Wright State University Institutional Review Board

**Informed Consent Checklist**

**General Data Protection Regulation (GDPR) Requirements, if applicable**

*The following elements should be included when applicable. If your participants are physically in a country that is part of the European Economic Area (EEA), you are required to use the following elements of consent if your study is not anonymous.*

* Must use an active (opt-in) informed consent process. Consent must be an affirmative action. No opt-out procedures are permitted.
* Consent must be freely given*.* Individuals in a position of authority cannot obtain consent, nor can consent be coerced. This means that faculty members or teachers cannot obtain consent from their own students.
* Each participant has a right to withdraw at any time. They must be informed of this right prior to giving consent. Withdrawal of consent must be as easy as giving consent. You must have an executable plan to remove data in the event a participant requests to have their data removed.
* To the extent possible, verify that any 3rd-party website or apps being used for data collection are GDPR-compliant (e.g. Qualtrics, Dropbox, etc.).
* Consent records, including date and time of consent, must be maintained for each participant. For cases of undocumented consent (oral, online, phone, etc. ), the PI is responsible for maintaining a consent log indicating each participant by name or participant number and the date and time consent was provided.
* Consent must be specific, informed, unambiguous, and explicit. If the consent form serves multiple purposes (e.g. consent form that is also a recruitment email), then the request for consent must be clearly distinguishable.
* Consent information must be provided in a clear and plain language in an intelligible and easily accessible format.
* In the event of a data breach, notify the IRB office immediately (within 24 hours) so that appropriate steps can be taken by the university. Data breach requirements are very strict and must be done quickly.
* Specific Items to Include:
  + Identity of the Principal Investigator
  + Purpose of data collection
  + Types of data collected, including a list of special categories
    - Racial or ethnic origins
    - Political opinions
    - Religious or philosophical beliefs
    - Trade union memberships
    - Processing of genetic data
    - Biometric data for purposes of unique identification
    - Health data
    - Sex life/orientation information
  + The right to withdraw from the research and the mechanism for withdrawal
  + Who will have access to the data
  + Information regarding automated processing of data for decision-making about the individual, including profiling
  + Information regarding data security, including storage and transfer of data
  + How long data will be stored (this can be indefinite)
  + Whether and under what conditions data may be used for future research, either related or unrelated to the purpose of the current study.