## A. Submission Guidelines

**All research involving human subjects must be approved by the IRB before any research activities may begin. This includes all surveys, interviews, and/or data collection involving human subjects, whether it is administered online or face-to-face. Failure to submit a research proposal to the IRB for approval may result in discontinuation and/or removal of university support for the project.**

**The following is a step-by-step guide for human subject researchers to follow when preparing a proposal for IRB review.**

1. **Complete the ethics certification course. All persons involved in the administration of the research, including investigators, sponsors, and approving agents, must complete the Research Ethics and Compliance Training online course before a research proposal can be reviewed. This online course is located at https://about.citiprogram.org/en/homepage/. The course requires approximately one hour to complete.**

2. **Save a digital copy of the certificate at the end of the course. Sponsors and approving agents may wish to save a copy to be kept on file. This certificate must accompany the application packet.**

3. **Consider the IRB application process for research proposals and target completion of the application with these timelines in mind.**

    a. **All applications will be processed on a rolling basis.**
        1. **An application/proposal for a Full Review will be addressed at the next convened IRB meeting, assuming there is at least 3 weeks for members to review the proposal. Although the IRB attempts to meet once a month, this is not guaranteed and therefore the decision of a Full Review may not be made for several weeks.**
        2. **An application/proposal for an Expedited Review will be disseminated to the subcommittee and a vote will be conducted within 3 weeks.**

        **NOTE: if the subcommittee does not vote to approve or conditionally approve the study, it will then be brought to the entire board at the next convened meeting, similar to the Full Review process described in 1.**

        3. **Applications submitted in the Exempt from Review category may be submitted at any time and will be processed on a rolling basis as quickly as possible, however, in some instances the process may still require 1-2 weeks.**

    b. **No exceptions will be made.**

4. **Determine whether the research may be approved using exempt, expedited, or full-review criteria.**

    a. **Only the IRB chair can make the final determination as to whether the research is exempt, expedited, or needs full review.**
    b. **If an application submitted as "exempt" does not meet the "exempt" criteria, it will automatically be considered for "expedited" review.**
    c. **If an application submitted as "expedited" review does not meet the "expedited" criteria, it will automatically be considered for "full review."**

5. **Complete the appropriate application. All application files and checklists are available on the IRB website www.nsula.edu/irb and are in fillable PDF format.**

    a. **"Expedited" and "full review" applications are identical with the exception of the second and third page of the "expedited" review. These pages list "expedited" criteria. At least one of the criteria must be met to qualify for review under that status.**
    b. **When completing the application forms, do not complete any item with "Not Applicable." All statements and questions must be addressed.**
    c. **Do not leave any sections blank.**

6. **Obtain the appropriate signatures. In order to complete this task electronically, the principal investigator (PI) should electronically sign and date the application before emailing it to the faculty advisor (FA), if applicable. The FA should electronically sign and date the document before emailing it to the appropriate department/budget/unit head to obtain their electronic signature and date. An official electronic signature is not necessary, in fact it tends to lock the document so that it is no longer fillable, instead all parties should type their names and dates directly into the designated boxes to serve as signatures.**

7. **View the checklist for proposal submissions to ensure all materials are completed and included.**

8. **Submit the application packet directly to the IRB via email irb@nsula.edu.**

    a. **When submitting an IRB application, save each file separately (i.e. Informed Consent form, ethics training certificate, survey instrument, etc.) as a Word or PDF format.**

b. **On the first page of the application, the PI should specify which attachments are included in the submission packet.**
c. **The PI should carbon copy (CC) every person who electronically signed and dated the application in the submission email.**
d. **If a faculty advisor was required in the process, a copy of their separate checklist must be included in the PI's completed application packet. The FA's checklist must contain their electronic signature and date to be acceptable.**

9. **A letter with IRB recommendations or approval will be sent to investigators, sponsors/advisors and approving agents. No research may begin until an approval letter from the IRB is received. Actions the IRB may recommend are:**
    a. **Approval: Research may begin.**
    b. **Conditional Approval: Investigator must revise application to meet the conditions recommended by the IRB. Conditional approval may be resubmitted at any time and does not have to meet the regular IRB deadlines. However, if all conditions are not met, the IRB chairperson may elect to have the entire committee or a subcommittee re-review the application for recommended action. In this case, the application will be reviewed at the next IRB meeting. Procedures for re-submission of conditional reviews are:**
        1. **Resubmit the entire application with changes specified, appropriate signatures, and all necessary attachments to irb@nsula.edu NOTE: All appropriate signatures must be obtained again to reflect that all persons involved are aware of the changes.**
        2. **Include a copy of the conditional approval letter/email as an attachment in your application email.**
    c. **Resubmit: Investigator must revise the application and resubmit under appropriate guidelines for either "full," "expedited," or "exempt" review.**
        1. **Resubmit the entire application with changes specified, appropriate signatures, and all necessary attachments to irb@nsula.edu NOTE: All appropriate signatures must be obtained again to reflect that all persons involved are aware of the changes.**
        2. **Include a copy of the resubmission letter/email as an attachment in your application email.**
        3. **Resubmitted proposals will be treated as new proposals regarding deadlines for submission.**

10. **At the completion of the research (within six weeks of completion at the latest), submit an electronic final report to the IRB. An abstract or a copy of**

**the final report or article is acceptable. NOTE: It is not necessary to include a copy of the proposal. However, the final report must have the identical title as stated in the proposal and the same identifier (i.e. 02.19.006). The IRB will consider the research open for continuing review until this is completed.**

11. **If proposed research is a continuation of previously IRB approved research, a Continuation/Change in Protocol Application must be submitted before research may continue past the original project completion date. Please refer to the submission guidelines for the appropriate category of research (i.e., full, expedited, or exempt). A copy of the original proposal must be attached.**

12. **If adverse effects are detected at any time by the investigator, other research personnel, participants, or IRB member, research will terminate. The investigator will complete an adverse effects report with recommended action and submit it to the IRB. Research cannot recommence until the IRB approves the amended proposal.**

13. **If, during the continuing review, an IRB representative finds problems or areas of concern, research must terminate. The IRB chairperson will contact appropriate personnel and inform them in writing of the findings and IRB recommended actions. The researcher must complete and submit to the IRB a Continuation/Change in Protocol Application or an Adverse Effect Form and wait for written approval before the project may continue.**