Expedited Changes of Protocol Examples
Updated March 2019

This table includes examples of the most common types of changes of protocol along with a brief description of whether such changes can qualify for expedited review. This list is NOT exhaustive and only provides general guidance on what type of review may be required for a change of protocol. In all cases, the IRB may, at its discretion, refer changes submitted as expedited for full IRB review. Please see the Expedited Change of Protocol Guidance for additional information. Generally, if a study qualified for expedited initial review, changes to the study will be reviewed under expedited procedures unless the changes result in the study no longer falling under an expedited review category.

What is being changed?	Can this be an expedited change?	When would this require a full change?
STUDY DOCUMENTS (e.g. surveys, questionnaires, data collection sheets, recruitment materials)		
Minor changes to study documents	Yes, if the changes to the study documents 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.	A full change may be needed if document changes reflect a design change (e.g. addition of a new aim) or add questions regarding sensitive topics that were not previously addressed in an approved survey.
Adding new study instruments or supporting materials	Yes, if the documents do not change the nature of subject participation or negatively impact the risk/benefit ratio. For example, adding a survey that does not include new sensitive topics, and does not represent a new aim or objective.	A full change is needed if new study documents negatively affect the risks to study participation, or if they add or expand the approved research objectives.
Providing certified translations of documents for subjects	Yes, if the IRB previously approved the inclusion of non-English speaking subjects.	A full change of protocol will generally be needed if new subject populations (e.g., Spanish-speaking subjects) are being added.
FUNDING		
Adding/removing funding source	Yes.	A full change is needed if changes to funding require other substantial changes (e.g., revised or new aims/purpose, substantial changes in study procedures) to the study or involve adding federal funding that triggers new regulatory requirements.

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STUDY LOCATION		
Adding a UW-Madison/UW Health Location	Yes.	A full change may be required if substantial changes are being made to the study and/or if the new study location raises concerns given the type of study procedures that will be conducted there (e.g., clinical procedures being conducted in a non-clinical setting)
Adding a new site, study location, or personnel not affiliated with UW-Madison/UW Health	Yes, if UW-Madison will NOT serve as IRB of record for the personnel not affiliated with UW-Madison/UW Health.	A full change may be required if UW-Madison will be asked to serve as IRB of record for the personnel not affiliated with UW-Madison/UW Health. Please consult with the Reliance Team (irbreliance@wisc.edu) for guidance.
SUBJECT RECRUITMENT AND REMUNERATION		
Adding new or changing recruitment methods	Yes, if the new or altered recruitment method is similar to those already approved for the study (e.g., adding a flyer when an ad has already been approved) or if the new or altered method is consistent with IRB guidance and does not have significant privacy or confidentiality implications.	A full change may be required when the new recruitment method deviates from institutional policy or IRB guidance on recruitment or has broader privacy or confidentiality implications.
Changes in subject remuneration	Yes, if the changes for remuneration do not present undue influence.	A full change may be required if remuneration for children or other vulnerable population is being significantly altered or if substantial changes are being made to the remuneration plan (e.g., such as no longer prorating remuneration or delaying compensation).

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SUBJECT ENROLLMENT		
Increasing/decreasing local enrollment for multisite studies (NOT investigator-initiated)	Yes, if overall study-wide enrollment is not being increased or decreased.	A full change is needed if study-wide enrollment is being increased or decreased.
Increasing/decreasing enrollment for investigator-initiated studies (multi- or single site)	Yes, if the following are true: • The study is minimal risk; AND • The change is not the result of a change in design (e.g., the addition of a new study aim).	A full change may be needed if the study is more than minimal risk, the change reflects new or revised study aims or statistical analysis methodologies, or is the result of greater than expected subject withdrawals
Modifying eligibility criteria	Yes, in the following situations: • The IRB has determined the study constitutes minimal risk to subjects; AND • No new subject populations are being added.	A full change is generally required if: • The IRB has determined that the study presents more than minimal risk to subjects; AND • A new subject population is being added OR • Assessment by a medical reviewer is required.
Adding a new subject population	No. Adding new subject populations typically requires a full change.	

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SAMPLE COLLECTION/ANALYSIS		
Decreasing number/volume of samples collected directly from subjects	Yes, if the decrease in sample collection does not negatively alter the study's risk/benefit ratio or substantively alter the study objectives or design.	A full change is required if the decrease in sample collection requires assessments for impact on subject welfare (e.g., changes in samples collected for safety monitoring) or suggests a substantive change to study design or objectives.
Increasing number/volume of samples collected directly from subjects	Yes, if the samples are collected in a non-invasive manner (e.g., cheek swab) or the assessment of the increase does not require medical review to ensure subject safety is maintained.	A full change is required if medical review is required to ensure subject safety is maintained or samples are collected via invasive methods that may pose more than minimal risk (e.g., bone marrow aspirate).
Modifying number of existing or residual samples to be used for a study	Yes, if the modification does not alter the design of the study or the risks of participation for subjects, including privacy or confidentiality risks.	A full change is required if the increase or decrease is being made as a result of a change in research design (e.g., addition of new research objectives) or increases the risks of participation.
Adding a new source of samples to be used for the study.	Yes, if the new or changed source of samples is similar to the source(s) previously approved by the IRB and does not reflect a significant change in design.	A full change may be required when the new or changed source is substantially different from the source(s) previously approved by the IRB (e.g., adding prospective collection of leftover surgical tissue to a study previously approved to collect existing archived samples only).

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DATA OR SAMPLE SHARING		
Sending or receiving data or samples from/to an external entity	Yes, if the following are true: • UW HS IRBs will not serve as the reviewing IRB for the external entity; • The sharing is consistent with the consent/HIPAA documents, if applicable; AND • The sharing is not the result of a new study aim or objective.	A full change may be required if: • The UW HS IRBs will serve as the reviewing IRB for the external entity; • The sharing is not consistent with consent/HIPAA documents; OR • The purpose of the sharing represents a new aim or objective.
DATA STORAGE/SECURITY		
Modifying how study data are transmitted or stored	Yes, if the changes will maintain a similar or increased level of confidentiality protections for study data.	A full change may be required if data will be directly identifiable or if using a data transmission method that does not comply with institutional requirements for transmission and security.
DATA SAFETY MONITORING PLAN (DSMP)		
Removing a previously approved Data Safety Monitoring Plan (DSMP) or reducing frequency of safety monitoring	No. A full change is required to remove a previously approved DSMP or reduce the frequency of safety monitoring.	
Increasing frequency of safety monitoring	Yes, only if the increased safety monitoring is NOT a result of new risk information and does not require medical review.	A full change is required if medical review is required or the frequency of safety monitoring is being increased as a result of new safety information or a reportable event.

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What is being changed?	Can this be an expedited change?	When would this require a full change?
STUDY PROCEDURES		
Adding new or altering medical procedures	Yes, only if they constitute minimal risk, are not in response to new risk or safety information, do not substantively alter study design, and do not require medical review.	A full change is required for new or altered medical procedures that are more than minimal risk or are in response to new risk or safety information, substantively alter study design, or require medical review.
Changes in the number of study visits or study duration	Yes, if the changes are not: • Based on new risk information; • As a result of substantial design changes; • Decreasing safety monitoring; OR • Adding invasive study procedures	A full change is required if new risk information exists or if medical review is required to assess the potential impact on subject safety.
Adding/removing a study arm or phase	No. A full change is required for substantial changes in study design, such as adding/removing a study arm or phase.	

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What is being changed?	Can this be an expedited change?	When would this require a full change?
PERSONNEL		
Change in PI	No. A full change of protocol must be submitted for any change in PI.	
Changing any other personnel who are NOT the PI	• If no other changes are being made to the study, a personnel change should be submitted when any personnel other than the PI are being changed or if the roles of personnel are changing. • If other changes are being made to the study, changes in personnel may be submitted as part of either a full or expedited change of protocol. • If personnel not affiliated with the UW/UW Health/Madison VA are being added, an expedited or full change of protocol is required (not a personnel change).	
Reading Center/Statistical Data Analysis Center (SDAC)/Analysis center for data, specimens and/or images application		
Changes which directly affect the analysis center activities at UW-Madison.	Yes, if the changes will maintain a similar or increased level of confidentiality protections.	A full change may be required if the change deviates from institutional policy or IRB guidance on analysis centers or has broader privacy or confidentiality implications.
INFORMED CONSENT/HIPAA		
Administrative/editorial changes to informed consent or HIPAA authorization documents	Yes. Administrative or editorial changes include updating contact information, correcting typos, or clarifying approved language.	A full change may be required for consent or HIPAA authorization edits that may alter the substantive meaning of the document or for new documents that have not been reviewed by the convened IRB previously and are substantively different than those previously approved.
OTHER CHANGES		
Submitting new risk information	No. New risk information may need to be submitted as a reportable event AND a full change of protocol. Please see the "Events Requiring Reporting to the IRB" page of the HS-IRBs website for guidance.	