

## **UMSL Institutional Review Board Release Notes**

This document will explain the updated consent forms, terms for use and the newly created definition guidance.

### General Notes:

- The use of the new consent forms will be required beginning 10/10/2022.
- After 10/10/2022, if a study is submitted with a consent form using the old template, investigators will be asked to submit using the new consent template during the revision process.
- Previously approved IRB applications will be grandfathered in. However, if an investigator submits an Amendment that makes revisions to the consent form, they will be required to update to the new consent template at that time.
- The IRB is not requiring re-consenting of already enrolled subjects on the new consent templates.

### New Exempt Consent Form Notes:

- Similar to previous consent template
- This consent form should be used for Exempt Studies only
- Key Summary at the beginning of the consent was removed
- Language regarding course credit was added
- More specific language was added regarding confidentiality and risks
- The contact information for the IRB was updated and an email address was provided
- Signature lines were removed

### Social Behavioral Educational (SBE) Consent Form Notes:

- This consent form should only be used for Expedited or Full Board studies
- Addition of required regulatory language for biospecimens, research results, and confidentiality
- Addition of required regulatory language for mandatory reporting, NIH clinical trials and certificates of confidentiality
- Detailed injury language
- Multiple signature lines to fit different research participant scenarios

### Social Behavioral Educational (SBE) Consent Form with Waiver of Documentation of Consent Notes:

- This consent form should only be used for Expedited or Full Board studies that are waiving documentation of consent
- Most changes that were made in the SBE consent form were made on this version
- All signature lines have been removed

**New Supplemental Consent Language Notes:**

- This contains supplemental language for studies that are NIH funded with a Certificate of Confidentiality
- This language would only be inserted in the Expedited/Full IRB consent template

**IRB Definition Guidance:**

A list of definitions of common IRB terms