Lesley IRB Information for Researchers, Advisors, and Students

- All research that involves data from human subjects must be prospectively approved by the IRB.
- The IRB determines what is exempt and what is not exempt, what is expedited and what requires full review.
- The most recent IRB application form should always be downloaded from the Lesley website. *If a student is applying, Section 2.1 of the application must clearly identify the advisor as the Principal Investigator and the student as the co-investigator.*
- The IRB requires that data collected must be kept in protected format for 5 years and then destroyed. That must be stated in section 5.1 of the application.
- Consent forms must contain this standard text about the IRB listed in the application:

  There is a Standing Committee for Human Subjects in Research at Lesley University to which complaints or problems concerning any research project may, and should, be reported if they arise. Contact the Committee Chairpersons at irb@lesley.edu

  - Do not list the IRB Co-Chairs' individual email addresses in the consent.
  - Children under the age of 18 must give assent in addition to parents giving parental consent.

- Once approved, all applicants including students, must keep the IRB approval letter.
- IRB approval is good for one calendar year only *from the approval date*. Requests for renewal or extension of approval may be made to the IRB if no changes in any previously approved procedures or personnel have been made. Always refer to the assigned IRB reference number when communicating with the IRB about a specific application.
- If the research will extend past one year, or elements of the research change, all researchers need to submit an amendment request to the application for IRB approval.
- Changes to an approved project must be submitted to the IRB for approval as an addendum (these include any new mode of data collection like adding a survey or interview, any new data collection sites, etc.). Always refer to the assigned IRB reference number when communicating with the IRB about a specific application.
- All applications to the IRB must be accompanied by a certificate of training from a human subjects training program such as PHRP or CITI or a similar program issued within the last 5 years. See the IRB website for more information on access to training.
- Researchers, including students, must plan ahead for submitting to the IRB; approval *may take up to 6 weeks or longer* if revisions to the application are required by reviewers. *Revisions should be submitted within 6 weeks of a request to revise by the IRB or the application will be closed.*

- To facilitate the IRB review, name standardized measures to be used and include interview and survey questions with the IRB application.

- The IRB Policy and Practices document on the website contains detailed information on consents and an example consent, and there is a document “Example Consents on the website.