This table provides guidance regarding when changes of protocol should be submitted via ARROW for studies determined by the IRB to be exempt human subjects research. In general, in order for the IRB to confirm that the conditions under which the research was determined to be exempt have not changed, any updates to the study that meets the following criteria should be submitted for review if they could:

- Increase risks of participation and place them at risk for criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation
- Adversely alter the risk:benefit ratio of the study
- Affect research participants' willingness to participate in a study

Type of change	No change to the IRB application needed	Submit change to the IRB to allow for regulatory assessment
Personnel change	Most personnel changes unless the new personnel have a potential conflict of interest.	Change of PI or addition of personnel from outside UW- Madison.
Updates to conflict of interest information, including addition of management plans	If the conflict of interest and management plan are not related to the research study	If the conflict of interest and management plan are relevant to the research study.
Administrative or editorial changes to study documents	Administrative or editorial changes to study documents, e.g. updating contact information, correcting typos, or correcting discrepancies among IRB approved documents.	Administrative changes that indicate a change of PI or addition of an outside site.
Minor changes to study documents	Changes to the study documents that do not alter the meaning of the documents or change the nature of subject participation. For example, revising a survey instrument such that the overall meaning and purpose is not changed.	Changes to the study documents are substantial in nature or quantity. For example, adding questions regarding sensitive topics that were not previously addressed in an approved survey.
Adding new study documents, including new surveys/questionnaires/interview tools	Documents that are a) largely similar to those already reviewed by the IRB and that would not negatively affect the risks of study participation (e.g., they do not add the collection of sensitive data) and b) do not add to or expand the approved research objectives.	Tools or instruments that a) are not largely similar to those already reviewed by the IRB, b) could negatively affect the risks of study participation (e.g. adding collection of sensitive data); and/or c) add to or expand the research objectives already reviewed by the IRB.
Adding a new study procedure	Procedures that are a) largely similar to those already reviewed by the IRB and that would not negatively affect the risks of study participation (e.g., they do not add the collection of sensitive data); b) do not add to or expand the approved research objectives; and c) would not affect subjects' willingness to participate in the study.	Procedures that a) are not largely similar to those already reviewed by the IRB; could negatively affect the risks of study participation (e.g., they do not add the collection of sensitive data); add to or expand the approved research objectives; or could affect subjects' willingness to participate in the study.

Type of change	No change to the IRB application needed	Submit change to the IRB to allow for regulatory assessment
Adding a new site or study location	If the IRB reviewed the study as being conducted at the UW-Madison or UW Health and a new location within those entities is being added and the performance of research in the new location will not adversely affect safety or privacy and confidentiality protections.	If the site is added outside of the UW-Madison, UW Health, or Madison VA Hospital. Note, research at the Madison VA Hospital must be covered by a standalone exemption (i.e., it cannot include the conduct of research at the UW-Madison or UW Health). The new site or location could change the safety or confidentiality/privacy protections required for the research.
Providing certified translations of documents for subjects	If the IRB previously reviewed the inclusion of non-English speaking subjects as part of the exemption determination as well as a process for translating documents, the translated documents do not need to be provided.	If new subject populations (e.g., Spanish-speaking subjects) are being added.
Adding funding source or study sponsor	Internal (e.g., departmental) funding sources and sponsors.	The addition of any federal and private funding sources or sponsors as well as any changes to funding require other substantial changes (e.g., revised or new aims/purpose, substantial changes in study procedures) that could trigger new regulatory requirements.
Adding new or changing recruitment methods	New or altered recruitment method that is similar to those already approved for the study (e.g., adding a flyer when an ad with the same information has already been reviewed).	Adding a new recruitment method that is substantially different from previous methods approved, uses a new technology or system not previously reviewed, or targets a new population.
Changes in subject remuneration	Changes to remuneration that do not present undue influence.	Changes to remuneration that present undue influence, especially in a vulnerable population. However, this would be highly unusual for exempt studies.
Adding a new subject population	N/A	Adding new subject populations typically requires a change of protocol.
Modifying eligibility criteria	The modification is minor AND no new subject populations are being added.	The modification indicates an expansion of the research objectives OR a new subject population is being added.

Type of change	No change to the IRB application needed	Submit change to the IRB to allow for regulatory assessment
Increasing the number of subjects included in the study	No notification is necessary as long as the subject population remains the same, e.g. a query to identify potential subjects turns up more than originally expected.	If the increase in number of subjects is a result of any of the following: • A new subject population or study site is being added • A new study activity is being added
Increasing the number of existing or residual biospecimens to be used for a study	Modification that does not alter the source of the samples or change whether they are identifiable	If the increase is a result of a change in research design (e.g., addition of new research objectives) or addition of a new subject population.
Adding a new source of biospecimens to be used for the study	Adding a new commercial source to a study that was previously obtaining samples from a different commercial source.	A new source that is not a commercial source or the addition of a commercial source if not previously included in the exemption application.
Adding a new source of private identifiable data	The data are publicly available.	The data are not publicly available
Increasing the number of records to be accessed	The data are publicly available.	A new subject population or study site is being added or a new data set is being added that is not publicly available.
Adding specific data elements to be collected from records	If there is no change to the subject population, the records to be accessed, the HIPAA status of the study, or the risk level of the study with regard to breach of confidentiality.	If collecting the additional data element(s) results in any of the following: • A new data source must be added in order to collect the new data • Limited identifiers (e.g. dates of birth, death or service, or geographic area smaller than a state) will now be collected • Sensitive information (e.g. HIV status, illicit drug use, some mental health data) will now be collected.
Modifying how study data are transmitted or stored	If the changes will maintain a similar or increased level of confidentiality protections for study data.	If substantive changes to data access are being made (e.g., study data would now be accessible to researchers outside the study team) or where data are stored (e.g., changing data from a closed system to a cloud system).
Changes in consent documents	Revisions that do not alter the meaning of applicable consent document(s) or change the nature of subject participation	Revisions that alter the meaning of applicable consent document(s) or change the nature of subject participation