post-doctoral students, and graduate students. The service is not available to undergraduate students. Contact information: (313) 577-9992 (313) 577-9992, RDAUnit@wayne.edu, http://www.clas.wayne.edu/unit-inner.asp?WebPageID=4001

20. If you are struggling with what to include in the protocol that you will be attaching, read the tip sheet for what to include in a protocol under Helpful Materials on the Education webpage: http://irb.wayne.edu/education/what_to_include_in_a_research_protocol_12_21_2011_post_to_education_page.doc

21. If you are struggling with anything else that was not covered, refer to the Handbook for Investigators – it goes into detail on every topic (step 3). You can also call us along the way at (313) 577-1628.

22. After all of the above, prepare your completed Protocol Summary Form and appendices following the instructions for the number of copies and whether to send electronically or not on the directions page of the Protocol Summary Form and by referring to the additional directions for submissions to M1, B3, and PH1 (only):

    - M1 (Medical IRB)
    - B3 (Behavioral IRB)
    - PH1 (Phase 1 IRB)

23. Deliver the ***signed original*** Protocol Summary Form and other appendices and forms, along with **the appropriate number of copies,** to the IRB Administration Office ☺

- Location: 87 E. Canfield, Second Floor.
- The IRB hours are 8:30am to noon, 1pm to 5pm, Mon-Fri.
- The IRB Administration Office may close early for holidays.
- The phone number is (313) 577-1628.

24. Once submitted, you may be contacted by the Reviewer with questions. If your protocol is receiving full board review, answer the questions as soon as you are able, as the more issues that are resolve before the committee meets, the faster things will move along. The full board committee can approve, request specific minor revisions, table, defer or disapprove your protocol. Tabling requires the protocol to come back to the full board meeting in a month, so trying to resolve issues in advance can help get you approved and started sooner. Refer to the deadline and meeting date schedule to know the date of the meeting: http://irb.wayne.edu/meetings-deadlines.php

25. Your protocol will be reviewed by either a single reviewer (exempt and expedited) or by a full convened IRB committee. In IRB speak, 'Expedited' does not mean faster… it refers to the fact that one member reviews the protocol, rather than a full panel of reviewers.

25. The IRB committee or single reviewer comments will be summarized in a memo and sent to you via email.

26. If changes to the research are requested of you, submit the revisions to the IRB via the instructions provided in the request.

27. Once all changes have been made and approved, an IRB approval letter will be sent via email and hard copy.

28. Once you have received the IRB approval letter, your research can begin, provided there are no further stipulations in the approval letter. Further stipulations would be given for research involving prisoners, for example, which requires further review after the IRB's review before research can begin. Other types of special research may also require further review, but in general this is not the case and would be stated in the memo to you.

29. You're not done. If you want to make any changes to the approved study (protocol, consent, etc., or *any* changes), you must first submit an amendment to make the changes. Once you receive approval from the IRB, then you may make the changes. This applies to exempt studies, as well.

30. If you have any adverse events, protocol deviations, or unexpected problems along the way, these need to be reported to the IRB right away if they are considered reportable events. See these resources for help determining your course of action.

    - http://irb.wayne.edu/determine_up_unanticipated.pdf
    - http://irb.wayne.edu/17-2b_unexpectedproblem_checklist.pdf
    - http://irb.wayne.edu/up_algorithm.pdf

    The Unexpected Problem Form is on the forms page of the IRB website: http://irb.wayne.edu/forms-requirements-categories.php

31. You're still not done. Your IRB approval will be valid for a set amount of time if it was full board or expedited. You, as the PI, *must* either (a) submit a continuation form well before it expires, or (b) submit a closure form before it expires.

You must do one or the other.

Failure to do so is considered non-compliance under the federal regulations and may be reportable, even if you have since graduated. Continued non-compliance is also reported and reviewed by the full board IRB.

We do not require a closure form or a continuation form for exempt studies.

Now you are done.