**EXECUTIVE SUMMARY TEMPLATE**

**(For research studies using new software/hardware)**

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| **Contacts** |  | **[Subtitle]** |
|  | **PURPOSE**  The purpose of this executive summary is to…Vetting will involve TC Institutional Review Board (IRB), Computing and Information Services (CIS), and the Office of the General Counsel.  **INTRODUCTION TO Software/hardware**  The Department…aims to create a…. Utilizing [software and/or hardware name]…we will be able to... Other researchers use this….  The **benefit** for researchers...  The **concern** for researcher…  The **potential risks** to users…  The **potential risks** to research participants… |

**INTRODUCTION TO [Software/hardware] FOR REVIEWERS**

Founded in 2002…. The software aims to…The software offers…More information about the [software/hardware] visit [URL].

**Precedent:** [Names or Institutions] have used this [software/hardware] in the past and have reported…..

**Registration and Administration of [software/hardware]:** All registrants (i.e., researchers and prospective participants) to [software/hardware will require an email address to sign up. [If possible: *It can be specified if registration uses TC UNI*]

**Using [software/hardware] for TC Research Studies:** If researchers would like to use…, they would need to include a statement about confidentiality concerns of using…when submitting protocol to TC IRB.

To facilitate posting studies to the System, researchers will have an appointed Systems study coordinator (“Coordinator”). When researchers are submitting an initial request for their study to be added to….The Coordinator will then cross-check with appointed TC IRB administrator that the approved study protocol indicates use of the study pool system. The System can be configured to what will be most acceptable to the TC IRB research compliance standards.

**Example IRB Consent Form Text Using [software/hardware]:**

“*If you agree to be in this study, you confirm that you are 18 years or older and have access to reliable internet and can complete the contents of this study through [software/hardware]. You also acknowledge that [software/hardware] is an online platform for collecting data. To access research studies, [software/hardware] requires you to register through their website using your Teachers College email address and submit log-in credentials like your name and school affiliation. The researcher(s) of this study will not retain any of that personally identifiable information for research purposes. Your name or identity will not be used in this study and any information with your name or other personal information will be removed from this study or replaced with a unique code.*”

**PRIVACY AND CONFIDENTIALITY**

[Software/hardware] has certified to the U.S. Department of Commerce that it adheres to the Privacy Shield Principles of Notice, Choice, Accountability for Onward Transfer, Security, Data Integrity and Purpose Limitation, Access and Recourse, Enforcement and Liability. More information about [software/hardware] Privacy can be retrieved online here: [URL].

**Research Guidelines Compliance:** [Software/hardware] is in compliance with all major research regulations and guidelines worldwide. [Software/hardware] claims that participant data is safe and secure, guarded 24/7 at their data facility, and that they take extra steps to protect universities. They have a “Business Associate” contract addendum available for universities needing to comply with HIPAA and HITECH. They state they also have no-show handling options that are in compliance with OHRP guidelines, and meet all EU data privacy guidelines, including certification under the EU-U.S. Privacy Shield Framework. To ensure studies cannot recruit participants past their approval date, they enforce IRB (ethics) approvals and expiration dates. They also supply electronic acknowledgements for human subject policies, privacy policies, SSL encryption, and anonymous ID codes for added privacy. More information about [software/hardware] Compliance can be retrieved online here: [URL].

**Subject Information and Confidentiality:** [Software/hardware] collects the following personally identifiable information provided by participants enrolled in the system: full name and email address of each user, and user’s language preference for the system interface. The registrant may choose to provide the following information at his/her own discretion: university identification number, telephone number, course enrollment information, study sign-up information, research data collected in online surveys, data collected as part of prescreening for eligibility in research studies.

Subject information will be used only to: (1) perform the services set out in the agreement between TC and [software/hardware]; (2) maintain the infrastructure that supports the services; and (3) in response to an inquiry by TC or the participant providing the Subject Information to [software/hardware] to troubleshoot services.

The Coordinator will have access to the subject information stated above. Access to information will be used only to: (1) monitor participants (e.g. intervene on participants who repeatedly/continuously no-show for multiple research studies they have signed up for); and (2) trouble shoot with and help instructors who may need to give credit to their students after they have completed participation.

**Data Aging Policy**: [Software/hardware] can be configured to delete all participants who have not logged into the system since a specified date. If a participant is deleted from the System, all data associated with their account, including a record of their study sign-ups, are deleted.

**[Software/hardware] FEASIBILITY TEST**

With support from the department, [names], plan to run a 30-day feasibility test (June 2019 – July 2019) with research assistants role-playing as study participants for existing TC IRB-approved studies.

**OTHER PERTINENT INFORMATION:**

[include any other relevant information here]