Guidance for Using REDCap Platform for EXEMPT Study Participant Information Sheet

*Please note that this guidance is intended for use with exempt category studies where a signature(s) is(are) usually **not** obtained. The REDCap platform is currently **not** for use in exempt studies involving children or those requiring a Legally Authorized Representative.*

The research community is showing increasing interest in using electronic media to supplement or replace paper-based participant information documents and participation agreement confirmation. REDCap is a secure, web-based, HIPAA-compliant, data collection platform that can be used to develop and deliver study information to a potential study participant and obtain their agreement to participate (as applicable). It is important to note that **the information provided to the study participant and the investigator's responsibilities do not change regardless of the media** used.

Signed consent is usually **not** required for exempt research, and the process for providing information about the research can be much simpler than those required for non-exempt research (full consenting process). For exempt studies where there are interactions with participants, the investigator is expected to provide the following information (at a minimum) to a prospective study participant and confirm their agreement to participate:

1. the activity involves research,
2. participation is voluntary,
3. brief description of what participants will be doing,
4. whom to contact with questions (generally the principal investigator)

Additional information may be voluntarily included or required to be in the information sheet in order to better inform research participants about the study (e.g. about HIPAA, CT.gov, compensation, registries, etc).

The VCU Institutional Review Board (IRB) must approve the intent to use the REDCap platform for Exempt Information Sheets with the following items included in the initial RAMS-IRB submission:

1. The Information Sheet in WORD should be uploaded into the IRB submission (to facilitate redlining/track changes for any edits needed).
2. On the Study Procedures page, a description should be provided of how the REDCap platform will be utilized and the process for providing the information sheet to participants (see IRB example #4).

Following IRB approval, the approved language that is in the WORD Information Sheet should then be transferred into the REDCap platform (e.g., copy/paste, screenshot). Participant attestation, as applicable, may also be obtained within the REDCap platform. A REDCap Information Sheet template providing possible formatting/structure for the electronic version is available within the REDCap platform. A copy of the information sheet bearing the VCU IRB "APPROVED" stamp should be made available as a file within the REDCap Information Sheet (use a Descriptive Text field with a file attachment) that study participants can download and keep. If changes are made to the content of the Information Sheet, investigators may need to submit an amendment (refer to the Conditions of Approval in the IRB approval letter).