Research Utilizing Surveys

Research involving surveys requires IRB review. In most cases, the IRB may review the research under an *exemption. However, participant consent is still required.

*Exempt category 2 includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or observation of public behavior (including visual or auditory recordings. The surveys can be recorded in an anonymous OR individually identifiable OR confidential manner. If the surveys are not anonymous an honest broker can be assigned to link individuals to survey responses and provide the study team with de-identified data. The honest broker will maintain the linking key.

IRB Requirements to be Completed Prior to Submission:

- All investigators and key personnel who participate in the design, conduct, and/or reporting of human subjects research must be trained in the protection of human subjects. WMed uses CITI a web-based human research courses to satisfy this requirement. Visit https://wmed.edu/cititraining for instructions or contact IRB Staff at 269-337-4345 for assistance.
- Because the IRB has a responsibility to assess investigator qualifications as part of their mandate to protect the rights and welfare of research participants the IRB strongly recommends investigators provide a current CV with their submission. You can upload your CV into the electronic system or send it to irb@wmed.edu and it will be uploaded for you.

IRB Application/Submission Packet:

The IRB application has built-in logic designed to route you to applicable sections according to how the questions are answered. If they are not answered correctly, you may not be routed properly. The following are the 12 sections with tips for selecting the appropriate answers specific to requests for survey studies.

1. **General Information**

2. **Add Departments**

3. **Assign Key Study Personnel (KSP) Access to the Study**
   Note: If you are utilizing the WMed Virtual Data Warehouse (VDW) for honest broker services and/or data storage add Theresa McGoff as the Data Manager. If your survey or data will be collected in REDCap add Mara Jessup as the Database Specialist (REDCap). If you are unable to locate an individual when setting up study personnel, contact the IRB to determine if they have an active iMedRIS account.

4. **Site Information**
   - 4.2 Did you utilize the Project Request and Triage Form during protocol development? If so, select “Yes” and select research services as applicable. This helps us keep track of who has been involved prior to submission.
   - 4.3 Select the appropriate site(s) where the survey will be conducted. For online surveys select “other”.
   - 4.4 Does your project involve collection of data should be answered Yes. Select “other” as the type of project being developed and list “survey”. If the project uses VDW services – this must be answered “Yes”.
   - 4.12 Select the population to be included if applicable (i.e. student data, resident/fellow data or faculty data).

5. **Research Determination**
   5.6 Select “No” to question one (intervention) and “Yes” to question 2 (interaction).

6. **FDA-Regulated Products** “No”

7. **Funding Sources** If funding has been awarded, answer “Yes” and provide the source of the funding (e.g. WMed student grant)

8. **Risk Level Involved** “Yes” Minimal Risk

9. **Research Procedures & Techniques**
   9.1 Select the third option, “Does the research procedure involve surveys or questionnaires?
   9.4 Does the research involve surveys or questionnaires? Answer “Yes”
   - Are validated surveys or questionnaires going to be used in this study? Answer “Yes” or “No”. Include name of the survey/questionnaire and if it is validated or investigator designed.
   - How often participants will be asked to complete the survey/questionnaire and how long it will take to complete. (e.g. one time survey will take approximately 5 minutes to complete).
   - Will identifiers be maintained? If answered “Yes” the process for storing the identifiers must be included in the protocol.

10. **Study Subjects**
    10.1 Include the maximum number of subjects anticipated to be enrolled. Enter the inclusion/exclusion criteria.
    10.2 Answer “Yes” if survey includes any type of payment.
    10.3 Answer “Yes” if using recruitment materials including QR code slide with invitation to participate and link to survey, emails invitation to participate, etc.
    10.4 Select the targeted population if applicable (e.g. students, residents or fellows, employees or staff). Note: Once a targeted population is selected additional sections will display to include the rationale for including the population, additional safeguards to protect their rights and welfare and plans to mitigate the perceived notion of coercion or undue influence.

11. **Use of Protected Health Information (HIPAA)**
    This should be answered No.

12. **Participant Privacy & Data Confidentiality**
    12.1: Check all that apply. Typically, option #2, 3, 4 and 5 may apply for collecting surveys.
    12.2: Check all that apply. Option #2 applies to confidential surveys that will be labeled with a code that can link to personal identifying information (coded) this often involves the use of an honest broker to de-identify the data before it is provided to the study team. Option #3 applies to anonymous surveys where the responses cannot be linked to the participant.
    12.3 Indicate where data will be stored. If electronic, select “Local Server” for studies that will be stored in the VDW or SharePoint.
    12.5: Select option # 1 if a linking code will be maintained until completion of the study. Select option #6 for anonymous surveys where no direct identifiers are being collected.
    Select option # 9 “other” if storing data in the VDW and include this summary: The data set (and any copies of the data set) will be stored in the VDW SharePoint Hub for two

years following the data the investigator is granted access. If data needs to be maintained past the two-year timeframe, a modification request will be submitted to track data for another two years

13. Attach the appropriate documents as follows:

- Study Protocol (Cross-Sectional available at https://wmed.edu/node/723)
- Implied consent Form
- Data Collection Form (i.e. paper survey; REDCap; Excel with data variables)
- Recruitment materials (i.e. information sheet; QR slide, recruitment email)
- Any other documents that may apply to the study and/or acquisition of data (i.e. data use agreement)

Please note, it is highly recommended to include version dates on submission documents.

Once the IRB reviews the protocol, you will receive a determination letter from the IRB outlining the category of exemption or other based on level of risk. **Be sure to review the letter.** If the parameters of the determination are incorrect or if you have questions, please call the IRB at 269-337-4345.